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Is Genetic Use Restriction Technology (GURT) a Viable Alternative to the Utility Patent for the Protection and Promotion of Innovation in Genetically Engineered Agricultural Seeds?

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IS GENETIC USE RESTRICTION TECHNOLOGY (GURT) A
VIABLE ALTERNATIVE TO THE UTILITY PATENT FOR THE
PROTECTION AND PROMOTION OF INNOVATION IN GENETICALLY
ENGINEERED AGRICULTURAL SEEDS?

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Abstract:

Patent protected genetically engineered (GE) agricultural seeds allow farmers to increase the quality and yield of some of the world's most important food crops. The ability of GE seed firms to use this technology to capture value and promote innovation may be compromised by patent regimes that are not designed to prevent the misappropriation of self-replicating, biologically-based inventions.

Unlike patents, genetic use restriction technology (GURT) provides a primarily self-contained technological method of intellectual property (IP) protection effective in weak IP environments. Currently, GURT is subject to an international commercialization moratorium because of concerns over potential negative economic, environmental, health and social consequences of its use.

This thesis investigates whether GURT is a viable alternative to the utility patent to promote and protect innovation in GE agricultural seeds. It does so by comparing the viability of these two IP protection paradigms through an analysis of the interconnections among five viability criteria: global food security; the environment (biosecurity and biodiversity); economic well being (industry and farmers); national and international policy and regulation; and consumer acceptance.

The results indicate that GURT technology offers greater overall IP protection for GE seeds than the utility patents alone. At the same time, GURT would improve global food security while limiting the unwanted spread of artificially introduced genes. However, the capacity for this technology to promote innovation and to affect biodiversity is questionable. Ultimately, farmers in the developed world would see little short term benefit from GURT, while developing world farmers would be subject to greater GE seed firm control over their livelihoods. Ethics-based resistance to GURT could be a viability and consumer acceptance wild card.

In the public sector, GURT commercialization and its endless technological monopoly would require policy and regulatory changes to reinvigorate the societal bargain that has been integral to the success of the patent system.

The conclusion of this thesis is that GURT GE seeds do not currently present a viable alternative to non-GURT patented GE seeds for the promotion and protection of innovation in this technology.

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Chapter 1

Introduction to the Thesis

1.0 Overview

The genetic engineering of agricultural seeds is revolutionizing agriculture by challenging long-held scientific, technological and intellectual property (IP) tenets. At the same time, this innovation is affecting serious global agricultural issues such as food security, biodiversity, farming systems and consumer attitudes to food in a world of increasing population and diminishing agriculturally suitable land.

The transformative potential of genetic engineering in agriculture is a subject of interest and concern for the both the private and public sectors. As the science of genetic engineering advances, the private sector sees opportunities for growing profits, for new avenues of innovation, and for industry growth. In contrast, the public sector recognizes the challenges that this new technology presents for policy development and regulation to ensure safety, to control potential private sector excesses, and to manage this new disruptive technology for the benefit of society. At the core of this technology is innovation.

Innovation depends on the ability of the innovator to gather the required resources, including human resources, in an environment heavily influenced by established national and international IP regimes. Inventiveness is a vital source of innovation in both the private and public sectors yet that alone is insufficient to market state-of-the-art products and processes. Those within the GE seed industry suggest that, without robust property rights, private firms will not have an incentive to engage in costly knowledge-creating research and development (R&D) thereby depriving society of potential benefits.

In 2013, Wendelyn Jones (Global Regulatory Affairs for DuPont Crop Protection) wrote that an industry survey conducted between 2008 and 2012 found that the cost of commercialization of a single GE biotechnology trait was \$136 million USD. She indicated that 26% of that cost could be attributed to regulatory testing and registration. In addition, she noted

that the total time from conception to commercial launch for a new GE trait was thirteen years.¹

The obvious question that arises from these statistics is why would a firm undertake the time and high costs of innovation without some assurance of an adequate level of IP protection. Without effective IP protection, a competing firm could simply wait for others to innovate and then reap the same benefits through copying and imitation. This view of the importance of IP protection for the success of agricultural biotechnology innovation is common among many who write on the subject of agricultural biotechnology. Authors such as Andrew Nilles, John Quick, Mark Janis and Jay Kesan focus many of their writings on the interrelationship between IP protection and the advancement of agricultural biotechnology. These authors also concur that patent-based intellectual property rights (IPRs) encourage innovation in agriculture, and that without IPRs, innovators would likely intensify their efforts to secure alternative forms of protection.²

The research carried out for this thesis examines one such alternative form of IP protection, genetic use restriction technology (GURT). This thesis delves into why the IP protection offered by GURT is so unique and why it represents a serious alternative to the utility patent (here forward referred to as “patent”) as a source of effective IP protection.

Historically, the effectiveness of the patent as an indispensable tool in innovation protection is based on the protection that it offers to a key source of innovation, the invention.

In agricultural biotechnology, the viability of patent protection has become a concern for firms and governments in both strong and weak IP environments as the boundaries of patentable subject matter are expanded, and the complexity of IP regulation has grown. In this new expanding frontier, private firms often have a financial incentive to take advantage of the quirks

¹ Wendelyn Jones, “GMO Answers” (2013) in Layla Katiraei, *Patents and GMOs: Should biotech companies turn*

² Andrew F Nilles, “Plant Patent Law: The Federal Circuit Sows the Seed to Allow Agriculture to Grow” (2000) 35 *Land and Water Law Review* 355; John Quick, “Intellectual Property: Plants Patentable Under the Utility Patent Statute, PVA, and PVPA” (2002) 30 *Journal of Law, Medicine and Ethics* 426; JP Kesan, “Intellectual Property Protection and Agricultural Biotechnology: A Multidisciplinary Perspective” (2000) 44:3 *American Behavioral Scientist* 464 at 475 [Kesan]; Mark D Janis & Jay P Kesan, “Weed-Free I.P.: The Supreme Court, Intellectual Property Interfaces, and the Problem of Plants,” (2001) *Cincinnati Law Review* at 36 [Janis and Kesan].

and inadequacies in national and international IP regulatory environments to maximize profits at the expense of other stakeholders such as farmers and consumers. National governments and national and international public sector organizations have had to deal with the fallout from the existence of these various IP environments.

For example, according to the Organization for Economic Cooperation and Development (OECD), IP as source of competitive advantage in OECD countries has grown with the globalization of innovation.³ The protection and promotion of that innovation are two key elements influencing its importance as a force enhancing competitive advantage. Internationally, the OECD recognizes that competitive advantage in the private sector can be promoted through innovation and that governments will invest significant resources to build their competitive advantage over other nations.⁴

Strictly speaking, the term competitive advantage is applied frequently to describe attributes that help private firms compete [through differentiation, cost advantage or customer focus]. However, public institutions involved in innovation also search for competitive advantage while competing with the private sector for scarce resources such as funding, facilities, and the human capital needed to promote and protect innovation. The importance of innovation protection undoubtedly reflects on the continued prominence of the patent as a means of protection.

The emphasis on patents as a fundamental value capture mechanism has been bolstered with the internationalization of technological innovation and the framework that supports that innovation.⁵ In the past two decades, this use of patents has incentivized innovation in GE seed biotechnology. However, the use of patents has had unintended negative consequences for innovation and the viability of some key stakeholders.

³ OECD. *Patents and Innovation: Trends and Policy Challenges* (Paris: OECD Publishing, 2004), online: OECD <<http://dx.doi.org/10.1787/9789264026728-en>> at 15.

⁴ Ibid at 7.

⁵ Ibid at 9.

1.1 Formulation of the Thesis Question

This thesis focuses on the complex relationships among patents, innovation, and the private-public tensions associated with value creation and value capture in the GE seed industry. It questions whether GURT represents a superior, viable, primarily non-legal alternative to the patent for the protection and promotion of innovation.

Today, the major players [multinational corporations, public research organizations (PROs) and governments] and the rules [national and international IP laws and regulations] direct the growth and development of GE seed biotechnology. However, farmers, consumers and a broad assortment of non-governmental organizations (NGOs) also influence, and are influenced by, this biotechnology.

The Problem/Issue Statement

The problem that this thesis addresses is the continued focus of the GE seed industry, policy-makers and regulators on the traditional use of a patent-based, primarily closed innovation⁶ paradigm to develop and implement economic and social value creation and value capture strategies.

The problems of the existing patent system are magnified in the agricultural biotechnology sector due to this sector's heavy reliance on IP protection. One problem area involves the significant costs of patenting in this industry. This is an issue that is common to many high technology sectors such as information technology. However, few other sectors can match the value leakage potential of GE seed biotechnology. Simply by planting a patented seed and harvesting the result, anyone can appropriate many years of costly R&D.

Another area of concern is the high cost of existing patent invalidation through court litigation. This activity raises the level of property rights uncertainty, which lessens the incentives for innovation activities. Also, the high cost of litigation can encourage some opportunistic behavior on the part of patentees. For example, in the hope of obtaining reduced

⁶ Closed innovation involves a dependence on internal R&D and the protection and control of the results of that R&D for commercialization.

licensing fees on inventions, patentees may make overly broad or invalid claims of their own. Sorting through this uncertainty can delay or block innovation and significantly increase its costs.

A further drawback of the patent IP protection model is that patents may raise the cost of innovation by encouraging competitors to design around patents. This is not an uncommon occurrence if the licensee considers the license fees to be too high or the licenses too restrictive. Part of the increase in innovation cost results from the inefficiency of R&D duplication that can result from designing around patents.

Another drawback of patents in biotechnology is that they can reduce the incentive for follow-up innovation because of the need to obtain licenses to employ the upstream patents upon which innovation depends. Here again, transaction costs become a serious issue, as the effort to package the necessary foundational knowledge at reasonable cost can be challenging.

A unique patent concern for GE seed biotechnology is patent enforcement at the user level (i.e. the farmer) because the patented product can self-replicate. In the GE seed industry, the most serious industry value leakage risk occurs at this point. Specifically, the risk occurs at the second and later generations of seed production from GE crops. The scenario begins when the GE seed company sells the first generation of value added GE seed to the farmer. The farmer legally uses the seed to grow a crop to sell as food or for food production, as his contract with the GE seed company stipulates. Because the second-generation seed is also patent protected, the farmer cannot legally use this seed to plant another crop. In fact, a farmer legally using this technology has signed a licensing agreement that clearly contains this restriction. This agreement will be highlighted later in the thesis.

The farmer also has the option of selling the harvested GE seed to a third party such as a grain elevator for either animal or human consumption. As third party grain elevators mix seed from many sources, the elevators may contain both GE seed and non-GE seed. Although this seed is not meant for planting, some farmers purchase this relatively inexpensive seed for late season planting when weather irregularities may threaten crop outcomes. One can easily imagine how this could be problematic for GE seed companies. Intentionally growing any seed that is of the GE variety would infringe on the seed company's patent. But how would a farmer know that

some of the seeds from a grain elevator might be patent protected? The answer is that the farmer would not know unless he deliberately set out to make this determination. This is the situation that occurred in the *Bowman v. Monsanto* case to be expanded upon later.

The problem areas noted above involve the illegal use of protected seed by either the owner of the first generation seed (a farmer) or the farmer who purchases or obtains the seed from another farmer or grain elevator for use as seed. In all cases, the primary IP problem occurs at the farmer level.

The above review makes it clear that the research involving viable alternatives to the traditional use of patents to protect and promote innovation must stress IP protection at the farmer level rather than at the level of industry competitors. The reason is that there are relatively few competitors in this industry and traditional patents do reasonably well in protecting GE seed technology from rival firms. On the other hand, there are millions of farmers all over the world and the cost of monitoring patent compliance is practically impossible. The farmer “problem,” as the industry sees it, is an important component for understanding the thrust of this thesis and is discussed in more detail later.

In the GE seed industry, patents and the IPRs associated with them represent the current gold standard for the protection of one of the key sources of innovation, the invention. Although patents have become a dominant source of protection for life-based inventions, the effort required to force a round life-based invention into a square industrial-era patent hole has led to a firm-supported expansion of the boundaries of patentable subject matter. This has resulted in well-publicized push back from national and international organizations and legal entities that struggle to accommodate the concerns of multiple stakeholders (the general public, NGOs, private firms, farmers, public research institutions, national governments, and national and international regulatory bodies and agencies). The pushback comes in the form of regulation for environmental safety, biodiversity support, farmer and aboriginal rights, fair business competition, and the maximization of societal benefits such as global food security. These areas are all affected by the promotion and especially the protection of innovation in GE seeds.

In response to the use of patents as a key component of business strategy,⁷ national and international agencies and regulatory bodies have expended considerable effort to develop regulations and policies to address patents and other forms of IP deemed essential for innovation promotion and protection in the agricultural biotechnology industry. Several significant relevant agreements that are applicable to this sector are the Agreement on the Trade-Related Aspects of Intellectual Property Rights (TRIPS 1994); the Convention on Biological Diversity (CBD); and the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGR).⁸ In addition, other organizations and agreements have impacted agricultural biotechnology as well. They include the International Union for the Protection of New Varieties of Plants (UPOV); the World Intellectual Property Organization (WIPO); the World Trade Organization (WTO); the Paris Convention (1967); and the Patent Cooperation Treaty (1970).

The Thesis Question

Is Genetic Use Restriction Technology (GURT) a viable alternative to the conventional use of utility patents to promote and protect innovation associated with the genetic engineering of agricultural seeds?

The problems associated with the traditional use of patents as a method of innovation promotion and protection in agricultural biotechnology have encouraged the search for alternative methods of innovation protection and enhancement on the part of the GE seed industry. The relatively recent development of GURT offers a potential solution to the GE seed industry's worries over value capture at the farmer level of the supply chain. GURT potentially represents an extremely secure inventor-controlled primarily biotechnological method of securing GE seed IP.

The United States Department of Agriculture and Delta and Pine Land Company developed the first practical GURT technology in 1998. U.S. Patent No. 5,723,765 titled, "Patent

⁷ Robert M Grant, *Contemporary Strategy Analysis* 6th ed (Oxford: Wiley-Blackwell, 2008) at 132.

⁸ Geoffrey Tansey, "Food for Thought – Intellectual Property Rights, Food and Biodiversity" (Spring 2002b) 24:1 Harvard International Review 54.

for the Control of Plant Gene Expression” was the first such patent.⁹ The original technology is now owned by Monsanto, which purchased Delta and Pine in 2006. It was not long before GURT became associated with the derogatory term for this technology, “Terminator”. This term refers to the fact that the progeny seeds from the first generation of one GURT variation (V-GURT) are sterile (i.e. will not grow if planted) and, therefore, are “self-protecting” from an IP perspective. However, the potential effects of GURT on innovation and its viability with respect to all stakeholders is in doubt as this technology raises many new questions about the role and manipulation of genetics in agriculture. The question of viability is paramount to any comparative analysis of patents and GURT because what may appear to be extraordinary benefits of one method of IP protection may be limited to few stakeholders and may come with significant drawbacks for other stakeholders.

Additional specifics about GURT technology are outlined in the concepts portion of this thesis. First, however, it is important to clarify the term viability as it relates to GURT as a potential alternative to patents. The concept of viability is key to addressing the demands of the thesis question.

According to the Oxford Dictionary, viability denotes feasibility and sustainability over an extended period. However, from the perspective of this thesis, where one is looking for a viable alternative to something that already has a significant degree of viability, this is insufficient. For a GE seed patent alternative to be viable, it must be superior to what already exists in both simplicity of use and the public and private benefits that may accrue from its implementation. One potential difficulty in the selection of an alternative to patents is that viability must give some level of consideration to the requirements of all stakeholders. Therefore, the establishment of criteria by which to judge an alternative is crucial to addressing viability and the overall thesis question.

In spite of the fact that patents did not originate as a means of protecting life-based inventions, they remain the strongest current form of IP protection in the GE seed industry. Traditionally, patents protected inventions that lacked two key GE seed attributes; attributes that will not occur in, for example, a bread toaster. Those attributes are first, the ability to grow and

⁹ “Patent for the Control of Plant Gene Expression,” US Patent No. 5,723,765 (7 June 1995).

second, the ability to reproduce. The IPRs associated with a toaster are relatively easy to understand and apply. If a subsequent toaster is needed, it must be purchased. Unlike a GE seed, a toaster will not reproduce itself. Nor will it inadvertently appear and grow on a neighbour's property putting that neighbour at risk of patent infringement, as is the case with a GE seed. A toaster's survival will not impact the diversity of other appliances in the way a GE seed may affect other plants and specifically crops (biodiversity). A toaster's existence does not create concern [warranted or not] that its molecular structure can mutate and cause harm to life and the environment if it is used as intended.

Unfortunately, the perceived success of patents as a means of innovation promotion and protection in agricultural biotechnology has acted as a deterrent to the development and implementation of new, potentially more cost-effective and more universally beneficial innovation paths and methods of IP protection. This has occurred because the patent is deeply entrenched as *the* primary method of invention (and therefore innovation) protection for GE seeds. Any alternative could negatively affect those who benefit from the existence of the patent model such as national and international regulatory agencies, departments, commissions, bodies, offices and organizations.

I submit that the use of patents in agricultural biotechnology and specifically when applied to the genetic engineering of agricultural seeds can also have adverse effects on stakeholders such as farmers, large and small biotechnology firms and public, academic institutions. The issues affecting these stakeholders are discussed at greater length further into this thesis; however, a few brief comments are in order at this time.

One serious shortcoming of patents is the potential for patents to hinder the diffusion of foundational knowledge and, thereby, obstruct innovation. Although patents require invention disclosure, the patenting of processes can inhibit the ability of inventors to take the next inventive step because the means to do so may require the use of that patented process. Another issue is that the international nature of the GE seed industry makes it susceptible to national regulatory inconsistencies and revisions. As such, the patent regimes that must protect industry IP are subject to those same inconsistencies and revisions creating situations where it is not

possible to patent a product in a country that claims that the patent will negatively affect certain local public interests.¹⁰

The problems inherent in patents have been discussed for many years. In 1951, Edith Penrose articulated a less than flattering view of patents in her book on the international patent system, “The Economics of the International Patent System”. In his 1952 review of her book, Jacob Schmookler highlights a critical observation made by Penrose. He notes that Penrose argues that the existence and complexity of patents is an integral part of the IP system. As such, it would be difficult to successfully unravel the extensive patent linkages. That being said, Schmookler remarks that Penrose would find it difficult to make a positive case for patents if that form of IP protection had not already been developed.¹¹ In this sentiment, it is clear that Penrose is reflecting on how, despite its shortcomings, the patent system is firmly entrenched as a means of IP protection.

It may be that Edith Penrose is correct, and that it is difficult to make the case that patents should be eliminated. It may be that the patent system in both the private and public sectors is so ingrained that any alternative is simply not *viable* in the GE seed industry. However, the opportunity to intercept and redirect the patent paradigm presents itself whenever disruptive new technologies appear. This is the case with GURT. However, the key issue with any dramatically new paradigm is viability.

Viability in the context of this thesis is not merely about feasibility but also about an improvement in the cost/benefit outcome. The viability of patents and GURT must be viewed from three perspectives. The first perspective is the private firm. Here, viability refers to an improvement in short and long-term value creation and capture. The second perspective is the public sector where viability reflects governments’ enhanced ability to invest in national industries and innovation that culminates in superior societal benefits in national and international economic welfare and food security. Finally, the third perspective is the public-

¹⁰ TRIPS: Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, THE LEGAL TEXTS: THE RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS 320 (1999), 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994) at Article 27.2 & Article 27.3.

¹¹ Jacob Schmookler, Book Review of *The Economics of the International Patent System* by Edith Tilton Penrose, (1952) 12:3 The Journal of Economic History at 289.

private interface, where viability signifies a mutually beneficial cooperative relationship between these two sectors. This third perspective is perhaps the most significant and also the most difficult to reconcile since the public and private sectors often have dissimilar goals and unique, sometimes conflicting methods for achieving those goals.

1.2 Thesis Scope and Limitations

Thesis Scope

This thesis is internationally focused, although there are prominent national characteristics that affect its international dimensions. For example, multinational corporations involved in this sector may be nationally based and subject to national laws and regulation, but the importance of these corporations to the GE seed industry is based on the scope and scale of their international activities. Another reason for the dominance of the international dimension of this thesis is that many national policies or regulations associated with GE seeds invariably affect and are affected by the development and implementation of international policy or regulation in this field.

This interdisciplinary thesis builds on several fields of study: business strategy; public policy and regulation; intellectual property; and agricultural biotechnology. At the outset of this thesis, it is necessary to define or unpack several material concepts (i.e. concepts that provide foundational knowledge necessary to understand and address the primary thesis question). The primary material concepts referred to are the genetic engineering of seeds, value creation and capture, innovation and innovation strategy, business structure, the regulation of agricultural biotechnology, global food security, and patents. These concepts are all interconnected, and each represents an essential element in understanding the overall narrative.

Since the diversity of discussion within each of these fields of study is enormous, it is imperative to maintain a careful thesis focus to avoid drifting into a tangential discussion of unrelated issues. For example, the varieties of GE seeds, their characteristics, and the techniques used to produce them vary substantially. Seeds have been genetically engineered to be resistant to drought, viruses, mold, herbicides, and insects. They have been designed to produce a greater yield per plant and per acre and to improve the nutritional value of food. Only one's imagination, financial resources, the extent of the knowledge base that one can develop or access, and the

current state of national and international regulations limit the product possibilities. Furthermore, there are debates over the safety of GE seeds; their effect on biodiversity; their effect on farmers and GE firms; and their effect on national and international IP systems. However, as important as these dialogues may be, this thesis is concerned with the attributes and the impacts of GE seeds only to the extent that they differ when comparing the innovation protection and promotion features of patents versus GURT.

Thesis scope is also a concern when studying the public sector attitudes to the GE seed industry. In the public sector, national and international economic, social and environmental interests influence innovation strategy. Examples of these interests include international trade in agriculture and processed food; farmers' rights to plant and grow crops; biodiversity and food security; and globalization in agri-business. In spite of the many interests that should be reflected in this thesis, it is vital to maintain a relatively narrow focus to address these key issues in a manner that directly reflects the limited scope of the thesis question.

In the private sector, innovation strategy supports business strategy and represents a firm's plan on how it will commercialize new ideas to create value for the firm. Innovation strategy often represents the core of a firm's business strategy. To varying degrees, the same interests that guide innovation strategy in the private sector overlap those in the public sector.

In this thesis, the focus is on a concept that connects the interests of both the private and public sectors. That concept is how innovation protection and promotion can best be accomplished to provide maximum benefit to the greatest number of stakeholders at a reasonable cost. It is essential that "cost" be understood to be more than a dollar and cents issue. For example, cost also reflects innovation, environmental, and food security gain or loss.

At the national level, policymakers are represented by government bodies responsible for the regulation of food and agriculture; related industry and economic development (including innovation); the environment; and intellectual property concerns. Internationally, policymakers are represented by those global organizations that complement their national counterparts by addressing those issues that require multinational consensus as they cross boundaries. Examples of such organizations are the WTO, WIPO and the Food and Agriculture Organization of the

U.N. (FAO). This thesis also considers, as policy makers, those within the private sector who are responsible for decisions that impact the strategic and tactical direction of firms.

Of the various stakeholders, three that stand out are GE seed firms, farmers and consumers. The reason is that these are the stakeholders that are most likely to affect and to be affected by the viability of patents and GURT through either direct contact with the product or through the ramifications of its use. That *viability* is represented by viability criteria that are deemed to be most relevant to this thesis and which are described later in this thesis. These criteria are based on areas of emphasis by authors in the literature review.

Thesis Limitations

There are a number of research limitations that may influence the conclusions of this thesis..

- 1) The qualitative aspects of the research have highly subjective components, which may be interpreted differently by various readers.
- 2) Viability is a highly subjective term, which has been defined by the researcher to meet the thesis requirements. Readers may not necessarily agree with all aspects of the definition chosen and the interpretations that flow from it.
- 3) The selection and weighting of quantitative and qualitative criteria for measurement are subject to researcher bias.
- 4) There is the potential for researcher bias in the interpretation and analysis section of this thesis due to the influence of the researcher's previous research and academic background. The researcher has a background primarily in the human health field and in international business strategy.
- 5) The researcher also has a background in science research (two years of research in oral medicine and microbiology) where one seeks to identify principles that are both explanatory and predictive and where empirical data is the basis for conclusions. Applying these research concepts to this primarily qualitative research would severely limit the quality and quantity of useful research materials available to this thesis.

- 6) The quantitative research available for this thesis is often historic in nature and, in some instances, it is used to make predictions that are qualitative in nature. Once again this is subject to researcher bias in data selection.
- 7) The dynamic nature of the GE seed industry and the biotechnology that is associated with it can change quickly even within the course of the thesis time frame. This may invalidate earlier assumptions and conclusions and may alter the thesis path as the research progresses.

1.3 The Thesis Path

This thesis can be broken down into six steps, which are diagrammatically illustrated in Appendix A and Appendix B. Step 1 creates a detailed foundational understanding of relevant concepts and terms.

Step 2 focuses on four background areas of importance that are critical to understanding the environment in which GE seeds exist: recent trends in global patenting; global food security; GE seeds as a source of increased food production and food security; and the GE crop controversy.

Step 3 reviews the literature applicable to the promotion and protection of innovation in the GE seed industry. This begins with a critical evaluation of the current interrelationship between patents and innovation with an emphasis on the GE seed industry. This discussion includes an analysis of innovation and how the protection of innovation influences the present and future sustainability of GE seed biotechnology.

A description of the farmer/business interrelationship with food security and innovation then leads to a review of the various interests of the key regulators that influence IPRs in the GE seed industry. Here, I highlight global food security and innovation as vital agricultural and biotechnological regulatory interests as well as key concerns of stakeholders such as farmers. The literature review then focuses on the current environment and structural development of the GE seed industry and the industry's interest in short and long-term value creation and protection. This includes an explanation of how the GE seed industry currently manages innovation to maximize value creation and value capture. I then assess the extent to which the industry relationship with the public sector affects and is affected by their interaction. The literature

review continues with an examination of the current state of private and public strategies for the promotion and protection of innovation in the GE seed industry.

The literature review concludes with a look at GURT. This includes a detailed explanation of how GURT was arrived at as the primary alternative to be researched and compared to the patent as a method of innovation protection and promotion.

Step 4 establishes the research design, which is heavily influenced by the results of the literature review and is the reason that the research design portion of the thesis follows the literature review. This step identifies the innovation criteria and the means of measurement. This is followed by the development of criteria against which to judge the viability of the various alternatives and a suitable method of measurement for these criteria (qualitative and/or quantitative). At this stage, the key data and information sources are identified, and specific methods and techniques for acquiring and processing this data and information are discussed.

In Step 5, data and information gathering and processing occur.

Step 6 involves analysis and interpretation of the research and includes a *feedback loop* to Step 5 as requirements for additional data present themselves.

From this elaboration of the research path, it is obvious that three elements drive the structure of this thesis. They are the designated problem statement; the research question that is derived from this problem statement; and the six steps to complete the thesis.

1.4 Thesis Contribution and Goal

Previous research has established the important role of intellectual property rights in the protection of technological innovation. In the field of biotechnology, and specifically in the genetic engineering of seeds, the use of patents has been thought of as the gold standard for this protection just as it is for more traditional technologies such as information technology. The new technology known as genetic use restriction technology has introduced a unique technologically based potential solution to the IP protection dilemma in biotechnology. That issue is that the traditional IP protection of GE seeds allows for the illegal appropriation of value by simply planting a seed. Previous research in the genetic engineering of agricultural seeds has addressed many of the issues related to both the protection and promotion of innovation in genetically engineered seeds. This earlier research has also tackled many of the concerns that are associated

with both the existing method of IP protection of GE seeds, patents, and the new untested technological method of IP protection, GURT.

The literature has much to say about innovation protection and readily concludes that, yes, GURT provides superior protection in the strictest meaning of the term. But this conclusion has limited value without the global framework of “viability.” The forthcoming literature review speaks to viability issues such as food security and the economic well being of farmers but refers to these issues as either positive or negative isolated attributes of the IP protection methods. However, there is more nuance to viability as various criteria interact and thus alter these positive or negative attributes based on this interaction. The existing literature is fragmented as the various authors deal with specific issues, such as food security, economic well being of farmers and firms, regulatory problems, environmental concerns, and consumer attitudes in a piecemeal manner; in silos that rarely or tangentially interact.

This thesis creates a framework that unites the various fragmented concerns brought forward by the many authors and addresses them as interconnecting viability issues that provide a broadly encompassing analysis to question whether the patent or GURT methods of IP protection is superior for the protection and promotion of innovation. The viability concerns of the various authors are unified, and in this way, the interests of the various stakeholders are addressed as these viability issues are shown to interact. In this thesis, the motivations of individual stakeholders are not judged in isolation but on how they impact all stakeholders.

The primary objective of my thesis is to determine whether GURT represents a viable alternative to the conventional use of patents to promote and protect innovation associated with the genetic engineering of agricultural seeds. In the context of this thesis, the better alternative is the one that it is superior on a qualitative weighted assessment of the three perspectives outlined earlier: the private sector perspective; the public sector perspective; and the perspective of the private/public interrelationship.

The process of striving for this goal provides stakeholders with a view of the prospects and responsibilities of genetic engineering associated with agricultural innovation in the private and public sectors. It can also equip government policymakers with an improved understanding of the strategic concerns of business (and vice versa) so that there may be a more collaborative

effort in the development and implementation of innovation policy affecting the genetic engineering of agricultural seeds.

Beyond this, the significance of GURT as a potential alternative to patents is that it represents a primarily biotechnological alternative to the traditional method of IP protection represented by patents. As such this technology has the potential to change the “game” in innovation protection and promotion not only in agriculture but also in the life sciences field as a whole.

Although there is value in this thesis for both the private and public sectors, the primary audience is the public sector because the major decisions that affect the future use and application of GE seed biotechnology occur in the public sector. It is with the hope that the public sector can better understand the concerns of the private sector that this thesis will identify those private sector features of innovation that are relevant to improved public discourse on this subject. This thesis can act as a common reference to both of these groups and therefore provide a basis for future discussion of the thesis question.

Chapter 2

Foundation and Background

2.0 Value and Innovation

A repetitive theme throughout Joseph Schumpeter's book, "History of Economic Analysis" is the idea that long-term value and profits are a direct result of innovation.¹² Although innovation appears to be Schumpeter's focus, a more nuanced view is that it is value where the focus should be because it is the ability to capture value that is at the heart of the IP system that incentivizes innovators.

Value capture has significance in both the public and private sectors. However, the inability to capture value has a greater immediate impact on private organizations due to their dependence on value capture for economic survival. Unlike the private sector, the public sector can have non-monetary social goals that may define successful value capture.

For business organizations, an important source of value creation is innovation and the ability to capture value from innovation is vital for the success and sustainability of the business firm. Private business innovation can be found in new and unique products, services or business processes. The public sector can also act as a source of value. For example, governments can provide an environment in which business innovation can flourish through programs or regulations that incentivize innovation.¹³ However, value in the public sector can represent even more than a contribution to innovation; it can also be a consequence of innovation that produces societal benefits.

While value capture is a primary consideration for private sector business, the long-term benefits of value creation extend beyond this narrow consideration. Value creation encourages not only innovation but also the development of knowledge networks and human capital that then further supports value creation and allows it to endure.¹⁴

¹² JA Schumpeter, *History of Economic Analysis* (London: Allen & Unwin, 1954, 1986).

¹³ David P Lepak, Ken G Smith & M Susan Taylor, "Value Creation and Value Capture: A Multilevel Perspective" (2007) 32:1 *Academy of Management Review* 180 at 186.

¹⁴ Joseph Rosenblat, "The Interrelationship Between Patents and Innovation in Biotechnology (With Emphasis on Genetically Engineered Seeds in Agriculture)" (2012) A Paper Submitted in Fulfillment of the

Understanding how value and value creation is linked to innovation begins with an appreciation of the difference between invention and innovation. According to Duhaime's Legal Dictionary, an *invention* is, "Any new and useful art, process, machine, manufacture or composition of matter or improvement thereof."¹⁵ In contrast, a business looks at invention more practically by referring to an invention as the development of new products, services or processes from new or recycled knowledge.¹⁶ Frequently, it is existing knowledge presented in new combinations that is the source of inventions. Although each view of invention has merit, the allusion to products and knowledge in the latter definition allows invention to become more than simply an interesting idea. It foreshadows the possibility of something greater... innovation.¹⁷

While the definition of an invention is relatively straightforward, the same cannot be said for the term *innovation*. Unlike the term invention, defining innovation is not based on legal parameters. Many different organizations and experts have proposed definitions for innovation, and often those definitions are molded to fit the requirements of those defining it. In the past, I have found a business definition of innovation to meet my needs and believe that it will, to a great extent, serve the requirements of this thesis because of the emphasis on commercialization.

From a business perspective, the term innovation is understood to be "the expression, combination, or synthesis of knowledge in original, relevant, valued new products, processes, or services."¹⁸ This definition actually argues that to a large extent it is commercialization that transforms an invention or combination of inventions into innovation. Clearly then, innovation is not a predetermined result of all inventions and innovation does not necessarily depend on new inventions. For example, the automobile was an innovation that combined both new and current technology.¹⁹

As my thesis involves both the private and public sectors and business and non-business facets of innovation, a more universally suitable definition of innovation would be more

Requirements for Directed Reading Course GSLAW 6040A, Osgoode Hall Law School, Toronto, Canada at 5.

¹⁵ *Glossary of Legal Terms* (2012) online: Duhaime.org.<<http://www.duhaime.org/LegalDictionary/I-Page2.aspx>>.

¹⁶ *Supra* note 7 at 290 – 291.

¹⁷ *Supra* note 14 at 5.

¹⁸ *Supra* note 7 at 292.

¹⁹ *Supra* note 14 at 6.

appropriate. However, it is possible that the use of any definition at all is insufficient for an understanding of innovation. Shipp et al, in a 2008 paper titled, “ Measuring Innovation and Intangibles: A Business Perspective” that was prepared by the Science and Technology Policy Institute of the Institute for Defense Analyses in support of the U.S. Department of Commerce, Bureau of Economic Analysis, approaches the idea of a definition for innovation very effectively. First, to demonstrate the seeming futility of accepting a single all-encompassing definition of innovation, they list seven currently popular innovation definitions. These definitions are from authors, researchers and organizations involved in studying innovation and so they represent a solid set of alternatives.

i) Innovation is “the commercial or industrial application of something new—a new product, process or method of production; a new market or sources of supply; a new form of commercial business or financial organization.”

Schumpeter, Theory of Economic Development

ii) Innovation is the intersection of invention and insight, leading to the creation of social and economic value.

Council on Competitiveness, Innovate America, National Innovation Initiative Report, 2004

iii) Innovation covers a wide range of activities to improve firm performance, including the implementation of a new or significantly improved product, service, distribution process, manufacturing process, marketing method or organizational method.

European Commission, Innobarometer 2004

iv) Innovation is...the blend of invention, insight and entrepreneurship that launches growth industries, generates new value and creates high value jobs.

The Business Council of New York State, Inc., Ahead of the Curve, 2006

v) Innovation is...the design, invention, development and/or implementation of new or altered products, services, processes, systems, organizational models for the purpose of creating new value for customers and financial returns for the firm.

Committee, Department of Commerce, Federal Register Notice, Measuring Innovation in the 21st Century Economy Advisory, April 13, 2007

vi) An innovation is the implementation of a new or significantly improved product (good or service), or process, a new marketing method, or a new organizational method in business practices, workplace organization or external relations. Innovation activities are all scientific, technological, organizational, financial and commercial steps which actually, or are intended to, lead to the implementation of innovations.

OECD, Oslo Manual, 3rd Edition, 2005

vii) Innovation success is the degree to which value is created for customers through enterprises that transform new knowledge and technologies into profitable products and services for national and global markets. A high rate of innovation in turn contributes to more market creation, economic growth, job creation, wealth and a higher standard of living.

21st Century Working Group, National Innovation Initiative, 2004²⁰

²⁰ Alexandra Shipp et al, “Measuring Innovation and Intangibles: A Business Perspective” (2008) online: Institute for Defense Analysis, Science and Technology Policy Institute
< <http://www.athenaalliance.org/pdf/MeasuringInnovationandIntangibles-STPI-BEA.pdf>> at II-2.

What is apparent from these definitions is how business-oriented they are. So, rather than add to the list of definitions, Shipp et al. decided to look at the critical attributes of innovation to describe its boundaries. The attributes selected are as follows:

- i) Attribute 1: Innovation involves the combination of inputs in the creation of outputs
- ii) Attribute 2: Inputs to innovation can be tangible and intangible
- iii) Attribute 3: Knowledge is a key input to innovation
- iv) Attribute 4: The inputs to innovation are assets [because these assets are repeatedly used]
- v) Attribute 5: Innovation involves activity for the purpose of creating economic value
- vi) Attribute 6: The process of innovation is complex
- vii) Attribute 7: Innovation involves risk
- viii) Attribute 8: The outputs of innovation are unpredictable
- ix) Attribute 9: Knowledge is a key output of innovation [note the relationship to item iii]
- x) Attribute 10: Innovation involves research, development and commercialization²¹

The use of innovation attributes rather than a definition seems to be a more suitable guide for understanding innovation since these attributes resonate within many definitions and broadly emphasize the importance of innovation. This emphasis on the importance of innovation is supported by economist Chris Freeman author of “Innovation and Growth” who, in the mid 1990s, argued that 80% of productivity in the world’s richest economies is due to innovation. Furthermore, he suggests that 80% of gross domestic product (GDP) is a result of this productivity.²² According to Freeman’s figures, this means that 64% of GDP is due to innovation.²³

Not only are productivity and GDP closely tied to innovation but also R&D has an important place in the innovation discussion. R&D spending at the country level is an accepted key measure of innovation as well as a source of improved productivity.²⁴ Firms would argue that the innovation that develops from this R&D requires protection in order to be encouraged. There is unmistakable evidence that the increased mobility of capital, highly skilled workers, and

²¹ Ibid II-1–II-8.

²² Chris Freeman, “Innovation and Growth” in M Dodgson & R Rothwell eds, *The Handbook of Industrial Innovation* (Cheltenham, U.K.: Elgar, 1994) Ch 7 at 78-93.

²³ Supra note 14 at 41.

²⁴ C Criscuolo, JE Haskel & MJ Slaughter, “Global Engagement and the Innovation Activities of Firms” (2010) 28:2 *International Journal of Industrial Organization* 191 at 201 [Criscuolo]; *Intensive Agriculture*, (2014) online:< Britannica Academic Edition <http://www.britannica.com/EBchecked/topic/289876/intensive-agriculture>> at 5.

scientists has added to the growth in the international nature of innovation.²⁵ It is sensible then to conclude that the internationalization of innovation demands that innovation protection should follow suit.²⁶

R&D is one of the earliest solid measures of innovation because it is easy to quantify. However, Shipp et al. point out that measures of innovation have been evolving to include many measures such as innovation surveys, benchmarking, and process indicators such as networks and management techniques.²⁷ Other descriptors of innovation include form, geographical dimension, and intensity.

There are four well-recognized forms of innovation: product innovation; process innovation [involving changes in how a product is produced or provided to the customer]; business organizational innovation; and marketing innovation.²⁸

Geographically, innovation can be global or local [to the firm or to a nation] and each form of innovation can be represented in each geographical dimension. See Figure 1 below.

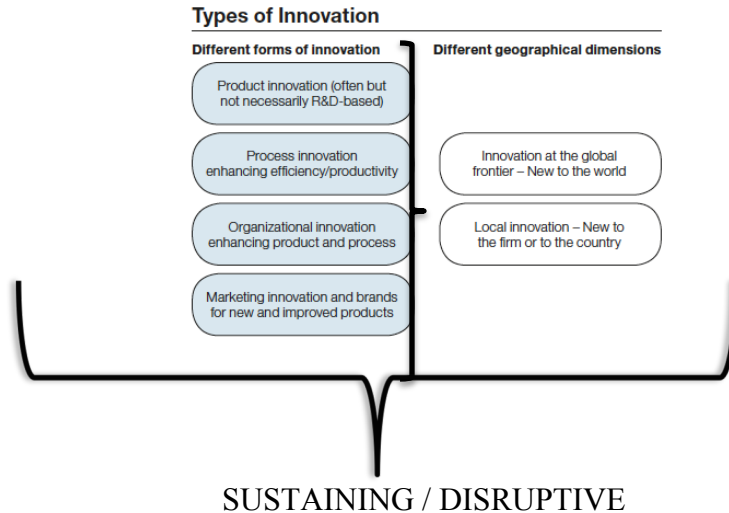
²⁵ Criscuolo, *supra* note 24 at 195.

²⁶ *Supra* note 14 at 8.

²⁷ *Supra* note 20.

²⁸ OECD/Eurostat, *Oslo Manual: Guidelines for Using and Interpreting Innovation Data, 3d ed*, The Measurement of Scientific and Technological Activities (Paris: OECD Publishing, 2005), online: OECD < <http://dx.doi.org/10.1787/9789264013100-en> > at 31-39.

Figure 1: Innovation Forms and Dimensions²⁹



Innovation form and geographical dimension are both easily applied to innovation in any sector of the economy. However, innovation intensity has an arguably more frequent application to high technology fields such as agricultural biotechnology where product development can often outpace immediate product need.³⁰

Innovation intensity can be either sustaining or disruptive and each type can oversee a set of innovation forms and geographical dimensions as illustrated in Figure 1 above. Customers who value existing products and technology and are searching for incremental improvements are the focus of sustaining innovation. Sustaining innovation reinforces the success of firms in existing markets.³¹

In contrast, disruptive innovation targets or creates new markets through the introduction of attributes to which fringe customers³² will be attracted. The end game for disruptive innovation is to eventually become mainstream and in this way to reap the profits associated with

²⁹ Ibid.

³⁰ Supra note 14 at 9.

³¹ Ibid.

³² Fringe customers are those willing to risk the adoption of technology that is not quite ready for “prime time” but with the potential to change “the game.”

widespread use.³³ A significant portion of the GE seed industry has reached the sustaining innovation stage, however, some aspects of this industry such as the development of GURT is a clear example of a disruptive technology hoping to become a disruptive innovation once commercialized. The protection of disruptive technology is a major factor in its potential success since its survival without this protection is far from assured at this stage.

Once established, innovation diffuses not only through customer purchase of the product or service but also by imitation by rivals who seek to appropriate some of the innovation's value.³⁴ This diffusion may amplify the economic and social benefits of the original innovation but it may also threaten the degree of value capture available for the original innovator.

The profitability of an innovation to the innovator depends on much more than the value created by the innovation. It is very much dependent on the ability of the innovator to capture a large share of that value. From a business strategy perspective, appropriability is “the set of conditions that influence the distribution of returns to innovation.”³⁵ In a strong appropriability environment, the innovator is able to capture a considerable share of the value created. This is often an environment with a strong IP system. Without this protection it is possible for other stakeholders to derive a large portion of the value.³⁶

Innovator value capture is often contingent on the establishment of property rights over the sources of the innovation. In the case of inventions, this often entails property rights in the form of patents. In the absence of legal IP protection, the degree of imitation by a competitor will depend on the ease with which the technology on which the innovation is based can be understood and communicated. For this to occur, two characteristics of the knowledge behind the innovation are important.³⁷

The first is the level of tacit knowledge associated with the innovation. If the level of tacit knowledge is low then the technology behind the innovation can be more easily codified. In this case, without IP protection, the resulting rapid diffusion of the innovation will negate any

³³ Supra note 14 at 10.

³⁴ Supra note 7 at 290-293.

³⁵ Ibid at 293.

³⁶ Ibid at 293.

³⁷ Supra note 14 at 11.

competitive advantage for the originator. On the other hand, if the knowledge *is* highly tacit, then imitation is difficult and IP protection is less critical over the short term.³⁸ This is a necessary point to consider in determining the protective capacity of an alternative to patents since if that alternative stresses tacit knowledge the need for patent protection might be reduced dramatically.

The second significant innovation characteristic is complexity of the innovation. Once again, complexity decreases the likelihood of imitation by a rival over the short term.³⁹ Also, as with tacit knowledge, complexity opens up opportunities for patent alternatives.

Tacitness and complexity do not provide lasting barriers to imitation for unprotected innovation, but they do offer the innovator lead-time [the time it will take followers to catch up]. An unprotected innovation with these two characteristics creates a temporary competitive advantage that offers a window of opportunity for the innovator to build on the initial advantage. The challenge for the innovator is to use the initial lead-time advantage to build capabilities and market position to entrench industry leadership while capturing value.⁴⁰

The complementary resources and capabilities needed to finance, produce, and market an invention can be extremely costly in high technology industries such as the GE seed industry. Innovation investment protection is a high priority for these biotechnology firms since, in many cases, this investment represents a significant portion of a firm's total assets.⁴¹ Currently, patents provide innovation protection and permit value capture. Tacitness and complexity offer added but not absolute protection.

However, what if close to absolute protection were possible primarily through the use of technology? Would this be desirable and what would be the financial and social cost? Before answering these questions as they relates to the GE seed industry, a review of the current position of patents in the global IP system is in order.

³⁸ Supra note 7 at 294.

³⁹ Ibid.

⁴⁰ Supra note 14 at 11-12.

⁴¹ Ibid at 12.

2.1 Recent Global Trends in Patenting

Over the past two decades, the international business community has expressed a desire for expanded and more effective international patent use in response to the development of decentralized R&D and innovation practices. The growing internationalization of knowledge networks and the markets on which innovation has become dependent has led the OECD to promote private and public sector patents to protect inventions. The intention is to promote economic development by encouraging innovation and the diffusion of knowledge in member states.⁴²

The increased OECD interest in patent promotion has corresponded to a transformation in patent regimes that has expanded not only what can be patented but also the protections available to patent holders. For example, GE seeds, which represent a previously non-existent category of patentable inventions, are now patentable and offer the inventors strong utility patent protection.⁴³

The 2011 “World Intellectual Property Report: The Changing Face of Innovation” reflects the increased OECD support for patents. The accelerating worldwide demand for patents is demonstrated by the growth in patent applications from 800,000 in the 1980s to 1.8 million in 2009. Much of this increase was from the U.S. and Europe but it also included the newly emerging economies of China and India.⁴⁴

It would not be unreasonable to suggest that the boom in computer technology that occurred in the mid-1990s played a large role in the increase in patent applications. This time period also coincided with the commercialization of GE seeds and the ability to patent those seeds. Both of these product categories accelerated the internationalization of patents as the innovations that made these products broadly accessible crossed borders. As a result, the

⁴² Supra note 3 at 7.

⁴³ Ibid.

⁴⁴ *World Intellectual Property Report 2011 - The Changing Face of Innovation* (Geneva: WIPO, 2011) (WIPO Publication No. 944E/2011)online: WIPO <http://www.wipo.int/econ_stat/en/economics/wipr/wipr_2011.html> at 52.

increasing dependence by firms on intangible assets such as patents has become a necessary source of value and value creation.⁴⁵

World Intellectual Property Organization data paints an evolving picture of world demand for IPRs. The bulk of that demand currently originates primarily from Europe, Japan and the US although a recent shift in demand from Asia has occurred. China is the most dramatic example of this shift. Patent applications from China grew from 1.8% to 17% from 1995 to 2009, a 844% increase.⁴⁶

One reason for the dramatic increase in patent applications in China is instructive as it demonstrates the value placed by innovators on the protection of the sources of innovation once there is something worthwhile to protect. For years China was notorious for flouting international IP laws and, as a result, the country managed to establish a growing manufacturing sector often based on copied products. More recently, China has become a centre of innovation and that has led to a realization within the country that IP protection is a fundamental requirement to shield that innovation and to capture the value associated with it. Interestingly, GE seeds and other areas of agricultural biotechnology are high on the list of innovation sources in China. This should not be surprising considering not only the increasing basic food demands of China's immense population but also, the growing demand for higher quality, resource-intensive food [e.g. meat] by a surging middle class with money to spend on luxuries.

Increased patent applications have been noted in most patent offices in OECD countries in the past two decades. This is particularly evident in the high technology areas of information and communication technology (ICT) and biotechnology. Biotechnology patent applications in the European Patent Office (EPO) grew "from 4.3% in 1994 to 5.5% in 2001 [filing years]. During the same period, the share of ICT... [patent applications]... climbed from 28% to 35%."⁴⁷ These patterns were repeated in the United States Patent Office (USPTO).⁴⁸ The correlation among patent numbers, inventions and innovation is strikingly positive for these two technologies.

⁴⁵ Ibid at 7.

⁴⁶ Ibid at 56.

⁴⁷ Supra note 3 at 11.

⁴⁸ Ibid.

There is strong quantitative evidence that behind this extraordinary surge in patenting is a dramatic increase in R&D expenditures in ICT and biotechnology. This has fuelled the development of both sustaining and disruptive technologies in both of these fields. However, changes in the economic landscape and in patent systems have also helped to increase the patent application numbers.⁴⁹ The modification in patent regimes has been particularly important in encouraging this trend over the past two decades.⁵⁰ Not only have changes in patent regimes promoted this trend but also these changes have been a consequence of market mechanisms that have led to the demand for more patents to meet new economic conditions. Especially significant is the increase in international competitive forces in OECD member countries as the importance of high technology firms has grown. This competition has been fuelled by the surge of new entrants in these high technology areas with a concurrent demand for more patents to accommodate this surge.⁵¹

Patents are in demand as a source of value capture because, historically, they are what business understands as a means of innovation protection through the protection of inventions. Just as Edith Penrose suggested in 1951, it is now difficult to make the case for the elimination of patents.

2.2 Biotechnology and Patents

There are thousands of biotechnology-based patents issued every year. Although most are issued in the developed world, the demand for these patents is global. A mere 20 years ago it was relatively difficult to patent biotechnology just as it was difficult to patent business methods and software. Today biotechnology patents are common and actively sought after by technology

⁴⁹ Samuel Kortum & Josh Lerner, “What Is Behind the Recent Surge in Patenting?” (1999) 28:1 Research Policy 1 *World Intellectual Property Report 2011 - The Changing Face of Innovation* (Geneva: WIPO, 2011) (WIPO Publication No. 944E/2011) online: WIPO < http://www.wipo.int/econ_stat/en/economics/wipr/wipr_2011.html> at 54; Samuel Kortum, Jonathan Eaton & Josh Lerner, “International Patenting and the European Patent Office: A Quantitative Assessment” (2003) in *Patents Innovation and Economic Performance: Conference Proceedings*, (28-29 August 2003) (OECD, forthcoming) as cited in OECD. *Patents and Innovation: Trends and Policy Challenges* (Paris: OECD Publishing, 2004), online: OECD <<http://dx.doi.org/10.1787/9789264026728-en>> at 15.

⁵⁰ Supra note 3 at 7.

⁵¹ Ibid.

firms and yet these patents are occasionally the subject of controversy.⁵²

The development and practical implementation of genetic engineering in the biological sciences has fuelled the demand for patenting by the biotechnology industry. Patenting provides the most secure IP protection available to two of the most important industries that are biotechnology-based, pharmaceuticals and agricultural biotechnology.⁵³

The introduction of patenting in biotechnology was not an obvious extension of patenting in other fields. The 1980 U.S. Supreme Court decision in *Diamond v. Chakrabarty*, which supported the patenting of a GE bacterium, was instrumental in initiating a surge in life-form patenting. This patenting of life forms has been extended in many OECD countries to include genes, gene fragments, GE plants and animals, and the tools and processes that are required to genetically engineer plants and animals. Internationally, court decisions have repeatedly confirmed the patentability of biotechnologically based genetic inventions. In addition, legislation has been established to support this patentability. Encouragement for this patentability is also found in international trade agreements and through the guidelines available in patent offices in North America and Europe.⁵⁴

The ability to patent life forms and the building blocks of life has not been without controversy. There are issues such as inadequate access to patented inventions that can hinder further research in both new products and processes if those inventions represent tools needed to make that progress. Accessing those tools may be possible but the cost to do so may be prohibitive.⁵⁵

Patent quality and scope are also issues of concern as patent offices increasing issue patents involving genes and gene fragments that may be problematic. The question that has been raised is whether the traditional criteria for patentability are being adequately met in some cases.

⁵² Nancy T Gallini, “The Economics of Patents: Lessons from Recent U.S. Patent Reform” (2002) 16:2 *Journal of Economic Perspectives* 131.

⁵³ *Supra* note 3 at 22.

⁵⁴ *Ibid.*

⁵⁵ *The Ethics of Patenting DNA: A Discussion Paper* (2002), online: Nuffield Council on Bioethics < <http://nuffieldbioethics.org/project/patenting-dna/> > [Nuffield]; OECD, *Genetic Inventions, IPRs and Licensing Practices: Evidence and Policies* (Paris: OECD Publishing, 2003a), online: OECD < <http://www.oecd.org/science/sci-tech/2491084.pdf> > at 24 [OECDa]; John P Walsh, A Arora & WM Cohen, “Effects of Research Tool Patents and Licensing on Biomedical Innovation” in *Patents in the Knowledge-based Economy* (Washington, D.C.: The National Academies Press, 2003) 285.

That is, are these “inventions” new, useful, and unobvious. If not, then the resulting overly broad patents that result could be detrimental to licensees in their negotiations with patent holders.⁵⁶

An example of this problem occurs with the questionable patenting of some gene fragments where many of these fragments are required for a single product. The firm carrying out the research for the product is then obliged to negotiate with multiple patent holders if each holder has a patent on a different fragment. This could hinder research to the point that the research needed to produce the product and the resulting innovation is stifled.⁵⁷ The resulting increase in transaction costs either raises the cost of the final product or acts as a financial barrier to undertaking the innovation in the first place.

As much as restricted access to even questionable patented material is a problem, the private and public sectors have established the means to maintain a good level of knowledge diffusion. Negotiations over licenses are a common although not always successful practice as is “*inventing around*”⁵⁸ a patent. However, these alternatives have a downside in that the time and effort involve invariably increases transaction costs.

While much biotechnology patenting takes place in the private sector, the public sector has also been actively patenting biotechnological inventions. For example, “U.S. and European PROs [Public Research Organizations] own 30% of all the patents for DNA sequences filed between 1996 and 1999.”⁵⁹ Academic patenting, involving inventions developed by universities and PROs, takes place not only in OECD member countries but also in many non-OECD countries.⁶⁰ National governments often support this growth in the hope that social and private benefits that result from the commercialization of academic research will benefit their domestic economies.⁶¹

Universities and PROs are responsible for most R&D in some countries. In China, non-

⁵⁶ Ibid; Nuffield, *supra* note 55; OECDa, *supra* note 55.

⁵⁷ *Supra* note 52 at 146.

⁵⁸ *Supra* note 3 at 23; “Inventing around” involves using as much of the information provided in a patent without infringing on the patent.

⁵⁹ Ibid at 22.

⁶⁰ OECD, *Turning Science into Business: Patenting and Licensing at Public Research Organizations* (Paris: OECD Publishing, 2003b), online: OECD < <http://www.oecd.org/sti/sci-tech/turningscienceintobusinesspatentingandlicensingatpublicresearchorganisations.htm> > at 19.

⁶¹ *Supra* note 3 at 19.

private basic research is virtually at 100% of all research carried out. The figure for Mexico is 90%; for the Russian Federation, 80%.⁶² Of course, this has led to a marked increase in patent applications by universities and PROs in these countries.

In developed countries, public sector R&D in biotechnology is less than the levels seen in countries such as China, Mexico and the Russian Federation. However, whether in developed or developing countries, transforming basic research into innovation often requires private sector input, especially when it comes to commercialization. As a result, synergies develop between the public and private sectors to ultimately bring products to market. There are, however, concerns that this close interaction may also have negative consequences for invention and innovation if, for example, the private sector identifies certain knowledge that should not be shared with the public sector for strategic competitive reasons. A particular concern for the public sector is that academic patenting for monetary gain by public institutions may limit the scope of follow-up research in complex technologies to those areas that have a substantial return on investment.⁶³ In this way, the public sector can act much like the private sector.

Rivalry in the private sector is certainly a key source of suspicion between public and private sector innovation promoters. Cooperative arrangements to advance innovation are common between the two, however, the level of trust required to maximize innovation potential is difficult to maintain when the goals of each sector often do not coincide.⁶⁴

One area where this cooperation is most vital is the area of global food security where agricultural biotechnology in general and GE seeds in particular offers the potential to positively address public sector concerns.

2.3 Global Food Security

It takes very little imagination to conclude that there are significant links among GE crops, innovation and the future of global food security. Even a cursory examination of their web site confirms that global food security is a critical concern of international organizations such as the United Nations Food and Agriculture Organization. As such, factors that influence food

⁶² Supra note 44 at 14.

⁶³ Ibid at 16.

⁶⁴ Supra note 14 at 25.

security are important to this and other international organizations that monitor and attempt to influence the level of global food security. These factors include among others innovation, patents, and business strategies in agricultural biotechnology. However, addressing these factors requires an understanding of the definition of food security.

The path to a final definition of food security was by no means straightforward as the end result passed through over 200 published iterations by the 1990s.⁶⁵ As the definition evolved over time, the process of definition development has created specific attributes that can be used to measure success in achieving global food security. With the development of so many interim definitions of food security, it is surprising that the concept had its origin as recently as the global food crisis of the mid-1970s. In the mid-1970s, it was basic food availability [i.e. a supply side model] nationally and internationally that was the measure of food security.⁶⁶

As the sources of famine began to be researched more thoroughly in the 1970s, and the consequences of hunger became better understood at the individual level, the supply side measures of food security were supplemented by a demand side view of the problem that attempted to address consumption issues as well as production.⁶⁷ While the public sector emphasized the supply side of food security, the private sector continued to look at how innovation could profitably enhance both supply and demand.

The 1996 World Food Summit's "Plan of Action" eventually developed the current definition of food security.⁶⁸ That definition is, "Food security, at the individual, household, national, regional and global levels [is achieved] when all peoples, at all times, have physical and economic access to sufficient, safe and nutritious food to meet their dietary needs and food preferences for an active and healthy life."⁶⁹

By 2001, the above definition of food security was firmly entrenched and broadly accepted although its measurement was still a contentious issue. Measurement was a problem

⁶⁵ Edward Clay, "Food Security: Concepts and Measurement" (2002) in *Trade Reforms and Food Security: Conceptualizing the linkages* (UNFAO, Economic and Social Development Department, 2002), online: UNFAO <<http://www.fao.org/docrep/005/y4671e/y4671e06.htm>> at 25.

⁶⁶ Ibid at 26.

⁶⁷ Ibid at 27.

⁶⁸ UNFAO, *Rome Declaration on World Food Security and World Food Summit Plan of Action*, (1996) online: UNFAO<<http://www.fao.org/docrep/003/w3613e/w3613e00.HTM>>.

⁶⁹ Ibid at Plan of Action para 1.

because of the subjective nature of many of the then accepted food security attributes such as levels of chronic hunger and poverty.⁷⁰ As a result, it was difficult to evaluate any attempts to improve the food security situation without a reliable objective method of measuring those attempts.⁷¹

The importance of food security measurement cannot be underestimated from a public policy perspective. If policymakers address the patent/innovation dilemma as a means to promote societal benefits and one of the key benefits is enhanced food security, then there needs to be a food security measurement that can identify the success or failure of any policy initiatives.

Two food consumption concepts, undernourishment and undernutrition, highlight the food security measurement problem. The first, undernourishment, describes a lack of caloric intake needed to meet an individual's dietary energy needs. The second, undernutrition, describes the inability of the human body to effectively utilize those nutrients that are consumed. Undernutrition is usually a result of undernourishment although undernutrition could also be related to the quality of the food consumed.⁷² Undernourishment and undernutrition are difficult attributes to measure either directly or accurately because of the lack of available comprehensive, high quality data that is broadly meaningful. For example, consumer expenditure and national income data, which may not be internationally comparable and are often meaningless in the food security discussion, are analyzed to arrive at conclusions that are of little or no practical value.⁷³

At the international level, food security is affected by the interaction of various food production and distribution methods, and food trade arrangements. Nationally, food security can be affected by a country's food supply over a specific period of time. As a result of these influences, food security measurements and the veracity of the data can vary widely between developed and developing countries. Even international categories such as wealthy individuals or poor individuals can rely on a mixed bag of measurements leading to questionable food security

⁷⁰ Supra note 65 at 29.

⁷¹ Joseph Rosenblat, "The Effect of Intellectual Property Rights Associated with Genetically Engineered Seeds on Global Food Security" (2012) A major research paper in partial fulfillment of the requirements for the degree of Master of Laws, Osgoode Hall Law School, Toronto, Canada at 6-7.

⁷² Supra note 65 at 29.

⁷³ Ibid.

data.⁷⁴

Even measurements that one might assume to be straightforward can mislead when attempting to quantify food security. Agricultural performance would appear to be an indisputable means of assessing some aspect of food security from the farm level to the global level. However, agricultural liberalization, which has altered the monitoring and reporting of agricultural production has made this data dubious. Other factors from the effect of weather to the economics of food pricing and even currency flows and manipulation affect food security measurement as they are all difficult to quantify to any standard that is reproducible. Risk and uncertainty, which is discussed later in this thesis in greater depth, also impacts the ability to quantify food security as the psychology of trade in food can match that, which occurs in the stock market.⁷⁵

Finally, to emphasize the vastness of factors affecting food security one need only suggest the importance of land and water availability as two key determinants of food security. Add differences in national infrastructures; environmental factors such as climate change; and political and legal systems that function with varying degrees of effectiveness and one can recognize the problems associated with selecting and measuring food security criteria that are not only acceptable to all but also are useful.⁷⁶

In spite of the difficulty in determining good food security measurement attributes, the FAO Agricultural and Development Economics Division published a policy brief in June 2006 in which four acceptable dimensions of food security are described that together allow for widely acceptable food security measurement: availability, access, utilization and stability.⁷⁷

This policy brief defines food *availability* as, “the availability of sufficient quantities of food of appropriate quality, supplied through domestic production or imports” [including food

⁷⁴ Ibid.

⁷⁵ Ibid at 33.

⁷⁶ Geoff Tansey, (2002) “Food security, biotechnology and intellectual property: unpacking some issues around TRIPS: a discussion paper” (Geneva: United Nations Quaker Office, 2002) at 3.

⁷⁷ EC-UNFAO, *What is Food Security - Food Security Information for Action Programme* (2008), online: UNFAO < <http://www.fao.org/elearning/course/FC/en/lesson.asp?lessoncode=0411>> [EC-UNFAO]; UNFAO, *Food Security*, Policy Brief (2 June 2006) Issue 2, Published by FAO, Agriculture and Development Economics Division (ESA) with support from the FAO Netherlands Partnership Programme (FNPP) and the EC-FAO Food Security Programme at 1 [UNFAO(a)];

aid].⁷⁸

The second dimension, food *access* refers to, “access by individuals to adequate resources [entitlements] for acquiring appropriate foods for a nutritious diet.”⁷⁹ In this case, entitlements are, “the set of all commodity bundles over which a person can establish command given the legal, political, economic and social arrangements of the community in which they live [including traditional rights such as access to common resources].”⁸⁰ Of course, money alone does not necessarily lead to food security since without food availability, there is nothing to purchase and there is food insecurity.⁸¹

Utilization, the third dimension of food security, refers to the consumption of nourishing and nutritious food and availability of the non-food requirements that allow this to take place. This includes, “an adequate diet [the combination of foods for optimum nutritional value], clean water, sanitation and health care to reach a state of nutritional well-being where all physiological needs are met.”⁸² Food security is, therefore, not simply a matter of quantity but also quality. It is the nutritional value aspect of utilization that is most applicable to GE seeds because genetic engineering can potentially alter the nutritional content of a crop.⁸³

Finally, the fourth dimension *stability* highlights the requirement that for food security to exist, an individual, household, or population must, “have access to adequate food at all times.”⁸⁴ This access should not be subject to, “sudden shocks [e.g. an economic or climatic crisis] or cyclical events [e.g. seasonal food insecurity].”⁸⁵ Stability stresses the need to “stabilize” availability, access and utilization.⁸⁶

In comparing the viability of patents and GURT with respect to global food security, it is the dimensions of food security that must be addressed quantitatively and/or qualitatively.

As the profile of global food security rises with the world’s population, scientific

⁷⁸ Ibid.

⁷⁹ Ibid.

⁸⁰ Ibid.

⁸¹ EC-UNFAO, supra note 77 at 10.

⁸² UNFAO(a), supra note 77 at 1.

⁸³ Supra note 71 at 10.

⁸⁴ UNFAO(a), supra note 77 at 1.

⁸⁵ Ibid.

⁸⁶ Ibid at 1, 3.

breakthroughs in agriculture have begun to impact what kind of food is grown and how it is grown. Among the most discussed and sometimes controversial scientific breakthroughs in agriculture is the genetic engineering of agricultural seeds.

2.4 Genetic Engineering in Agriculture

Genetic engineering in agriculture continues to evoke passionate debate as new advances in this field disrupt the agricultural status quo. Often it is *fear* that seems to be centre stage in the emotional tug of war between proponents and opponents of this biotechnology. For its opponents, genetic engineering in agriculture surfaces fears of adverse health consequence; fears of the loss of biodiversity; fears of corporate monopolization of food; and fears of the *unnatural*.

In contrast, proponents of this technology stress the need to promote and protect it and that there is no science-based reason for trepidation. Ultimately, the public is left to sort it out for themselves based on whatever information they can glean from available sources. The degree to which the public lacks an understanding of this subject is astounding given that virtually everyone seems to have an opinion. This fact is discussed in the viability section of this thesis where consumer acceptance of GURT vs. non-GURT GE seeds is addressed as a critical viability factor to be considered in making a choice between the two alternatives.

To be able to judge properly the alternatives for promoting and protecting innovation in GE seed biotechnology, it is necessary to understand what genetic engineering is and how it is accomplished. In this way, the topic can be removed from the realm of science fiction and placed firmly within the sphere of science. Initially, it is within a scientific context that one can begin to address the thesis question logically.

In addition, there is little value in discussing the viability of alternatives to protect and promote innovation in GE seeds if one does not clearly understand what GE seeds are, how they are created, and what science knows or does not know about the consequences of their growth. It is not that any conclusions about the acceptability of one choice over another should be based purely on science but rather that science is the starting point for the discussion.

Genetic engineering involves the artificial manipulation of genes and is, therefore, based on an understanding of the genetic aspects of cell biology. This area of cell biology focuses on how genetic information flows within the cell. Chromosomes, as carriers of this information, are

central to this information flow. According to the chromosome theory of heredity, the characteristics (traits) of living organisms are passed down from generation to generation through the inheritance of chromosomes which carry distinct physical units known as genes. A gene is a segment of DNA (deoxyribonucleic acid) that contains the information required to carry out one of two functions. One type of gene is responsible for the production of a protein that might serve as the building block for structures, enzymes or various other fundamental mechanisms that support life. The other type of gene is used to control the first type of gene. That control gene can, for example, instruct another gene to begin or cease producing a specific protein. It can also control another control gene by instructing it to become active or to shut down.

DNA has a long double helix atomic structure that is condensed into a chromosome, which is located within each cell of an organism (often within the nucleus). See Appendix C. (DNA Location and Arrangement)

Genetic engineering is a process that depends on understanding what DNA is, how it is created, how it is duplicated, how it is mutated, and the consequences of changing its structure. Changing genes within DNA results in changes to the proteins produced by cells. New proteins may be produced; old proteins may be inhibited. It is the ability to change or add to the proteins coded by DNA that is at the heart of genetic engineering.

For example, one can identify and copy a specific gene from an existing plant. For discussion purposes, let us say that this gene is responsible for the production of a protein that gives the originating plant the ability to resist a particular herbicide. If this trait would be beneficial in a soybean plant that does not currently possess it, the gene copy can be artificially inserted into the DNA structure of the soybean plant. That soybean plant will now produce a protein that confers the herbicide resistance to the soybean plant. In a field growing this GE soybean, the application of this particular herbicide will kill any plants that do not contain this gene. As a result, the “weeds” die, and the soybean plants survive. The outcome can be a greater yield of soybeans since the nutrients in the soil are not “stolen” by the “weeds”.

To summarize, genetic engineering involves the techniques of identifying useful genes and copying them so that they can be inserted into the DNA of a target plant. The target plant

will display the trait that the gene controls by producing the protein(s) that confer the desired trait. Traditional plant breeding can have the same outcome but the time frame is much greater; the results are less specific; and the potential source of value added traits is limited to plants of the same species.

Genetic engineering in this thesis refers specifically to transgenic plants. In this context, transgenesis involves the insertion of genes into a plant to produce a new phenotype.⁸⁷ These characteristics that are now a part of the new plant can be valuable to a variety of stakeholders including consumers, farmers and biotechnology firms.

GURT is a fairly recent, but not yet commercialized, subset of the genetic engineering of seeds and one that has the potential to change the fundamentals of innovation protection and promotion in agriculture.

The idea behind GURT originated during discussions in 1993 between the USDA scientists and representatives of DeltaPine (a seed biotechnology company). Mel Oliver, the principal inventor named on the first GURT patent (U.S. Patent No. 5,723,765, March 3, 1998), describes in an AgJournal.com interview in 2005 how the USDA approached DeltaPine to encourage the company to develop cotton hybrids.⁸⁸ Although DeltaPine declined this request, the company did express an interest in developing GE plants that produced sterile seeds.⁸⁹ By 1995 the USDA and DeltaPine had succeeded in producing tobacco plants with sterile progeny seeds. In 1998 a patent titled, “Control of Plant Gene Expression” was granted.⁹⁰

GURT relegates IPRs to a secondary role in IP protection. GURT’s primary purpose was to prohibit unauthorized seed-saving by farmers; in other words, to prevent farmers from saving second-generation GE seeds and using these seeds to grow a subsequent crop without paying for

⁸⁷ A new plant phenotype is a plant with new observable physical or biochemical characteristics.

⁸⁸ Interview of Dr. Mel Oliver by AgJournal.com (19 July 2005) in Stephen Hubicki & Brad Sherman, *The Killing Fields: Intellectual Property and Genetic Use Restriction Technologies* (2005) 28:3 UNSW Law Journal 740 at 741.

⁸⁹ Ibid.

⁹⁰ Supra note 9; The patent contains a number of claims including a method for making a genetically modified plant, a method for producing seed that will not germinate, and a method of producing non-viable seed. The patent also claims a number of products that result from the use of these methods.

the protected GE traits that those seeds contain. However, there are other uses for GURT such as the prevention of outcrossing.⁹¹

Although the commonly discussed version of GURT refers to the sterility of second-generation seeds as the means by which firms control their GE seed IP, this technology is about much more than seed sterility. There are in fact two biotechnological GURT principles involved in these seeds that create two strategically different types of GE seeds. One type of GURT seed is the variety-genetic use restriction technology (V-GURT), and the other the more benign trait-genetic use restriction technology (T-GURT). It is V-GURT that is associated with seed sterility and, therefore, where the term “terminator seed” originates. One variation of the V-GURT technology allows germination but with the desired trait “turned off.” In this latter scenario, the application of a spray [the *key* or *inducer*] can resurrect the desired trait.

On the other hand, T-GURT seeds contain one or more proprietary GE (value-added) traits that require activation to be expressed. Absent this activation, the seeds are perfectly viable as conventional seeds. One possible way to activate the value-added trait would require that farmers purchase a chemical inducer from the GE seed company that would target the specific genes in question. A better alternative, from the GE seed firm perspective because it gives the firm greater control, is to require the firm itself to activate the trait with the chemical inducer at a particular stage of plant development before seeds are harvested.

A good analogy to demonstrate the operation of T-GURT is the plain language algorithm in Appendix D. In Appendix D, the *dotted* actions and decisions represent the equivalent of what takes place if the T-GURT gene *is* activated. The T-GURT gene is represented by “Total.” If activated, this “gene” will result in a printout of the sum of the numbers “1” to “10.” The “0” in “Total = 0” represents the inducer being applied to activate the “Total” gene. Without the activation of “Total” by applying “0” at the first decision sequence, the algorithm will by-pass the special attribute of “Total” that allows “Total” to successfully add the numbers “1” to “10.”

⁹¹ Outcrossing is the unintentional movement of genes from GE plants into conventional crops or closely related species in a non-farm environment. Outcrossing can also involve the mixing of crops derived from conventional seeds with those grown using GE crops.

That is, the lack of activation of the “Total” gene by not applying “0” to it, leads to “Total = -1”. This is the same concept as a T-GURT genetic trait that is never activated by an inducer.

Table 1 is a comparison of the outputs from the activated “Total” gene (i.e. the equivalent of the activated T-GURT gene) and the non-activated gene that results from “Total = -1.” (i.e. the equivalent of the non-activated T-GURT gene):

Table 1: GURT-Like Algorithm Output

<u>Inactivated “Total = -1”</u>	<u>Activated “Total = 0 “</u>
<u>Algorithm Iterations</u>	<u>Algorithm Iterations</u>
1	1
2	2
3	3
4	4
5	5
6	6
7	7
8	8
9	9
10	10
“Total” output = NOTHING	“Total” output = 55

The “Total” output of “55” on the right side of the table represents the result of the activated “Total” gene. That is, applying the inducer “0” activates the “Total” gene and it can then fulfill its potential by adding up the iterations of the algorithm and produce the answer “55.” The “55” is the visible consequence of the activation of the “Total” gene. An example of an agricultural equivalent for ”55” is “drought resistance” that is conferred on a plant by the activation of a drought resistant gene by a chemical inducer. To summarize, the “55” is the equivalent of “drought resistance.” “Total” is the equivalent of the gene that confers drought resistance on the plant. The “0” is the equivalent of the chemical inducer that activates the drought resistant gene.

The “Total” output of “NOTHING” on the left side of the table represents the result of the inactivated “Total” gene. That is, the “Total” gene is unable to fulfill its potential because the

“0” inducer does not activate it and it is, therefore, unable to add up the iterations of the algorithm.

GURT allows the seed company to prevent the use of the seed beyond its contracted use, usually the current growing season and requires users to purchase new seed each year. Also, the GURT control attribute has environmental, farmer, regulatory, and IP consequences that are at the core of its viability as an option to patented-only GE seeds.

Since GURT seeds are GE seeds, the current international status of commercialized non-GURT GE crops can provide some insights into the potential for this very specialized version of GE seeds to succeed in the marketplace.

In 2010, patented GE crops represented 10% of total (1.5 billion hectares) global cropland under cultivation.⁹² This area of GE crops includes corn, wheat and rice which are particularly important to global food security.

Industrialized countries first grew GE crops in 1995 but by 1999 the rate of growth in GE crop acreage in developing countries began to exceed that in industrialized countries.⁹³ By 2010, the number of countries growing GE crops grew to twenty-nine from the twenty-five reported in 2009. At the time, these twenty-nine countries contained 59% of the total world population.⁹⁴

The 2010 ISAAA 2010 Brief on the Global Status of Commercialized Biotech/GM[GE] Crops reports that nineteen of the twenty-nine countries planting GE crops are developing countries. Overall, as of 2010, fifty-nine countries with 75% of the global population grow or allow the importation of GE crops or products.⁹⁵

Although the trend toward GE crops continues, there are important regional variations in the acceptance of GE crops. The most significant resistance to GE crop use and consumption occurs in the EU where the Precautionary Principle has been a central feature bolstering those

⁹² Clive James, “Global status of commercialized biotech/GM crops: 2009 - ISAAA Brief 41” (2010) online: ISAAA <<http://www.isaaa.org>> at 7-10.

⁹³ Clive James, “Global status of commercialized biotech/GM crops: 2010 - ISAAA Brief 42” (2011) online: ISAAA <<http://www.isaaa.org>> at 10.

⁹⁴ Ibid at 5.

⁹⁵ Ibid at 223.

who oppose what is often referred to as GMOs (Genetically Modified Organisms).⁹⁶ A fuller discussion of the Precautionary Principle as it relates to this thesis follows shortly.

Currently, international trade in GMOs and products containing GE materials is based on rules agreed to by the World Trade Organization (WTO) Members at the end of the Uruguay Round of trade negotiations. The specific rules are noted “in the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), the Agreement on Technical Barriers to Trade (TBT Agreement) and the General Agreement on Tariffs and Trade (GATT) 1994.”⁹⁷ In addition, the reliance of agricultural biotechnology on IPRs brings the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) into the picture. The international movement of GMOs has also led to specific non-trade related multilateral agreements.⁹⁸ One such agreement, the Cartagena Protocol on Biosafety, is particularly important to the GE crop and food debate and directly impacts the discussion of the safety of GURT.

The Cartagena Protocol on Biosafety was negotiated during the Convention on Biological Diversity in Rio de Janeiro in 1992. It was adopted on January 29, 2000, following four years of negotiations. The Protocol came into effect on September 11, 2003. Currently, 164 countries have ratified or acquiesced to this agreement.⁹⁹ The Protocol became effective at a time when certain countries were applying restrictive trade policies to agricultural biotechnology.

A central feature of the Cartagena Protocol is its use of a Precautionary Principle to judge the safety of GE food products. Article 1 of the Protocol references Article 15 [within which the Precautionary Principle is defined] of the 1992 Rio Declaration on Environment and Development. The Precautionary Principle contained in Principle 15 of the Rio Declaration states: “Where there are threats of serious or irreversible damage, *lack of full scientific certainty* [my emphasis] shall not be used as a reason for postponing cost-effective measures to prevent

⁹⁶ GMO is a term often used to describe an organism in which genetic engineering techniques have been used to alter the genetic code artificially. A GE plant is a GMO.

⁹⁷ UNCTAD, *International Trade in GMOs and GM Products: National and Multilateral Legal Frameworks* (UNCTAD/ITCD/TAB/30) (2005) online: FAO < http://www.fao.org/fileadmin/user_upload/gmfp/resources/UNITED%20NATIONS%20CONFERENCE%20ON%20TRADE%20AND%20DEVELOPMENT.en.pdf > at 24.

⁹⁸ Ibid.

⁹⁹ UNEP/CBD, *Cartagena Protocol on Biodiversity: Text of the Cartagena Protocol on Biosafety* (2015), online: Convention on Biological Diversity < <http://bch.cbd.int/protocol/text/> >.

environmental degradation.”¹⁰⁰ The Cartagena Protocol interprets the Precautionary Principle through the use of specific language that identifies living modified organisms (LMOs) “for intentional introduction into the environment” and also “LMOs for use as food, as feed, or for processing.” Articles 10 and 11 of the Protocol include precautionary language very similar to that contained in the Rio Declaration: “Lack of *scientific certainty* [my emphasis] due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of the living modified organism ..., in order to avoid or minimize such potential adverse effects.”¹⁰¹ In other words, the inability to prove with certainty that LMOs are harmful will not prevent their exclusion. The effective result of this “test” is that no matter how often LMOs [read GMOs or GE seeds] are shown to be safe, the possibility that harm may be shown to exist at some future time supports their exclusion. Interestingly, on this basis, this “test” if applied to the pharmaceutical industry would support the exclusion of every drug ever manufactured.

The Novel Foods and Novel Food Ingredients Regulation 258/97/EC(2) regulates GE food in the EU. A “novel food” has a number of characteristics to be classified as such in the EU. It must not previously have been extensively consumed in the EU; it must be safe; and it must be nutritionally substantially equivalent to food for which it is a replacement.¹⁰² This regulation [258/97/EC(2)] has been replaced by Regulation (EC) No 1829/2003. The new regulation allows for GE foods that have passed risk assessment and are properly labelled. So, while according to the Cartagena Protocol, nations may invoke the Precautionary Principle to exclude GE foods, the EU regulation has chosen to be somewhat less strident in their application of the Principle.

The Precautionary Principle allows precautionary measures to be taken by nations whenever unknown risks prove impossible to assess. This is the basis for applying this principle

¹⁰⁰ *Report of the United Nations Conference on Environment and Development: Rio Declaration on Environment and Development*. UNCED, Annex I, UN Doc A/CONF.151/26(Vol.I) (1992) online: United Nations <<http://www.un.org/documents/ga/conf151/aconf15126-1annex1.htm>> Principle 15.

¹⁰¹ *Supra* note 99 at 8.

¹⁰² S Harlander, “Safety assessments and public concern for genetically modified food products: the European view” (2002) 30 *Toxicology Pathology* 129.

to GE food. Since it is impossible to assess the nature of an unknown risk, the opponents of GE crops and food suggest that the precaution required is to prohibit the product or to label it in a manner that allows consumers to judge for themselves whether they wish to accept the “risk” of using it.¹⁰³ However, there is also a risk associated with refusing the potential benefits of a product. In this case the potential benefits may include increased food security, a feature that may be less of a concern in the EU than in a developing country that does not have “the luxury of taking part in a philosophical debate that would pit GE food against a future of food insecurity.”¹⁰⁴

The Precautionary Principle has established a strong following in the international environmental law community. The Rio Declaration, agreed to at the 1992 U.N. Earth Summit, states not only that “[w]here there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation,”¹⁰⁵ but also that “[i]n order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities.”¹⁰⁶ Other international treaties such as the Vienna Convention for the Protection of the Ozone Layer, the United Nations Framework Convention on Climate Change, and the Convention on Biological Diversity take a similar approach in referencing the Precautionary Principle. This principle is also at the forefront of other EU fields such as environmental protection and health (human, animal, and plant).¹⁰⁷

In the EU, the Precautionary Principle does not prohibit GE foods but it suggests that unless there is scientific evidence proving the safety of GE foods it is acceptable to presume that this food is unsafe.¹⁰⁸ This has inspired many GE food opponents to call for the regulation or

¹⁰³ Jonathan H Adler, “More Sorry Than Safe: Assessing the Precautionary Principle and the Proposed International Biosafety Protocol” (2000) 35 *Texas International Law Journal* 173 at 179.

¹⁰⁴ Joseph Rosenblat, “Labelling Genetically Engineered Food: a controversy Over the Assessment and Regulation of Unknown and Unknowable Risks” (2013) A Major Research Paper in partial fulfillment of the requirements for the degree of PhD (Law), Osgoode Hall Law School, Toronto, Canada.

¹⁰⁵ *Supra* note 100.

¹⁰⁶ *Ibid.*

¹⁰⁷ S Yearley, “Mapping and interpreting societal responses to genetically modified crops and food” (2001) 32 *Social Studies of Science* 151 at 154.

¹⁰⁸ Clare B Herrick, “‘Cultures of GM’: discourses of risk and labelling of GMOs in the UK and EU” (2005) 37:3 *Area* 286 at 289.

prohibition of GE products in the EU. The idea here is to prevent harm rather than to react to it.¹⁰⁹ Proponents of the Precautionary Principle stress that safety of any new technology, such as GE food, must be proved prior to use.¹¹⁰

The difficulty with this concept is that science can demonstrate that a product is effective or that it can cause harm. Demonstrating “safe”, however, is problematic. What evidence would an opponent of GE food require to demonstrate that GE food is “safe”? Of course, there is no answer to this question because it is not possible to prove that GE food or any other food is “safe”. There is only evidence, and in the case of GE food that evidence is extensive, that no harm has yet been determined. The Precautionary Principle as it is related to GE food suggests that although there is no evidence of harm, this lack of harm does not confirm that there is no risk.¹¹¹ The result of this reasoning is that a lack of absolute certainty that GE food is safe provides sufficient risk to support the prevention of this technology’s use.¹¹²

It is evident that the Precautionary Principle is employed to regulate GE foods in a manner that is beyond that imposed on non-GE foods without any serious consideration of the potential benefits of these GE products. As a result, the “uncertainties” of biotechnological science consistently result in European regulators finding the risks too great to proceed with certain GE food introductions. Since science is not able to give an absolute answer to the risk question for Europe, the public is left to make this determination based on some social or political definition of risk.¹¹³ As a next step, advocates of the Precautionary Principle suggest that these “risks” justify regulation. However, is it really risks that are at issue here?

There is an unambiguous difference between risk and uncertainty. While the opponents of GE foods note risk as their main concern, the GE debate is a problem of uncertainty more than it is one of risk. Risk requires statistics from which the probabilities of future events can be calculated. In contrast, uncertainty exists when there is insufficient information to establish

¹⁰⁹ Supra note 103 at 177.

¹¹⁰ Ibid at 194.

¹¹¹ Supra note 108.

¹¹² Ibid.

¹¹³ Supra note 107 at 152.

probabilities.¹¹⁴ In the case of GE foods, a lack of available information prevents the establishment of probabilities that an unknown and unforeseeable consequence of the use of GE food may adversely affect human health sometime in the future.¹¹⁵

If one were to suggest that arguments for the strict adoption of the Precautionary Principle are well-founded, then these arguments should be applicable not only to the public policy realm but also to the private sector. However, there has been little effort to hamper the private sector in this way outside of agricultural biotechnology.¹¹⁶

The GE seed controversy affects multinational biotechnology corporations, farmers, food processors, retailers, governments, and consumers all over the world. Europe, where concerns have been raised over the safety of GE foods; the profit motive of agribusiness; and the lack of adequate governmental regulatory control over GE products, seems to be a focus of this controversy.¹¹⁷

Three concerns over GE seeds and foods have been uppermost in the minds of those inside and outside the EU who are opposed to this technology. The first involves the potential for environmental damage. This damage has been promoted to range from harm to other life forms, pesticide resistance, and the unwanted spread of genes to non-targeted species. The second concern involves long-term dangers to human health since this technology has been commercialized for only 20 years leaving only a short study period for the effects of this technology. Finally, there is widespread concern over the economics of this technology. This technology requires costly and long-term investment before it can be brought to market making a return on investment a potentially difficult proposition. There is also the issue of patenting that is a feature considered necessary to capture value from this technology but also one that leads to the control of this technology by a small number of corporations. A consequence of this control

¹¹⁴ Frank H Knight, *Risk, Uncertainty and Profit*, (Boston: Houghton Mifflin, 1921).
as cited in Jill E Hobbs & Marni D Plunkett, “ Genetically Modified Foods: Consumer Issues and the Role of Information Asymmetry” (1999) 47 *Canadian Journal of Agricultural Economics* 445 at 450.

¹¹⁵ Ibid.

¹¹⁶ Chris MacDonald & Melissa Whellams, “Corporate Decisions about Labelling Genetically Modified Foods” (2007) 75:2 *J Bus Ethics* 181 at 184.

¹¹⁷ USDA, *The First Decade of Genetically Engineered Crops in the United States* by Jorge Fernandez-Cornejo & Margaret Caswell (EIB-11) (Washington D.C.: USDA, Economic Information Bulletin, 2006),_online: USDA, Economic Research Service <<http://www.ers.usda.gov/publications/eib11/eib11.pdf>> at 15.

can be economic hardship for consumers if the technology has a detrimental impact on global food security or results in artificially high prices. In addition, there is the possibility of economic hardship for farmers who may be left with limited options for seed sourcing.¹¹⁸

In response to the fears such as those noted above, the European Commission banned the importation of a number of GE products from the U.S. between 1998 and 2004.¹¹⁹ Specifically, five European countries banned GE products altogether, and several other countries prevented the importation of GE crops, food products, and seeds. In response to these actions, the U.S. and two other major GE crop-producing nations submitted their case to the WTO where they received a favourable ruling on February 7, 2006. The WTO ruled that the EU was in breach of international trade rules by restricting the importation of GE products.¹²⁰

Internationally, consumer attitudes to GE technology and its products vary greatly. Not surprisingly, consumer concern is generally greatest in Europe where it has significant government support. In the rest of the world, the primary opponents of GE crops and foods are advocacy groups such as NGOs and some farmer and consumer groups. In the U.S., fewer than half of Americans realize that GE foods are widely available on supermarket shelves.¹²¹

Consumer concerns over GE crops are magnified by the availability of conflicting information found in “studies” supporting opposing points of view. In one example, Germany banned a Monsanto GE product [MON810 maize] based on two studies that showed that it had a negative influence on certain domestic insect species. At the same time, the European Union gave their approval to the very same MON810 maize based on other studies and specifically noted the lack of verifiable risk.¹²²

¹¹⁸ Ibid at 2; Elisabeth Rosenthal, “Biotech Food Tears Rifts In Europe”, *The New York Times* (6 June 2006) online: The New York Times

<<http://www.nytimes.com/2006/06/06/business/worldbusiness/06gene.html?fta=y>> [Rosenthal].

¹¹⁹ Tom Wright, “Swiss back ban on modified crops” *The New York Times, Europe* (27 November 2005) online:

The New York Times, Europe <http://www.nytimes.com/2005/11/28/business/swiss-voters-approve-ban-on-genetically-altered-crops.html?_r=0> [Wright]; A Pollack, “World Trade Agency Rules for U.S. in Biotech Dispute”, *The New York Times* (8 February 2006) online: The New York Times

<http://www.nytimes.com/2006/02/08/business/worldbusiness/08trade.html?_r=0> [Pollack].

¹²⁰ Pollack, *ibid*.

¹²¹ *Genetic Modification Food Facts (2008)* online: Suite 101 <http://agricultural-biotechnology.suite101.com/article.cfm/genetic_modification_food_facts>.

¹²² *Restrictions on Genetically Modified Organisms: Germany*, (2016) online: Library of Congress <<https://www.loc.gov/law/help/restrictions-on-gmos/germany.php>>.

Regulators typically assess the safety of GE based foods on a case-by-case basis, and as a result, it is not possible to make blanket statements about the safety of all GE foods. All GE foods currently available internationally have passed basic risk assessments and their consumption, where allowed, has not demonstrated any adverse health effects.¹²³

The U.S. and Canadian governments do not evaluate GE foods any differently than non-GE foods. In the U.S., the FDA does not review safety data for GE foods, nor does it support the labelling of GE foods. As a result, most of the GE food available in the U.S. is not tested for safety by a government agency simply because it is GE. Just as with other food, it is left up to the manufacturer to test the products. As previously noted, there is no conclusive evidence as to the *absolute* safety of GE foods. Of course, the same can be said for virtually any food or non-food product.

The FAO and the WHO have given their approval for the use of GE seeds, and they have noted their limited concerns. The current Health Canada website has the following entry:

Is there any scientific evidence to suggest that genetically modified foods are less safe than those foods produced using conventional techniques?

After twelve years of reviewing the safety of novel foods, Health Canada is not aware of any published scientific evidence demonstrating that novel foods are any less safe than traditional foods. The regulatory framework put in place by the federal government ensures that new and modified foods can be safely introduced into the Canadian diet. Safety assessment approaches are well established to address the potential risks associated with foods.¹²⁴

It is more likely than not that the issues that have led to the GE seed controversy will be raised again if GURT seeds are commercialized. The added attributes of GURT seeds that differentiate them from conventional GE seeds will add to the controversy and will likely add to the opposition by those who are determined to limit this area of agricultural biotechnology.

¹²³ Supra note 117 at 6,15.

¹²⁴ *The Regulation of Genetically Modified Food* (2012), online: Health Canada < http://www.hc-sc.gc.ca/sr-sr/pubs/biotech/reg_gen_mod-eng.php>.

Chapter 3

Literature Review and Analysis

3.0 Introduction

This literature review is structured with two objectives in mind. First, it provides a summary of the current state of the literature encompassing the subject matter of this thesis. It is intended to convey the relevant knowledge that has been established and is therefore descriptive of these ideas. Second, this literature review aims to go beyond merely describing what has gone before. It is designed to provide a critical appraisal of these ideas. In this way, the literature review not only identifies areas of controversy directly related to the thesis topic but also allows for active engagement with the authors in order to identify gaps that the thesis question can address.

Governments and international organizations often pursue growth in agricultural productivity through a form of policy development that promotes private and public sector investment in science and technology. A principal source of this productivity growth is innovation.¹²⁵ As such, science and technology policies along with IP laws and regulations have been used specifically to create both private and public sector incentives for innovation. Currently, some of the most dramatic agricultural innovations are those involving the genetic engineering of agricultural seeds. In this field, the promotion of innovation has stimulated the quest for improved methods of IP protection, which have in turn encouraged further innovation. These activities have necessitated the identification, development and the implementation of public sector policies and regulations to manage business activities, food products, food security and environmental safety. Often these public sector interventions are reactive rather than proactive. The response to the development of the genetic engineering of agricultural seeds falls primarily into this reactive pattern. On the other hand, with the development of GURT, the pendulum has swung to the other extreme as an abundance of caution has led to an international moratorium on GURT commercialization.

¹²⁵ Supra note 3 at 7.

To be able to assess GURT as an alternative to patents for the future protection and promotion of innovation, one must appreciate the historical and contemporary development and importance of patents and innovation in agricultural biotechnology and the position of GURT in this environment. The themes of this literature review address the major areas that touch on the potential of GURT to act as a viable alternative to the utility patent for the protection and promotion of innovation in agricultural seeds. The review begins with an appraisal of the conventional wisdom surrounding patents and innovation and how this applies to agricultural biotechnology. This is followed by an assessment of key conflicts surrounding innovation protection and promotion in agriculture. Building on this evaluation, the literature review proceeds to assess the relevant stakeholder interrelationships in agricultural biotechnology. The focus of the review then addresses the global issues associated with GE seed patents followed by the structural evolution and strategies of the GE seed industry.

While the place of GURT as it relates to each of these themes is noted throughout, the final segment of the literature review intensively focuses on GURT using the previous themes to guide the exploration and analysis of the current literature on this subject. Finally, the literature review surveys the relevance of the private and public sectors to the two alternatives under consideration.

3.1 Patents and Innovation: “Conventional Wisdom”

OECD countries place a heavy emphasis on competitive advantage as an important element of business strategy. The spread of innovation across borders has heightened its importance as a major determinant of competitive advantage.¹²⁶ As the value of innovation to national economies has grown, the demand on the part of innovators for reliable and internationally recognizable protection for innovation has developed. In particular, the requirement for protection of invention as a key source of innovation is considered to be paramount.¹²⁷

Protecting intellectual assets such as inventions is vital for all companies but it is of particular importance for high technology companies because these assets make up an average of

¹²⁶ Ibid at 15.

¹²⁷ Ibid at 9.

80% of their market value.¹²⁸ Microsoft provides an excellent example of the extraordinary amounts of value found in a company's intellectual assets. Microsoft's book value per share on Dec 30, 2011 was \$7.09. At the same time, the company's market value per share was \$26.11.¹²⁹ Intellectual asset value is equal to the difference between the two and for Microsoft this value on Dec 30, 2011 was 72.85% (\$159.88B) of its market value (\$219.47B).¹³⁰

A company's intellectual assets often represent a foundation from which pre-commercialization funding can emerge. Until a technology firm commercializes a product, two critical external sources of funding are most frequently available for invention/innovation development. The first is the result of the association that technology companies may have with non-profit research institutions such as universities. These institutions represent a rapidly growing source of patent applications funded by many governments.¹³¹ A second source of funding is venture capital from investors who are willing to finance higher risk business ventures.¹³² Return on investment (ROI) is important for both of these funding sources and that ROI is usually closely tied to IP portfolio size and quality. Kesan, in "Intellectual Property Protection and Agricultural Biotechnology: A Multidisciplinary Perspective" (2000) is rightly convinced that the strength of this portfolio can also act as a source of additional funding and competitive advantage. By emphasizing this, Kesan is overtly making the case for patents as the key to innovation in the past and the present. Kesan is persuasive in this assertion because, at the time of his writing, patents represented the ultimate protection for a key source of agricultural biotechnology innovation, the invention. Had he been aware of a more effective method of protection, it is likely that he would have supported it as a potentially valuable inducement for innovation.

IP and the rights associated with it represent a valuable company asset and it is widely accepted that this asset should be protected because it can preserve differentiation and sustain competitive advantage. The effectiveness of innovation protection mechanisms and the IP assets

¹²⁸ Supra note 7 at 288.

¹²⁹ *Microsoft Historical Book Value (Per Share) Data 2011*, online: YCHARTS<http://ycharts.com/companies/MSFT/book_value_per_share>.

¹³⁰ Ibid.

¹³¹ Kesan, supra note 2 at 466.

¹³² Ibid.

associated with them varies across industries. Often this effectiveness depends on whether the innovation is a product or a process. The Mansfield Study, discussed shortly, highlights the industry-specific nature of patent usefulness for protecting innovation and its sources.

The patent system as a means of protecting innovation has existed for centuries, and the advantages and disadvantages of this system are constantly debated. Some of the relevant patent-related questions that continue to this day are:

- 1) Can the system offset potential over or underinvestment in R&D and innovation?
- 2) Does the patent system positively or negatively influence technological progress?
- 3) How does the patent system affect static efficiency and dynamic efficiency¹³³ through its impacts on competition?¹³⁴

Attempts to respond to these questions highlight the longstanding controversy over the usefulness of patents as a means of protecting innovation. An influential work on the economics of IPRs [emphasizing patents] by Arrow (1962), as described by Ove Granstrand, argues that private firms will underinvest in R&D because they cannot capture sufficient value from their investment.¹³⁵ Others take an opposing position that capitalist economies overinvest in R&D and innovation. They suggest that patent races may produce R&D duplication leading to societal returns that are less than the value of the investment.¹³⁶ This disparity in positions highlights the controversy over the ability of patents to affect a key source of invention and a foundation of innovation, R&D.

Another issue affecting the protection of innovation with patents is the duration of that protection. Nordhaus (1969) argues that increased patent length intensifies dynamic efficiency at

¹³³ Static efficiency refers to the most efficient combination of resources at a given point in time; dynamic efficiency concerns the development of improved technology and working practices, which improve production efficiency over time.

¹³⁴ Ove Granstrand, "Innovation and Intellectual Property Rights" in Jan Fagerberg, David C Mowery and Richard R. Nelson eds, *The Oxford Handbook of Innovation* (Oxford University Press, 2005) 266 at 278.

¹³⁵ Kenneth J Arrow, "Economic Welfare and the Allocation of Resources for Invention" (1962) in Richard R Nelson ed, *The Rate and Direction of Inventive Activity: Economic and Social Factors* (Princeton: Princeton University Press for the National Bureau of Economic Research, 1962) 609 as cited as cited in Ove Granstrand, *Innovation and Intellectual Property Rights*" in Jan Fagerberg, David C Mowery & Richard R. Nelson eds, *The Oxford Handbook of Innovation* (Oxford University Press, 2005) at 279.

¹³⁶ Supra note 134 at 279.

the expense of static efficiency. The resulting increased protection results in less competition, higher prices and slower innovation diffusion.¹³⁷ Nordhaus, whose 1969 book “Invention, Growth and Welfare” has been extensively cited, considers optimal patent length to be a trade-off between these two types of efficiency.¹³⁸ This trade-off is one that the public sector, through policy and regulation, imposes on the private sector and it can represent a source of tension between the two.

Mansfield’s (1985) influential study on the importance of patenting in various industries points out that in some situations patenting itself can hinder the protection of innovation. This is because the disclosure required to obtain a patent hastens the diffusion of the patented material. However, Mansfield notes that this diffusion can have numerous, often contradictory, effects. These effects include: reducing R&D duplication; promoting the inventing around of existing patents; stimulating new innovations; providing a basis for competitive intelligence;¹³⁹ and encouraging technology exchange and cooperative activities.¹⁴⁰ One can easily see that the benefits mentioned are those that accrue primarily to society and rivals in the industry rather than to the original inventor/innovator. As a result, through a patent, the inventor is paying a price or at least not maximizing his value capture in return for his temporary monopoly.

The “Conventional wisdom” that patents act as a source of innovation protection while promoting innovation is not universally accepted in all industries. Studies such as that carried out by Edwin Mansfield in 1986 indicate that business leaders in different industries place varying degrees of importance on patents for innovation promotion and protection.¹⁴¹ However, the number of studies questioning business leaders, as Mansfield did, is limited for many reasons such the intrusive nature of the inquiries. Another reason making high quality empirical data on this subject difficult to come by is the historical nature of the original decisions around whether to patent. Often those responsible for crafting the decision to patent or not are no longer available

¹³⁷ WD Nordhaus, *Invention, Growth and Welfare* (Cambridge, Mass.: MIT Press, 1969) as cited in Ove Granstrand, “Innovation and Intellectual Property Rights” in Jan Fagerberg, David C Mowery and Richard R. Nelson eds, *The Oxford Handbook of Innovation* (Oxford University Press, 2005) 266 at 279.

¹³⁸ Ibid.

¹³⁹ Competitive intelligence is the broad range of information gathering and analysis that provides management with a basis for making strategic decisions within an organization.

¹⁴⁰ Edwin Mansfield, “Patents and Innovation: An Empirical Study” (1986) 32:2 *Management Science* 173.

¹⁴¹ Ibid at 176.

to be interviewed on their decision-making process. To further complicate matters, the decisions are often based on firm specific strategic goals that take into account a variety of criteria that are highly subjective. As a result, where one firm in an industry may decide to patent another in the same industry may not.¹⁴²

Mansfield's study is frequently referenced even today because of the extensive nature of the interviews that he carried out. In this study, Mansfield was looking to answer two questions:

- 1) To what extent would the rate of development and commercialization of inventions decline in the absence of patent protection?
- 2) To what extent do firms make use of the patent system, and what differences exist among firms and industries in their propensity to patent?¹⁴³

The industry-wide estimates that resulted from this study indicate that patent protection is considered to be vital to develop or commercialize 30% or more of the inventions in the pharmaceutical industry [patent protection essential for the *development* of 60% of inventions; patent protection essential for the *commercialization* of 65% of inventions] and the chemical industry [patent protection essential for the *development* of 38% of inventions; patent protection essential for the *commercialization* of 30% of inventions].¹⁴⁴

The relevance of the Mansfield study to this thesis is that it identifies potential strengths and weaknesses in the patent system as a legal means of innovation protection and promotion. This identification sets a baseline from which to judge a possible non-legal, technological IP protection method such as GURT; one that Mansfield could not have imagined at the time of his study.

A key point to note about the data in the Mansfield study is that in 1986, genetic engineering and, specifically, agriculture based on genetic engineering was in its early stages of development with its full potential as yet unrealized. However, although Mansfield's study predates much of the significant activity in the GE seed industry, it is possible to link his study to the biotechnology sector and specifically to genetic engineering. This linkage is possible because genetic engineering biotechnology has much in common with pharmaceutical biotechnology, an

¹⁴² Supra note 14 at 14-15.

¹⁴³ Supra note 140 at 173.

¹⁴⁴ Ibid at 174.

important industry in the Mansfield study. Both of these high technology industries have unusually high R&D costs and extended timelines for product development; both deal with highly disruptive, cutting-edge technologies that require specialized knowledge, equipment and capabilities; both deal with the interaction of technology and living organisms; both are based on technology that is relatively easily, although not necessarily effectively, protected with patents; and, finally, both are subject to a high level of governmental regulation. As such, it is not unreasonable to extrapolate many of the findings in the Mansfield study that deal with the pharmaceutical industry to the agricultural biotechnology industry today.

In his study, Mansfield finds that the importance of patents grows in an industry as the level of R&D intensity grows. Therefore, it is not surprising that leaders in the heavily R&D dependent industries such pharmaceuticals and chemicals considered patents to be very important for success.¹⁴⁵

One could hypothesize as to why this is the case. It could be that inventions from the more R&D-intensive firms have attributes that are more readily patentable. Another explanation might be that the large investment by the more R&D-intensive firms encourages them to do whatever is possible to protect their investment including making every possible attempt to patent their inventions even if the patent application appears to be weak.¹⁴⁶

In his conclusion, Mansfield reports that, excluding the pharmaceutical and chemical industries, innovation rates are not closely related to the patenting of new inventions. However, he emphasizes that whether or not patents are considered to be necessary for the commercialization of an invention, the invention is invariably patented in all industries. Furthermore, to demonstrate the almost knee-jerk attachment by industry to patenting Mansfield maintains that in patent rich industries like pharmaceuticals and chemicals, more than 80% of the patentable inventions are patented whether they are to be commercialized or not.¹⁴⁷ This high level of patenting implies that the reasons behind business patenting of inventions go beyond the protection of inventions for commercialization.

One explanation for non-self-protective patenting in business is preventive in nature. That

¹⁴⁵ Ibid at 175.

¹⁴⁶ Supra note 14 at 17.

¹⁴⁷ Supra note 140 at 176.

is to prevent competitors from accessing technologies to improve their competitive advantage even if that technology is of no immediate value to the patenting company. Strategic patenting of this type can be a successful business strategy, however, it tends to undermine innovation by hindering the commercialization of new ideas.¹⁴⁸

The loss to society from strategic patenting is directly related to the restrictions that it places on access to upstream foundational knowledge and the processes that this knowledge produces. As such, strategic patenting invariably has a direct negative effect not only on R&D at the firm level but also on the economic growth goals of national governments. Strategic patenting also creates an opening for governments to introduce regulatory actions to limit this form of private sector induced market failure.¹⁴⁹ On this basis, strategic patenting also has the potential to act as a source of tension between the public and private sectors; tension that might hinder cooperation for mutual economic benefit. In spite of the public/private tensions that patenting can incite, patenting remains a highly sought after method of IP protection.

This high regard for the business usefulness of the patent suggests that it would be difficult to sell an alternative to the patent as a means of innovation protection and promotion to those industries that currently depend on this method of IP protection. An alternative would have to offer significant benefits to business for it to be accepted as an alternative to the patent. The Mansfield study is not alone in its conclusions about industry patenting behaviour.

There is other empirical evidence supporting Mansfield's conclusion that patents promote innovation in the pharmaceutical and chemical industries. However this additional evidence adds the biotechnology industry as one where patents promote innovation. Surveys of U.S., European and Japanese firms representing these three industries reveal that they consider the ability of patents to promote innovation as a key source of their competitive advantage.¹⁵⁰ These surveys also report that firms in other industries are more reliant on non-legal methods of invention protection such as secrecy, market lead, learning by doing, product or process complexity, and

¹⁴⁸ Supra note 14 at 19-20.

¹⁴⁹ Market failure is a condition in which there is a misallocation of resources. It can result in situations where there is a public good, market control, an externality, or imperfect information.

¹⁵⁰ Supra note 3 at 9.

the encouragement of complementary asset development.¹⁵¹ Some of these non-legal techniques may have some potential as alternatives to the traditional use of patents as a source of innovation protection under the right circumstances. The key feature of all of them is that, like GURT, they are not primarily dependent on a patent as their primary source of IP protection.

In 2001, Joshua Lerner analyzed the relationship between patent strength and innovation using an international framework. With greater emphasis on the attributes of patents than is displayed in Mansfield's study, Lerner's study reveals that there is a point where increasing patent strength is detrimental to innovation by no longer maximizing expected innovation rewards.¹⁵² At that point, Lerner's study predicts imitation by rivals becomes a more likely outcome of increasing patent strength than is the encouragement to innovate by those same rivals. In fact, Lerner suggests that the losses to innovation from imitation will at some point overtake any gains seen from increased patent strength.¹⁵³ The implication of this patent issue is that the potential losses to innovation from attempts to increase patent length legally may be reason enough for firms and governments to look for alternatives that offer longer protection without losses to innovation. A bonus to this search would be a method of protection that also avoids the disclosure of invention details that traditional patenting requires.

GURT represents one such alternative as it provides a "timeless" technological means of IP protection for GE seeds, which if not patented eliminates the disclosure requirements inherent in traditional patents. This would reduce the "patenting around" problem since the foundational knowledge normally disclosed in a patent would not necessarily be disclosed. Inventing firms may be quite pleased with this non-legal endless protection; however, competitors and governments may find this degree of protection untenable. This suggests that the commercialization of such a technology could be challenged as "not viable" from a number of perspectives. These could include the disruption of established international and national IP regimes or the loss of societal benefits that the traditional patent regime promotes.

In his paper, "Innovation and Intellectual Property" (2005), Granstrand concurs with much of what Mansfield and Lerner have argued. However, Granstrand suggests additional

¹⁵¹ Ibid.

¹⁵² Josh Lerner, "150 Years of Patent Protection." (2002) 92:2 American Economic Review 221 at 224.

¹⁵³ Ibid at 225.

explanations for the differences in IPRs across industry sectors. He highlights the importance of industry and market structure and the nature of the technology [technological opportunities, codifiability, capital intensity, etc.] as key factors for these differences. Granstrand elaborates on the fact that patents are more supportive of knowledge-intensive industries with low ratios of imitation to innovation costs [ie imitation costs are low, and innovation costs are high]. He notes that these low ratios are more likely in industries with substantial R&D costs that are easily codifiable and where reverse engineering is inexpensive.¹⁵⁴ A good example is the pharmaceutical industry where the relationship between the brand name firms and the generic firms is often strained, especially in Canada with its generic-friendly regulatory environment.

Generic pharmaceutical firms find it relatively cheap and easy to reverse engineer brand name drugs, making strong patents vital to the brand name industry participants, just as Mansfield's study indicated. It is the activity of rivals that make patents so important in the pharmaceutical industry. However, while there are many similarities that allow for a useful extrapolation to the GE seed industry, the importance of reverse engineering is not one of them. In addition, it is not rivals that are the greatest source of value attrition in the GE seed industry.

For the GE seed industry, much of the discussion over IP protection revolves around protecting the second and later generations of GE seeds from being illegally exploited. The pharmaceutical industry has no fear that drugs will self-replicate in the hands of consumers as is the case with GE seeds and farmers. Pharmaceutical companies also do not face the difficulty of maintaining some control over their product once it is sold to a user, whereas GE seed companies do face this problem. This is where patent enforcement becomes a severe problem for GE seed companies, and the existence of an alternative that protects their product once it is in the hands of the purchaser [farmer] would be highly valued. This is not an issue that Mansfield, Lerner or Granstrand deals with, as agricultural biotechnology was less advanced at the time of their studies.

In other high technology industries, such as information technology and communications, there have been other challenges to the traditional value of patents as a source of innovation protection and promotion. The concept of *open innovation* has emerged in these industries to

¹⁵⁴ Supra note 134 at 283.

disrupt the traditional use of patents in a closed innovation model; a model in which R&D and innovation are highly internalized.

Internal R&D has always been a valuable strategic asset for large corporations such as DuPont, IBM and AT&T. Historically, these firms would compete by undertaking the most internal R&D and those that did would reap the largest profits in their industries.¹⁵⁵ Each of these firms acted as a virtual isolated island of R&D.

In his 2003 book, “Open Innovation: the New Imperative for Creating and Profiting from Technology”, Henry Chesbrough takes a broad approach to the understanding of R&D and innovation. That same year he summarized the main points of his book in a paper in MIT Sloan Management Review.¹⁵⁶ He suggests that companies have altered the manner in which they research and develop new ideas and that doing so internally is no longer as strategically valuable as it had been in the past.¹⁵⁷ Chesbrough refers to the self-reliance model of innovation in which firms maintain control of innovation by internalizing all of its facets from research to servicing the final product as the *closed innovation* model.¹⁵⁸ This is the model that was successful for most of the 20th century.¹⁵⁹ Coincidentally, this is also the model that predominated during the boom in patenting in the 20th century. Furthermore, this is the model that universities and other public institutions involved in R&D supported in the past and continue to support to a great extent today. However, this is a model that has been rapidly changing.¹⁶⁰

Chesbrough notes that today, a company that carries out the costly research for an invention may not be the one to develop that invention into a commercially viable product. In addition, the company that does profit from the commercialization of the product will not necessarily reinvest those profits into future R&D.¹⁶¹ What Chesbrough is describing here is the

¹⁵⁵ Henry W Chesbrough, *Open Innovation: the New Imperative for Creating and Profiting from Technology* (Harvard Business Press, 2003a) at 29-30.

¹⁵⁶ Henry W Chesbrough, “The Era of Open Innovation” (2003b) 44:3 MIT Sloan Management Review 35.

¹⁵⁷ *Ibid* at 36.

¹⁵⁸ *Ibid*.

¹⁵⁹ *Ibid*.

¹⁶⁰ *Supra* note 155 at 43-45.

¹⁶¹ *Supra* note 156 at 36-37.

migration of the innovative process beyond the confines of a single firm.¹⁶² In fact, Chesbrough diagrams this concept as a porous innovation funnel through which diffusion occurs beyond the firm at various stages of the innovative process.¹⁶³

Chesbrough refers to this more recent innovation model as *open innovation*. In this model, firms develop and commercialize ideas from multiple sources inside and outside the confines of the firm.¹⁶⁴ This type of innovation has become popular in the information technology and communications industries, and it has seen significant application in agricultural biotechnology innovation as well, especially in the public sector where plant variety development for farmers has a long history.

Chesbrough claims that the open innovation model can effectively challenge and even replace the traditional closed innovation model completely.¹⁶⁵ If that is the case, perhaps the importance of the traditional patent system can also be challenged if it were required to adapt to a more freewheeling open innovation model. Yet, one might wonder whether private industry would so easily spend vast sums on R&D only to lose control over the ability to set the terms for payback. Private sector based agricultural biotechnology does not seem to find the concept of open innovation to be particularly attractive as demonstrated by the high level of patenting and internal development that takes place. As will be discussed shortly, GURT development occurred, among other reasons, in an attempt to have greater firm control over IP; a high level of control that patents can simply not match.

Schenkelaars et al. also refer to open innovation in their paper.¹⁶⁶ They point out that elements of open innovation do appear to be finding their way into some aspects of the GE seed industry. Their paper is more recent than Chesbrough's work and more focused on agricultural biotechnology. The work by Schenkelaars et al. has the added benefit of addressing innovation in both the private and public sectors. These authors stress the dual requirement of innovation

¹⁶² Ibid at 38.

¹⁶³ Ibid at 37.

¹⁶⁴ Ibid at 36-37.

¹⁶⁵ Supra note 155 at 51-52.

¹⁶⁶ Piet Schenkelaars, Huib de Vriend & Nicholas Kalaitzandonakes, "Drivers of Consolidation in the Seed Industry and its Consequences for Innovation" (2011) a report prepared for the Commission on Genetic Modification (COGEM), online: COGEM < <http://www.cogem.net/index.cfm/en/publications/publicatie/drivers-of-consolidation-in-the-seed-industry-and-its-consequences-for-innovation> > at 38.

protection and innovation openness in biotechnology to maximize the benefits of IP. The real challenge for these authors is to determine novel ways of reconciling the needs of the private and public sectors.¹⁶⁷

To promote this type of opening of innovation, Schenkelaars et al. highlight a report from a McGill University expert group meeting on biotechnology, innovation and intellectual property. This report argues “that the current system of ‘Old IP’ rests on the belief that if some IP is good, more IP is better...[and]...that this thinking increasingly risks becoming counterproductive in sectors like agriculture.”¹⁶⁸ Rather than moving down this unproductive path Schenkelaars et al. suggest that new IP models require a multi-faceted co-operative environment to be successful.¹⁶⁹ In other words, move towards a form of open innovation that represents an alternative to the traditional use of patents in a closed innovation model. While the expert group correctly focuses on the need for collaboration and co-operation, it downplays the fact that these two characteristics are indeed present in the “old IP” system. For example, licensing agreements and joint ventures are often based on significant collaboration, co-operation and goodwill among the participants. The disadvantages of the “old IP” system are highlighted primarily when well-publicized disagreements develop.

The “new IP” concept proposed by Schenkelaars et al., which builds on the earlier open innovation model described by Chesbrough, is not merely an idea looking for its first practical application. Open innovation approaches for agricultural biotechnology are in operation today. However, these are public sector rather than private sector initiatives. One example is the Biological Innovation for Open Society (BIOS) begun by Richard Jefferson who helped to develop new agricultural biotechnology, which was offered internationally in a ‘protected technology commons’. Access to BIOS licenses requires only that the licensees share any information that they acquire from the use of biotechnology for improvement, safety, and other data. This allows others to use and improve the technology without restrictions that could hinder innovation.¹⁷⁰ Although this model has had some success, the lack of IPRs may limit the

¹⁶⁷ Ibid at 103.

¹⁶⁸ *Toward a New Era of Intellectual Property: From Confrontation to Negotiation*, A report by the International Group on Biotechnology, Innovation and Intellectual Property, hosted by the McGill University Montreal, Canada, The Innovation Partnership (Montreal: TIP/CIPP, 2008) as cited in Piet Schenkelaars, Huib de Vriend & Nicholas Kalaitzandonakes, “Drivers of Consolidation in the Seed Industry and its Consequences for Innovation” (2011) a report prepared for the Commission on Genetic Modification (COGEM), online: COGEM<<http://www.cogem.net/index.cfm/en/publications/publicatie/drivers-of-consolidation-in-the-seed-industry-and-its-consequences-for-innovation>> at 22.

¹⁶⁹ Supra note 166 at 103.

¹⁷⁰ Ibid.

participation by major private sector biotechnology firms that must answer to shareholders' needs for profit maximization. Once again the benefits of tight IP control that is offered by GURT seems to fit the corporate sector's desires.

Schenkelaars et al., like Chesbrough, see that the traditional use of patents can be a hindrance to innovation under certain circumstances. This is because, as Phillips and Gustafson note in their paper titled, "Patent Strategies in the Biotechnology Industry and Implications for Technology Diffusion" (2000), patent strategies have in some instances created barriers to entry for new firms and obstacles for both private and public research. Furthermore, as previously noted in the Mansfield and Lerner studies, Phillips and Gustafson highlight the strategic patenting issue in which the use of strong patent rights can exclude competitors in order to maximize the profitability of the patent holder.¹⁷¹ In their paper, Phillips and Gustafson underscore their concern that the competitor exclusion aspect of this strategy is often a key aspect of the firm's overall business strategy. They propose that this strategy of denial is somewhat removed from a more positive innovation strategy that promotes rather than prevents innovation. As much as Philips and Gustafson are correct in this belief, they ignore the notion that for most firms, business strategy often tends to be about how to maximize profits in the short term, not how best to innovate. For this reason, a technological method of IP protection that would increase the level of private sector value capture would likely have a warm reception in the boardrooms of the GE seed companies.

Chesbrough, Phillips and Lerner all emphasize some of the negative private sector impacts that strong patents have on innovation, but Schenkelaar et al. present a broader approach to the patent/innovation analysis by including a public sector dimension to this discussion. The use of patents in both the private and public sectors that Schenkelaar et al. discuss presents an interesting problem for policy development around the use of patents in innovation promotion. For example, society benefits both from an improvement in global food security through

¹⁷¹ Peter WB Phillips & Jillian Gustafson, "Patent Strategies in the Biotechnology Industry and Implications for Technology Diffusion" (2000), a paper presented for the 4th International Conference of the International Consortium on Agricultural Biotechnology Research (ICBAR) on "The Economics of Agricultural Biotechnology" (Ravello, Italy, August 24 -28, 2000) at 4.

innovation in the GE seed industry as well as from the economic growth promoted by the success of firms in this industry. However, one benefit does not necessarily support the other. In fact, they can be in conflict when innovation protection is dependent on patents. Determining how best to divide up the value captured from the use of patents could be one important source of that conflict. While both the private and public sectors may each wish to claim a greater share, the public sector has dual responsibilities. One responsibility is directed toward society in the form of innovation promotion and subsequent benefits such as an increase in food security. The other is to society through the economic success of the firms in the industry and the nations in which those firms exist. In contrast, a potential primarily technological approach to IP protection that GURT offers eliminates many of the “messy” legal issues that are often subject to litigation while at the same time creating stark outcomes that may affect this option’s viability in the public realm.

3.2 Plant Protection in a Conflicted World

Just as with other areas of biotechnology, R&D in agricultural biotechnology increasingly originates in the private sector rather than in a public sector dominated by government-sponsored programs.¹⁷² This is not surprising considering that the use of genetic engineering technology in agriculture is costly and time-consuming. Recovering their substantial investment in R&D is a major concern for private sector firms and they expect to appropriate a significant portion of the value they create from their innovations. As in other areas of biotechnology, agricultural innovators rely on IPRs as their best means of protection.¹⁷³

Although John Thomas in his 2002 paper titled, “Plants, patents and seed innovation in the agricultural industry” is fairly matter-of-fact about the importance of IPR use for protection, I would suggest that perhaps those responsible for the business aspects of biotechnology approach IP protection from a “highest comfort level” perspective. That is, if there is an invention to protect so that innovation can flourish, an established, historically successful method of doing so

¹⁷² Mark D Janis, “Sustainable Agriculture, Patent Rights, and Plant Innovation” (2001) 9 *Indiana Journal of Global Legal Studies* 91 at 92.

¹⁷³ U.S. Congressional Research Service. “Plants, Patents, and Seed Innovation in the Agricultural Industry”, (RL31568; 13 September 2002) by John R Thomas (Washington D.C.: U.S. Library of Congress, Congressional Research Service, 2002) at CRS16.

is the first choice. Patents are that method and invariably they are the choice even if, as stated earlier, it involves forcing a square life-based invention into a round industrial-era hole. The initial advantage that the patent system offers is an established structure for IP protection that acts as a cookie-cutter template for innovation protection.

Kesan (2000) points out one crucial requirement of that IP protection. The establishment of IP protection for GE seeds necessitates that this protection is established first and foremost in the United States. Seed companies often make a point of establishing this U.S. protection first as a foundation for the establishment of other international protections.¹⁷⁴ Reasons for this include the strength of U.S. seed firms on the international stage; the part played by these firms in helping to establish protection regimes for GE seeds; and the varieties of protection available in the U.S.¹⁷⁵

The discussion of patents has rightly focused on utility patents because of the high degree of protection they offer. However, historically, there have been, and continue to be, other methods of plant innovation protection such as that provided by plant patents, the Plant Variety Protection Act (PVPA), and trade secret law. Because each of these protection mechanisms provides a different scope and degree of protection, they are often used in combination to broaden the protection given.¹⁷⁶ The requirements of the specific protection method and the strategic aims of the inventor determine which method or combination of methods is most appropriate under a particular circumstance.¹⁷⁷ Kesan's point in reviewing IP protection in this industry is that, whatever protection is required, it can be appropriately handled by existing protection methods.

Technically, this may be true. However, once again those who must assemble the protection package will come face to face with two major problems. The first is the transaction cost issue. The legal costs of establishing the protection regime, of monitoring its effectiveness, and of defending it can be substantial. In the private sector, cost recovery can occur by raising prices. In the public sector, the funds required to establish this level of protection for an

¹⁷⁴ Kesan, *supra* note 2 at 485.

¹⁷⁵ *Ibid* at 484, 486.

¹⁷⁶ *Ibid* at 486.

¹⁷⁷ *Ibid* at 487-492.

invention may not be so readily available. The second problem is that legal protection requires a robust IP environment and the cooperation of the product users in adhering to the law.

The Plant Patent Act (1930, 35 U.S.C. § 163 (2002)) provides protection for distinct, new asexually¹⁷⁸ reproduced plants. This method of protection gives the right to prevent “others from selling, reproducing, importing, or exporting the protected plant for twenty years”.¹⁷⁹ The Plant Variety Protection Act (PVPA) 1970, 7 U.S.C. § 2321 (2002)) protects a particular new, distinct, uniform and stable, sexually reproducing plant with a specific genetic makeup. The PVPA provides the same protection to these plants that the Plant Patent Act provides to asexually reproducing plants.¹⁸⁰ A common feature of these types of protection is that they protect the whole plant. This is an important fact to consider because the utility patent is more nuanced in what it is able to protect.

The utility patent provides the strongest protection and it is available for self-pollinated inbred or hybrid plants that are the result of human intervention with nature.¹⁸¹ As with all utility patents, the plant must be useful, new, and not obvious [based on current knowledge in the art]. This patent provides twenty years of protection that excludes others from creating, selling, or using the patented plant.¹⁸² The key to the utility patent’s protection is that unlike the whole-plant based protection of the PVPA and the Plant Patent Act, the utility patent can cover individual elements of the plant and the processes for its creation.¹⁸³ The other two protection methods, plant patents and plant variety protection certificates, have a role to play but provide a lesser degree of protection.¹⁸⁴ It is the utility patent and the strong IPRs associated with it that is most sought after by global seed companies to protect their inventions and to provide a strong foundation for strategy development.

¹⁷⁸ Asexual reproduction in plants involves creating a new plant using means other than through the growth of seeds. This can include grafting, layering, budding, the use of cuttings, etc. The next generation of plants will be substantially the same as the parent plant.

¹⁷⁹ Kesan, supra note 2 at 487.

¹⁸⁰ Ibid.

¹⁸¹ Ibid; supra note 173 at CRS7-9.

¹⁸² Supra note 2 at 487.

¹⁸³ Ibid.

¹⁸⁴ Ibid.

As is the case in other high technology industry sectors, there are those who are convinced that strong IPRs act primarily to encourage innovation in agriculture. In fact, it is not unreasonable to assume that patents promote R&D in agriculture by providing IP protection comparable to that available in other fields of endeavour. However, genetic engineering is simply not like other fields of endeavour. Its unique characteristics, such as the artificial manipulation of naturally created DNA, suggests that perhaps genetic engineering requires unique solutions for innovation promotion and protection. Furthermore, the potential dramatic influence of genetic engineering on global food security, the environment, and farmers' livelihoods magnifies the importance of the public sector dimension of patents and innovation for this technology.

The belief that patents are vital to promote innovation in agricultural biotechnology is far from universal. There are those who argue that patents can often restrict farmer access to patented technologies and harm R&D by limiting access to prior knowledge by those who would take the net inventive step. For example, Joseph Mendelson III, Legal Director for the International Center for Technology Assessment and the Center for Food Safety argues that as more plant varieties are legally protected, the availability of genetic attributes for innovative purposes will become increasingly limited.¹⁸⁵ In support of this view, a National Academy of Sciences forum highlighted the difficulty that some academic researchers face in accessing inventions patented by private companies.¹⁸⁶

From a public sector perspective, the concern over the relationship between patents and innovation in agriculture has to do with more than innovation promotion in the business world. This concern involves the issue of global food security. As previously indicated, food security is primarily a public sector concern, and this suggests a key reason for that sector's growing preoccupation with GE seed innovation. Policymakers do not address this issue in isolation because the interrelationship between the public and private sectors directly reflects the needs of

¹⁸⁵ Joseph Mendelson III, "Patently Erroneous: How the U.S. Supreme Court's Decision in Farm Advantage Ignores Congress and Threatens the Future of the American Farmer" (2002) 32 Environmental Law Reporter 10698 as cited in U.S. Congressional Research Service. "Plants, Patents, and Seed Innovation in the Agricultural Industry", (RL31568; 13 September 2002) by John R Thomas (Washington D.C.: U.S. Library of Congress, Congressional Research Service, 2002) at 2.

¹⁸⁶ *Intellectual Property Rights and Plant Biotechnology* (Washington, DC: The National Academies Press, 1997), online: National Research Council <http://www.nap.edu/read/5882/chapter/1> at 2.

various stakeholders.

In “The Political Economy of Agricultural Biotechnology Policies” (2009), Gregory Graff et al. suggest that the policymaker’s objective is to maximize the weighted sum of benefits of the various stakeholders.¹⁸⁷ My concern with this contention put forth by Graff et al. is to question whether policymakers are in a position to objectively assess the relative importance of these benefits. Specifically, are the levels of bias, which policymakers may bring to the discussion compatible with the objective of maximizing the *weighted sum* of benefits?

Furthermore, are the biases that may exist among, for example, North American policymakers who support the genetic engineering of crops at odds with those of policymakers in the EU, who at best only grudgingly support their use? In the EU, hostility toward GE seeds and the foods that result from them is well documented in the industry’s regulations. The Precautionary Principle is a key feature of GE food regulation in the EU but not in North America. The labelling of GE food is another well-known example of the differing attitudes of European and North American governments toward GE biotechnology.

In Europe it is common to see food products labelled to indicate that the products contain genetically engineered components. This labelling is not something unusual for Europe but rather a result of a long history of European food labelling legislation that identifies production process as well as content and quality.¹⁸⁸

In contrast, Canada and the U.S. only require the labelling of GE food if the product is substantially different from its non-GE equivalent. It is differences in the product rather than the process by which it is created that is of concern in Canada and the U.S. In the U.S., the FDA uses the principle of “substantial equivalence”¹⁸⁹ to determine whether GE foods are labelled. GE foods are, therefore, only labeled as such if they are not substantially equivalent to comparable

¹⁸⁷ Gregory D Graff, Gal Hochman & David Zilberman, “The Political Economy of Agricultural Biotechnology Policies” (2009) 12:1 AgBioForum 34 at 38.

¹⁸⁸ Supra note 108 at 290.

¹⁸⁹ The concept of substantial equivalence is used as a guide in the safety assessment of genetically modified foods by comparing the novel food to its unmodified counterpart which has a history of safe use. This approach allows regulatory agencies to include in their consideration, the substantial history of information related to foods which have long been safely consumed in the human diet to aid in the identification of potential safety and nutritional issues.” : Health Canada http://www.hc-sc.gc.ca/fn-an/gmf-agm/fs-if/faq_1-eng.php).

non-GE foods.¹⁹⁰ As a result, since process is not relevant in this determination, there are virtually no labeled GE foods in the U.S. or Canada. It is these differences in attitudes between North American and European policymakers that can influence their approaches on how best to encourage and implement global food security and the innovation that underlies it.

If European regulatory agencies place roadblocks in the path of the successful commercialization of a GE food product, what incentive is there for firms to proceed through the costly process of patenting a new crop trait? In fact, why would a private firm in this industry innovate at all?

To bolster the patent's innovation promotion qualities in agricultural biotechnology, it has been suggested that reducing the strength of this type of protection for plants might shift R&D to other technologies. The loss of R&D funding might then negatively affect agricultural innovation.¹⁹¹ The primary public sector concern here is that without an adequate level of agricultural innovation, there could be a long-term decrease in global food security.

Another effect of possibly excluding plant innovations from the utility patent system could be the rise of alternative forms of protection that may have other adverse consequences on global food security or innovation promotion.¹⁹² Some alternative forms of protection include trade secret law, hybridization and GURT. These alternatives may have adverse societal consequences such as no requirement for public disclosure if, for example, the trade secret or hybridization methods are employed or a potentially timeless monopoly in the case of GURT.¹⁹³ For example, the trade secret method of protection defeats one of the key goals of the patent and that is for invention disclosure. Does a lack of disclosure represent an important viability hurdle for GURT as an alternative to patents if the GURT product is not patented? What about the

¹⁹⁰ G Nelson, J Babinard & T Josling, "The domestic and regional regulatory environment" in G Nelson ed *Genetically modified organisms in agriculture: economics and politics* (San Diego: Academic Press, 2001) 97 at 104.

¹⁹¹ Joseph Straus, "Patent Protection for New Varieties of Plants Produced by Genetic Engineering – Should 'Double Protection' be Prohibited?" (1984) 15:4 *International Review of Industrial Property & Copyright Law* 426 as cited in Margaret Llewelyn & Mike Adcock, *European Plant Intellectual Property* (Portland, Oregon: Hart Publishing, 2006) at 149.

¹⁹² Janis and Kesan, *supra* note 2.

¹⁹³ David Friedman, William Landes & Richard Posner, "Some Economics of Trade Secret Law" (1991) 5 *Journal of Economic Perspectives* 61 at 65.

importance of other viability “hurdles” such as food security and the economic health of farmers and seed firms?

It is clear that current IP protection mechanisms for agricultural biotechnology are controversial. It is also clear that, while a technological method of IP protection can eliminate some of these difficulties, such an absolute method of IP protection may dramatically affect the interrelationships among the various stakeholders, global food security and the IP environment.

3.3 Relevant Innovation Interrelationships: Stakeholder Engagement

Invariably, any discussion involving innovation in agricultural biotechnology must address the interrelationship between the two most directly involved stakeholders, farmers and the firms that supply them with GE seeds. Along the way, one should be cognisant of two vital features of this interrelationship. First, IPRs which significantly affect how this interrelationship functions, frame the overall narrative. Second, the societal imperative of global food security cannot be isolated from this discussion due to the broad normative inflection that agricultural innovation gives to the relationship between farmers and GE seed firms.

It is relatively easy to identify those with an agricultural background who acknowledge that innovation has had a positive effect on global food security although some may quibble over which innovation has been most significant. On the other hand, it may be more difficult to identify those with a deep understanding of food security, how IPRs affect it, and the interrelationship between farmers and agricultural firms. This is because this type of understanding requires an appreciation of the disparate cultures of the private and public sectors as well as some detailed legal IP background. Finally, those who meet the above criteria and also have the scientific knowledge to evaluate genetically engineered agricultural biotechnology unemotionally may be the most difficult to identify. Given the difficulty in meeting these stringent requirements, it is pleasantly surprising that some researchers and writers have successfully addressed these issues while simultaneously acknowledging their limitations and the limitations of existing knowledge in the field.

Philippe Cullet, Geoff Tansey and Hans Morten Haugen et al. have written extensively on the subject of food security and IPRs. In, “Food security and intellectual property rights in developing countries” (2004) Cullet explains that the 1996 World Food Summit Plan of Action

identifies that the purpose of introducing agricultural patent-based IPRs is to strengthen the private sector seed industry.¹⁹⁴ Geoff Tansey and others assert that patents are an instrument of innovation policy that may also have the added benefit of improving food security. However, Tansey agrees with Cullet that patents are more often conceived to promote the private seed industry.¹⁹⁵ Haugen et al. (2010) concur and suggest in, “Food Security and Intellectual Property Rights: Finding the Linkages” (2010) that private firms are continuously searching for enhanced IPRs mechanisms to maintain market position, reduce the risks of intellectual capital loss, and maximize profits.¹⁹⁶

While all this may be true, the question remains: are patents detrimental to food security or do they directly or indirectly enhance food security? The answer to this question is critical to this thesis because any alternative to the use of patents [i.e. GURT] must also address its impact on food security. In a previous paper, titled, “The Effect of IPRs Associated with Genetically Engineered Seeds on Global Food Security”, I argue that IPRs associated with patents enhance food security through their link to innovation.¹⁹⁷

However, while there is a good case [primarily put forward by the private sector] that patents are currently fundamental to food security and should, therefore, be strongly supported by policy makers, it is not clear that *only* patents will enhance food security; promote private sector profitability; foster public and private sector innovation; and support farmers in the developed and developing world. As part of this discussion one must also ask how the patents that promote innovation affect the farmer as a key link in the food security/innovation chain?

Historically, the crop seed market expected that many farmers would make an initial purchase of seeds for planting after which they would use saved seed for crop planting in subsequent seasons. The development of hybrid corn in the U.S. in the early 1900’s accelerated

¹⁹⁴ Philippe Cullet, “Food security and intellectual property rights in developing countries” (2004) Les Cahiers du RIBios 1 at 12 [Cullet]; supra note 68 at Plan of Action para 3.

¹⁹⁵ Supra note 76 at 13.

¹⁹⁶ Hans Morten Haugen, Manuel Ruiz Muller & Savita Mullapudi Narasimhan, “Food Security and Intellectual Property Rights: Finding the Linkages” in Tzen Wong, Graham Dutfield, eds, *Intellectual Property and Human Development Current Trends and Future Scenarios* (Cambridge University Press, 2011) PIIPA <http://www.piipa.org/images/IP_Book/Chapter_3_-_IP_and_Human_Development.pdf> at 12.

¹⁹⁷ Supra note 71 at 6-7.

the movement away from this seed saving model both in the U.S. and internationally.¹⁹⁸ The reason is simply that saved hybrid seed begins the cycle of genetic erosion that leads to increasingly poor quality crops. While new seed purchase was only a “best practice” with the original hybrid crops, it became a matter of legal necessity with the introduction of GE seeds which, unlike hybrid seeds, self-replicate perfectly. Today, GE seeds are strongly protected by patents and, unfortunately for farmers, the subsequent generations of the GE seeds are also legally protected property.

The patent protected status of next generation GE seeds has led to a mandatory, legally enforceable ongoing relationship between the firms supplying the seeds, and the farmers who wish to use GE seeds but are legally not permitted to plant subsequent generations of harvested GE seed. The protected status of the next generation GE seeds has been affirmed in court decisions in cases between GE seed companies and farmers. A notable case is *Monsanto Canada Inc. v. Schmeiser* 1 S.C.R. 902, 2004 SCC 34. This case will be analyzed in more detail later. As Moretti points out in, “Tracking the Trend Towards Market Concentration: The Case of the Agricultural Input Industry” (2006), this ongoing relationship [between farmers and seed companies] is not necessarily a freely chosen one but rather one forced upon farmers who have traditionally used harvested seeds for subsequent plantings.¹⁹⁹ Of course, Moretti is speaking about GE seeds that are patented. There is nothing to stop farmers from using non-GE seeds that are not patented and saving seeds from those crops for future plantings. However, by not using GE seed, these farmers forego the value added traits developed by the GE seed companies.

The apparent need for an ongoing relationship with farmers that Moretti mentions has altered how GE seed companies develop and implement their business strategies. To maximize farmers’ switching costs [i.e. to tie the farmers more strongly to the firm’s products] the seed companies’ business models have expanded to include complementary products; products which are required to optimize the efficacy of their GE seeds. This type of strategy is not unique to

¹⁹⁸UNCTAD, *Tracking the Trend Towards Market Concentration: The Case of the Agricultural Input Industry* (UNCTAD/DITC/COM/2005/16) (2006) online: UNCTAD < http://unctad.org/en/docs/ditccom200516_en.pdf > at 15.

¹⁹⁹ *Ibid* at 18, 19.

agricultural biotechnology. It is, in fact, standard business strategic management technique of the type that every business school teaches in their MBA programs.

Endres and Goldsmith suggest in their 2007 paper, “Alternative Business Strategies in Weak Intellectual Property Environments: A Law & Economics Analysis of the Agro-biotechnology Firm’s Strategic Dilemma”, that companies investing in GE seeds consider farmer-saved seed as a threat to profitability.²⁰⁰ The ability of the GE seed companies to capture value is currently highly dependent on national and international IPRs environments. These environments are critical to the GE seed industry’s ability to recover its substantial R&D expenditures. It is for this reason that much of the thinking surrounding innovation in this industry remains linked to the historical perspective of patents as a means of supporting and promoting a closed innovation model; a model that often forces a relationship on some farmers who might prefer a freer hand to grow their crops without restriction. It is also a model that impacts how regulators balance the needs of various stakeholders. After all, just like the agricultural seed industry, farmers also have representation that lobbies government regulators and policy-makers. An example of such an organization in Canada is the Canadian Federation of Agriculture. This is the largest farmers’ organization in Canada with a membership exceeding 200,000 farmers and farm families.²⁰¹

Although, according to Endres & Goldsmith, farmer-saved seed threatens industry profitability, both the private and public sectors recognize that farmers represent the industry’s customer base while also acting as a key link in the food security chain. This is particularly the case in developing nations where food security is often a daily, national concern. This once again raises the public policy and international regulatory question around patents and GE seeds but from the farming community’s perspective.

Further into their paper, Endres and Goldsmith partially reverse themselves and suggest that perhaps farmer-saved seed may not be a serious problem for the GE seed industry, even in the weak IP environments of developing countries. In such an environment, Endres and

²⁰⁰ AB Endres & PD Goldsmith, “Alternative Business Strategies in Weak Intellectual Property Environments: A Law & Economics Analysis of the Agro-Biotechnology Firm’s Strategic Dilemma” (2007) 14:2 Journal of Intellectual Property Law 23.

²⁰¹ Canadian Federation of Agriculture, (2013) online:CFA< <http://www.cfa-fca.ca/>>.

Goldsmith indicate that firm based solutions to the saved seed problem for the companies include the use of dynamic pricing, product bundling or the development of new technological methods of IP protection such as the yet to be commercialized GURT.²⁰²

As important stakeholders, farmers also have opinions on the value and significance of saved seeds and the impact of patents on farming. Farmers, like any other consumers, are not all of one mind. Certainly, the global nature of agriculture and the varying concerns and economic and cultural diversity among farmers requires multinational corporations who deal in GE seeds to have dynamic business strategies to address this diversity. Moretti (2006) notes that the dealings between farmers and multinational companies alter the effectiveness of business strategies because of the need for firms to adapt to differing IP requirements in developed and developing countries.²⁰³

An example of the differential treatment that takes place can be demonstrated by amendments to the TRIPS Agreement that allow some developing countries to avoid the introduction of product patents in select sectors of their choice.²⁰⁴ However, this special treatment for developing countries may be more of an illusion than a concession of material significance. This is because national policies or standards may be difficult to enforce in a private arrangement between a farmer and a multinational firm in a country where the rule of law may not be strictly enforced.²⁰⁵ This situation presents an opportunity for the international public sector to provide a regulatory solution to this problem. Unfortunately, regulatory solutions to international problems present challenges that are difficult to overcome, if the aim is to satisfy a variety of national stakeholders with domestic private and public interests on the line.

Endres and Goldsmith are convinced that the alternative strategies mentioned earlier can help reduce value slippage resulting from saved seed in weak IP environments that are common in many developing nations. Although obviously short term, these strategies can allow firms to take advantage of opportunities presented in many rapidly expanding markets.²⁰⁶ These authors

²⁰² Supra note 200 at 36-38.

²⁰³ Supra note 198 at 24.

²⁰⁴ Ibid at 37.

²⁰⁵ Ibid.

²⁰⁶ Supra note 200 at 40.

suggest that as these regions develop stronger farmer accepted institutional mechanisms to enforce property rights, the GE seed firms can shift their strategies back to more legalistic approaches, such as the limited license agreements common in the United States.²⁰⁷ The thinking behind this strategy as put forth by Endres and Goldsmith, suggests that their concern is focused on traditional IP and innovation strategies when perhaps there are alternatives that might be better suited to both developed and developing countries. They even allude to one of those recent technological alternatives themselves when they mention GURT.

On the other hand, perhaps there are other reasons beyond the direct value capture benefits of patents that might encourage strong IPRs in developing countries. For example, the existence of an effective patent regime may offer sufficient confidence in the level of property rights to a point where foreign direct investment (FDI) is encouraged. This confidence could provide enough reassurance to business that they would be willing to transfer technology and undertake R&D in these developing countries. Finally, these investment-friendly activities supported by strong IPRs could boost productivity in these countries.²⁰⁸ Cullet, Haugen and Downes have serious reservation about whether the potential of these alternatives is or could be realized.

Cullet argues that the chief feature of IPRs associated with GE seed is that these IPRs allow firms to control protected seeds by licensing their use to poor farmers under conditions that restrict how the seeds from the resulting crop may be used. For example, it is a common practice of GE seed firms to forbid the replanting of saved seed.²⁰⁹ In response, one might ask whether in spite of the control that GE seed firms insist upon, is it *profitable* for these farmers to pay for these seeds, grow more productive crops, and accept the imposed restrictions? Some might suggest that the answer to this question is, yes. To bolster this contention, extensive research by James (2011) has established that it is small, poor farmers in developing countries that are the fastest growing GE seed adopters.²¹⁰

But there are those who disagree with these positive assertions by GE seed supporters

²⁰⁷ Ibid.

²⁰⁸ Cullet, *supra* note 194 at 12.

²⁰⁹ Ibid at 13.

²¹⁰ *Supra* note 93 at 7.

such as James. Haugen maintains that the patenting of agricultural innovations such as GE seeds has negatively affected traditional farmers' rights. He asserts that farmer's have become licensees of GE seeds rather than being owners of seed as has been their tradition through the ages.²¹¹ Assuming Haugen's view is accurate, one should ask whether this has had a detrimental effect on global food security? Haugen does not provide a direct answer to this question but rather discusses it in terms of how the potential risks of GE seeds to farmers' traditional farming methods may affect food security.

Farmers in the developed world and the developing world who wish to use patented GE seeds must pay for new seed at the beginning of each planting season whether the purchased seed has new value-added attributes or the seed is no different than that purchased for the previous growing season. Most developing world farmers are involved in subsistence or near subsistence agriculture which suggests that they grow enough to feed their families with any surplus going to next year's planting with perhaps a small amount available for trade. If they are growing a GE crop, and are unable to save seeds for the next season's planting, both poverty and food insecurity can increase locally if, for example, price hikes occur on the most sought after GE seeds. If these farmers purchase these seeds, the funds required to do so might come from cutting other necessary household expenditures. According to Haugen, this could also mean price hikes in specific food varieties further jeopardizing food security in developing countries.²¹²

One might suggest in response that these farmers use an alternative to patented GE seeds. In reaction to this suggestion, Haugen points out that in some developing countries there are few options available as these farmers become dependent on GE seed firms from whom they must purchase protected seeds.²¹³ As much as this tenuous seed access issue affects farmer choice, has there been a demonstrable decrease in food security that can be attributed to this farmer dilemma? Haugen does not provide any such evidence. In fact, all the available evidence points to an increase in global food security as a result of the existence of patent protected GE seed. The success of GE seeds protected by patents raises the bar for the viability of GURT as an alternative to patents as a means of protecting and promoting innovation in this industry.

²¹¹ Supra note 196 at 12.

²¹² Ibid at 15.

²¹³ Ibid at 12.

Joseph Stiglitz in his book, “Globalization and Its Discontents”, sees GE crops as the future of agriculture. He predicts that the demand for patented seeds and their prices will initially increase because of a lack of competition. The same can be said for necessary complementary inputs.²¹⁴ There are two important points to note about Stiglitz’s concern over GE seed process. First, he correctly uses the term “initially”, and here he also correctly suggests that as with other new products, time increases competition and ultimately decreases prices. Second, there are substitutes available for GE seeds for those farmers wishing to farm as they always have in the past. As previously noted, non-GE seeds are available to those who cannot or will not use GE seeds. The use of non-GE seeds is common among European farmers who count on the European consumers’ fears over GE food to create a demand for non-GE food, which the European farmers gladly fill. Of course, this ability to differentiate non-GE food from GE food allows these farmers to extract a premium price from consumers.

Joseph Stiglitz writes that the underlying problem with the IP regime is that it primarily reflects the interests of the producers.²¹⁵ One could suggest that, while it may be true that the IP regime strongly reflects the interest of the producers, there is more to this story. The IP regime also reflects the interests of public institutions that depend on the patenting of new inventions to attract the private interests with which they partner for a mutually beneficial financial relationship through the commercialization of patent protected inventions. In any event, does this in some way negate the potential benefits of the technology? Even a monopoly is subject to the economic laws of supply and demand. A monopoly sells its product or service on a *market* demand curve which is also referred to as a “willingness to pay” curve. As such, there is a limit to what a monopoly can charge for a product as well as a limit on the product quantity that it can profitably produce.

Adding to the concerns over the cost of GE products, Gerard Downes claims that patented GE seeds will threaten food security in the developing world because of the high cost of these products combined with the high level of poverty that exists there.²¹⁶ Downes is correct

²¹⁴ J Stiglitz, *Globalization and Its Discontents* (Penguin: London, 2002) ff.

²¹⁵ Ibid.

²¹⁶ Gerard Downes, “TRIPs and food security: Implications of the WTO's TRIPs Agreement for food security in the developing world” (2004) 106:5 *British Food Journal* 366 at 368.

about the cost of inputs but that is only one-half of the equation. The innovation associated with these patents also increases productivity for farmers. It may well be worthwhile for farmers to pay a higher price for inputs if those inputs result in greater, more profitable outputs that also increase food security. But what might Downes have to say about GURT? If this technology increases the cost of inputs as expected, and further restricts the ability of farmers to use it freely, Downes may find that the patent regime he so dislikes may be less of a problem for him to accept.

The farmer represents one side of the business arrangement in this industry. They are the first line consumers of this industry's products. As such, they are subject to the business strategies of the firms that sell to them. However, these business strategies also affect other stakeholders, especially business rivals, suppliers and potential industry new entrants.

In addition, there is the global IP environment to consider as this has a great influence on both farmers and the industry as well as how the patenting of GE seeds impacts the public sector.

3.4 Global Issues and the Regulation of GE Seed Patents

For firms, there are international, practical difficulties associated with the use of patents as a means of directly protecting GE IP globally. One difficulty involves the need to patent in each country in which a GE seed or complementary product is to be sold. This is a concern especially in developing countries where adherence to patent requirements by the GE seed industry can be burdensome. From a national perspective, Cullet notes that developing countries can utilize the WTO's TRIPS agreement to their advantage by using its inherent flexibility.²¹⁷ He highlights the fact that since TRIPS requires minimum levels of IP protection, the scope of IP protection can vary by country. As noted earlier, under certain conditions outlined in the TRIPS agreement, developing countries may be able to use patented products freely. These are products that are not patentable within the developing country but which are patented in some developed countries.²¹⁸ This flexibility affects the degree of patent protection available to firms for agricultural innovations in general and GE seeds in particular. Even without the TRIPS confusion, national differences in patenting can create a market failure situation.

²¹⁷ Cullet, *supra* note 194 at 48.

²¹⁸ *Ibid* at 49.

One example of the international patent complexity problem is the failure of the patent regime to protect Monsanto GE soybeans in Argentina. Although other factors magnified the problem for Monsanto, the confusion of national patenting variability was a key element in the poor outcome for the company. The consequences for the company, the industry, and biotechnical innovation in Argentina underscore the industry case for the promotion of a technological method of IP protection that circumvents the legal weaknesses of the patent system. This case is discussed in more detail in the research section of this thesis.

Patenting can also be problematic because the public sector has an incentive to develop policies that offer stronger patents in order to encourage the potential social benefits of invention disclosure by industry. However, the social benefit to patenting must be balanced against the social cost of stronger (lengthier) patents such as patent underuse and postponed follow-up inventions due to extended patent durations. After all, while a disclosed patent can provide new ideas for inventors, the invention or patented process is not freely available.²¹⁹ This problem increases in complexity when one considers that national patent regimes vary considerably.

Global variations in patent regimes can deter firms from seeking patent protection in some jurisdictions where the legal system may not protect invention disclosure. In addition, differing national IP regimes increase the transaction costs faced by firms as they seek to protect IP internationally.

These issues suggest that, from an industry perspective, a reliance on IPRs for innovation promotion and protection should be accompanied by multiple strategic approaches for value capture. This is, in fact, the case. The GE seed industry strives for multiple value capture approaches in both strong and weak IP environments. Endres and Goldsmith (2007) submit that firms must adapt to the environments [both physical and legal] where they hope to operate.²²⁰ This correctly emphasizes that these firms must not only be aware of differing national policy aims but also that these firms must promote these aims as good corporate citizens in order to promote their IP concerns.

²¹⁹ Supra note 52 at 132.

²²⁰ Supra note 200 at 39.

It is through involvement in the molding of the legal and regulatory environment wherever they operate that industry helps itself to succeed in protecting its IP. A poignant example of this is the original TRIPS negotiations where U.S. firms led in directing policy development.²²¹ While one can argue that the position of the U.S. firms in this negotiation was primarily self-serving, the end result was a compromise that was largely agreeable to all. This outcome was another step in promoting an updated regulatory framework.

Advances in biotechnology have greatly influenced regulatory modification for biological resources.²²² In “Food Security, Biotechnology and Intellectual Property” Geoff Tansey summarizes how private sector IPRs and their influence on innovation, market power, and food security has heightened the relevance of three international agreements²²³ in understanding the interrelationships of these issues. In addition, Tansey identifies the International Union for the Protection of New Varieties of Plants (UPOV) and the World Intellectual Property Organization (WIPO) as key organizations in establishing the current IP environment for GE seeds.²²⁴

Once the patenting of genetically engineered life forms became established, it became clear that an international structure was needed to create a unified approach to IP issues in general and specifically in biotechnology.²²⁵ In 1995, the strong private sector influence over the regulation of biotechnology, especially in the U.S., greatly affected the development of such an internationally acceptable IP approach. The 1995 TRIPS agreement was the result of the international negotiations to create uniformity in IP and to specifically address international biotechnological IP.²²⁶

However, the road to a final TRIPS agreement was not a smooth one. In an apparent attempt to promote the U.S. position that the strongest possible international protection for IP was needed, the U.S. International Trade Commission released figures demonstrating that US companies were losing \$40 to \$60 billion per year to “foreign intellectual piracy.” By 1999, this

²²¹ Supra note 76 at 8.

²²² Ibid.

²²³ These agreements are: the Trade-Related Aspects of Intellectual Property Rights (TRIPS); the Convention on Biological Diversity (CBD); and the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGR).

²²⁴ Supra note 76 at 11-12.

²²⁵ Supra note 194 at 11,12.

²²⁶ Supra note 71 at 23.

figure had been increased to between \$100 and \$300 billion.²²⁷ The large IP portfolios in biotechnology related products and processes added greater urgency to the U.S. position and the pressure exerted by the U.S. companies to direct the outcome of the TRIP discussions in their favour was intense.²²⁸ In the end, these companies had a considerable influence on the final TRIPS framework. The U.S. government and other governments in the developed world supported this because they considered that the preexisting IP situation was unacceptable and unsustainable. The TRIPS agreement, however, was not all one sided. The final result incorporated private and public sector benefits not only for the developed nations but also for developing countries.²²⁹

The TRIPS Agreement was negotiated between 1986 and 1994 during the Uruguay Round of trade discussions and came into effect with the formation of the World Trade Organization (WTO) in 1995.²³⁰ The most important section of this agreement for this thesis, and the GE seed discussion, is the one that deals with IP associated with plants. Specifically, Article 27.3(b) is the article most relevant to establishing an international model for addressing GE seed IP by providing for a degree of discretion on patentability. In effect, this article gives WTO members some leeway in determining whether a plant, plant-creating process, or plant variety is patentable.²³¹ This article does not, however, absolve WTO members from providing some form of IP protection.

The consequences of the TRIPS IP protection requirement to which WTO members are subject are threefold. First, those countries without IP protection prior to 1994 could introduce life patents. As an alternative, a *sui generis*²³² system could be implemented. Third, the UPOV

²²⁷ G Dufield, "What impact do IPR rules have on food security? Science and Development Network" (2001) online: SciDevNet < <http://www.scidev.net/global/policy-brief/what-impact-do-ipr-rules-have-on-food-security-.html> >.

²²⁸ R Weissman, "A long strange TRIPs: the pharmaceutical industry drive to harmonize property rules, and the remaining WTO legal alternatives available to third world countries" (1996) 17:4 University of Pennsylvania Journal of International Economic Law 1076-1078.

²²⁹ Supra note 71 at 23-24.

²³⁰ Supra note 216 at 366.

²³¹ Supra note 194 at 53; supra note 76 at 25.

²³² TRIPS Article 27.3(b) states that "... Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* [a system conforming to TRIPS but having its own national character] system or by any combination thereof". (supra note 10 at Article 27.3(b)).

Convention plant breeders' rights model was considered to be an acceptable *sui generis* solution since it fulfilled the TRIPS IP protection requirements.²³³

As a result of this inclusion of IP rights in the WTO, member countries are subject to trade sanctions from the WTO's Dispute Settlement Understanding should they fail to update domestic legislation to meet their TRIPS responsibilities. To limit the potential for adverse consequences to the food security of developing countries, they were provided with extra time to conform their domestic legislation to meet TRIPS requirements.²³⁴

Tansey and Cullet both describe the difficult TRIPS negotiations and the challenges of implementation. They also discuss the benefits of implementation for all WTO members. However, there is little mention by either as to the effect that a failure to implement a TRIPS agreement would have on biotechnological innovation, knowledge diffusion and food security.²³⁵

What is pertinent to the patent/innovation discussion is the heavy emphasis in the TRIPS discussions on patents as the key source of innovation protection by industry representatives during the negotiation process. Before the discussions that culminated in the TRIPS agreement, the build up of IP portfolios based on genetic engineering and the high costs associated with the development of those IP portfolios virtually guaranteed that the TRIPS agreement would rely to a large extent on traditional patents as a basis for the agreement. After all, the corporations pushing for this agreement were looking for the strongest level of IP protection available and at the time of the TRIPS negotiations, the utility patent was the best available vehicle for that protection.

The *sui generis* flexibility is a developing world benefit that helped to "sell" TRIPS to those countries that may have suffered undue hardship from the agreement's initial implementation. There are other flexibilities in TRIPS that encouraged countries to fall in line. TRIPS allows states to encourage domestic basic research by creating exemptions for the use of patented materials or processes in that research.²³⁶ This, in effect, codifies the ability of

²³³ Supra note 194 at 54; supra note 76 at 8,11.

²³⁴ Supra note 216 at 366.

²³⁵ Supra note 71 at 25.

²³⁶ Supra note 194 at 13, 24, 43, 47.

developing countries to circumvent some IPRs protection and to apply the resulting benefits to their food security and domestic biotechnology needs.

Cullet suggests that the introduction of international agricultural IPRs through TRIPS could promote food security-enhancing technology transfer. This is the scenario envisioned by those who developed TRIPS.²³⁷ “In this, perhaps Cullet is overly optimistic since IP strategy for major biotechnology companies has many considerations beyond the relatively weak protections provided by international agreements that might encourage innovative global business activities.”²³⁸ One such strategy mentioned earlier is the common business practice of strategic patenting. As a business strategy, this is effective. However, it is certainly not an innovation strategy as it depends on stifling the innovation of rivals for its success.

Cullet suggests other ways that developing countries can benefit from the flexibility built into TRIPS. He recommends that these countries can and should use the TRIPS IPRs structure to bolster their domestic biotechnology industries. In this way, they can actively enhance their domestic food security.²³⁹ This may be wishful thinking on the part of Cullet since most developing countries lack the infrastructure to attract the foreign direct investment (FDI) needed to develop high-tech industries. And yet, there is no doubt that science and technology is being globalized, and GE seeds are a part of that globalization. A large portion of that globalization is occurring in countries such as China, India and Brazil that have recently become a destination for FDI as they industrialize.

It is difficult to disagree with Fukuda in his paper, “Introduction: Global actors, markets and rules driving the diffusion of genetically modified (GM) crops in developing countries” (2006), when he suggests that the spread of GE crops is an example of the globalization of science and technology.²⁴⁰ Industry plays a large role in internationalizing agriculture through global companies and markets. These global companies are often national companies with one eye on their bottom line and, in some cases, the other on their home country’s best interests.²⁴¹

²³⁷ Ibid at 25, 65.

²³⁸ Supra note 71 at 25-26.

²³⁹ Supra note 194 at 34,35,53.

²⁴⁰ Sakiko Fukuda-Parr, “Introduction: Global actors, markets and rules driving the diffusion of genetically modified (GM) crops in developing countries” (2006) 2:1/2 Int. J. Technology and Globalisation 1 at 5.

²⁴¹ Ibid at 5-6.

These multinational enterprises impact national economies, and their activities affect national and international regulations.²⁴²

However, it is not just industry that exerts a powerful influence over global GE technology regulation. For example, Graff et al. (2009) convincingly argue that in Europe, and some developing countries, there are industry, farm and civil regulatory interests that seek to negatively portray GE biotechnology for their own self-interest. At the same time, these interests demand regulations to hinder the introduction or advancement of GE biotechnology.²⁴³

Some have argued that regulators in Europe have been “captured” and reflect the agendas of organizations such as Greenpeace or Friends of the Earth more than that of farmers or working-class consumers.²⁴⁴ There is, however, another side to this theory of regulatory capture. There are those who argue that regulators are aligned too closely with regulated industries and that the regulators often put the interests of companies like Monsanto before those of the public. One way that this occurs is with industry representatives populating official positions of influence over regulatory bodies.²⁴⁵ This is not a situation that is unique to the GE seed industry but rather one that is common in many industry sectors. After all, how does one effectively regulate an industry without a thorough understanding of that industry? And who has a better understanding of an industry than those who have worked in that industry? It is difficult to balance the need to regulate for the benefit of all stakeholders with the unfortunate fact that those who are best positioned to carry out the regulation often originate and may continue to have connections with the industry being regulated.

²⁴² Ibid at 6.

²⁴³ Supra note 187 at 35.

²⁴⁴ Jay Byrne, “Deconstructing the agricultural biotechnology protest industry” in J Entine ed, *Let Them Eat Precaution: How Politics is Undermining the Genetic Revolution in Agriculture* (Washington, DC: American Enterprise Institute, 2006) ch7 at 144; T Gilland, “Trade war or culture war? The GM debate in Britain and the European Union” in J Entine ed, *Let them eat precaution: How Politics is Undermining the Genetic Revolution in Agriculture..* (Washington, DC: American Enterprise Institute, 2006) at 56.

²⁴⁵ Tom Hayden, “Globalization and GMOs”, *The Nation* (5 June 2003) online: The Nation <<http://www.thenation.com/article/globalization-and-gmos/>>; Peter Newell & Dominic Glover, “Business and Biotechnology: Regulation and the Politics of Influence” in Kees Jansen & Sietze Vellema eds, *Agribusiness and Society: Corporate Responses to Environmentalism, Market Opportunities and Public Regulation* (London: Zed Books, 2004) 200–232; Katherine Q Seelye, “Bush is choosing industry insiders to fill several environmental positions”, *The New York Times* (2001, May 12) online: The New York Times <<http://www.nytimes.com/2001/05/12/us/bush-is-choosing-industry-insiders-to-fill-several-environmental-positions.html?pagewanted=all>>.

This regulatory conflict has spread to developing countries and has had a greater effect there, if only because the stakes for global food security and industrial development are higher where these issues are most tenuous. There are those who view the agricultural biotechnology-based policy positions of developing countries as reflective of a North/South conflict between farmers in the South and corporations based in the North.²⁴⁶ In contrast, others see these policies as a response by government to the legitimate concerns of farmers over the potential loss of export markets in Europe if GE crops are allowed to potentially “contaminate” their land.²⁴⁷ Contaminate, in the context of this discussion, indicates the presence of inadvertent seed growth or genetic contamination due to GE seed products accidentally finding their way into a non-GE crop field. This becomes an interesting discussion when one realizes that one of the attributes of GURT is the prevention of the spread of transgenes. This feature of GURT is addressed in more detail later in this thesis.

One may conclude that perhaps overregulation is one outcome of the multiple influences on the regulators. The results of agricultural biotechnology overregulation can have dramatic effects on the GE seed industry, not the least of which is to foster an increase in IP protection to maximize what value capture remains available. Specifically, these effects can come about because regulation is often prone to forcing delays in the spread of recognized technologies, which then leads to a reluctance on the part of the private and public sectors to invest further in R&D in next generation technologies. This snowballing effect slows or eliminates these as yet unimagined technologies and any benefits that may arise from them.²⁴⁸

In spite of the regulatory challenges faced by the GE seed industry, and to some degree in response to these challenges, the industry has been able to develop numerous strategies successfully to create and capture substantial value. One of these strategies is the protection of IP through the patenting of GE seeds and traits. However, as the private and public regulatory environment increases in complexity and the transaction costs associated with this complexity continue to rise, it is questionable whether this industry success will continue. In addition, one

²⁴⁶ I Scoones, “Mobilizing against GM crops in India, South Africa, and Brazil” (2008) 8:2&3 *Journal of Agrarian Change* 315 at 339.

²⁴⁷ S Chaturvedi & S R Rao, “Biotechnology and international trade regime: Options before developing countries” (2004) 6:3 *Asian Biotechnology and Development Review* at 9.

²⁴⁸ *Supra* note 187 at 34.

may question whether the positive strides made to date in global food security, that are arguably the result of this industry success, will continue. After all, these advances also depend to a large degree on an effective regulatory environment; an environment that has played a critical role in the evolution of the GE seed industry structure; an environment built around the use of patents as a means of promoting and protecting innovation in this industry.

3.5 GE Seed Industry: Structure, Innovation and Strategies

Historically, government policies and regulations that have incentivized and responded to agricultural biotechnology innovation have influenced and been influenced by the structural²⁴⁹ evolution of the agricultural seed industry. As this evolution occurred, private sector strategies developed to magnify competitive advantage. These strategies played an important role in the structural transformation of this industry. They also affected the protection and promotion of innovation on which this industry depends for continued success.

In their 2011 paper titled, “Drivers of Consolidation in the Seed Industry and its Consequences for Innovation” Schenkelaars et al. discuss biotechnology, food security and environmental concerns in this industry and how they affect innovation. However, the authors add that regulations to limit the monopolistic potential of strong IP assets are another policy imperative that should be addressed.²⁵⁰ Their assumption is that this monopolistic potential is primarily a negative feature of industry consolidation and as a result the need for regulation should be obvious.

In fact, Schenkelaars et al. see strong IP assets as an important influence on seed industry structure through the monopolization that these assets promote.²⁵¹ The traditional textbook microeconomic view of monopoly is that the excessive profits that this type of market structure supports, often occur at a high cost to society in the form of decreased consumer surplus²⁵² and

²⁴⁹ Structure of an industry is most simply defined by Porter’s Five Forces Model of an industry: rivalry, buyer power, supplier power, threat of substitutes, threat of new entrants. Appendix E provides a brief “GE Seed Industry Analysis” and an assessment of the current structure of the GE seed industry is assessed.

²⁵⁰ Supra note 166 at 13,27.

²⁵¹ Ibid at 65.

²⁵² Consumer surplus is the difference between what consumers actually pay for a product and what they are willing to pay.

increased deadweight loss.²⁵³ This one-sided and simplistic view of monopoly is not one that is universally accepted.

In contrast, although not directly addressing the structural evolution of the seed industry, Traxler in “The GMO [genetically modified organism] Experience in North and South America” (2006), states that he is not entirely convinced about the validity of the position taken by Schenkelaars et al. with respect to industry monopolization; that is, that the distribution of the benefits of monopolization is captured primarily by the industry. Traxler suggests that excessive industry profits are not a predictable result of the monopoly promoted by IP assets associated specifically with GE seeds because, as he states, the benefits of GE seeds are widely distributed among farmers, food consumers and industry.²⁵⁴

In spite of Traxler’s downplaying of the IP/excessive profits connection, there is little doubt that the dependence of the private sector on patent laws has induced firms in this industry to push the boundaries of what can be protected as they strive for profit maximization. This boundary expansion has occurred to the point that the control of fundamental knowledge [the building blocks of invention] has become an established focus of patent protection.²⁵⁵ The monopolization of fundamental knowledge can promote the monopolization of an industry if the level of knowledge protection is unusually high. The negative consequences of that monopolization on innovation can be significant as it can potentially restrict access to products and processes needed to take the “next step” in innovation.

Authors, such as Bar-Shalom & Cook-Degan and others, maintain that patent protection that limits access to fundamental knowledge may hinder innovation. These authors assert that this is most likely to occur in new emerging technologies where innovation is cumulative and where patents protect foundational inventions.²⁵⁶ This is exactly the situation that currently exists

²⁵³ Deadweight loss is the loss to society caused by inefficiency due to taxes or monopoly pricing. For example, a monopoly produces a less than efficient quantity of product at a higher than efficient price.

²⁵⁴ Greg Traxler, “The GMO Experience in North and South America” (2006) 2:1/2 Int. J. Technology and Globalization 46 at 50.

²⁵⁵ A Bar-Shalom & R Cook-Deegan, “Patents and Innovation in Cancer Therapeutics: Lessons from CellPro” (2002) 80:4 The Milbank Quarterly 637 at 641-642 [Bar-Shalom]; Nuffield, supra note 55 at 13; OECDa, supra note 55 at 22-29; James Bessen & Eric Maskin, “Sequential Innovation, Patents and Imitation” (2009) 40:4 RAND Journal of Economics 611 at 613.

²⁵⁶ Bar-Shalom, supra note 255 at 642; Nuffield, supra note 55 at 65; OECDa, supra note 55 at 7; Ibid at 612.

with GE biotechnology. These authors agree that a patent holder's refusal to allow access to an upstream invention can inhibit follow-up inventors from building on that invention. This lack of access to foundational knowledge is one area where the patent/innovation dilemma is relevant to the question of whether there are viable alternatives to patents that can overcome this problem. Of course, there is also the possibility that an alternative can exacerbate this problem.

Stated succinctly, this dilemma pits the public and private benefits of future innovation against those of current value capture from patent protection, and questions whether these two benefits are mutually exclusive. The need to access foundational knowledge is also where one can make a connection to an evolving industry structure. After all, if one firm wishes to obtain protected foundational knowledge from another firm, there are a limited number of methods available for this acquisition. Two possible means of attaining this fundamental knowledge are through mergers or acquisitions. When these types of activities become widespread, industry structure is altered as the competitive environment among rivals shifts. As a result, it is possible that existing government policies and regulations developed for the earlier industry structure may no longer achieve what was originally intended. Whereas firms can rapidly adapt to changes and proactively plan for them, public policy and regulations may have a significant lag time as national and international consultative processes drag on. The result can be public policy that does not accomplish what was originally intended. That is, public policy may arrive to correct a problem which no longer exists or which has morphed into a form for which the policy was not specifically designed.

Patents, innovation and industry structure are often discussed together when the topic of biotechnology comes up in both private and public sector discussions. The importance and dynamic nature of the biotechnology sector tends to intensify this discussion.

Industry structure in the GE seed industry is highly dependent on the ability to promote and protect innovation and at this time patents are the prime method to attain this industry's innovation goals. At the same time, authors such as Schenkelaars et al. and Traxler view some features of patents as a hindrance to innovation. This creates an opening for the development and commercialization of an alternative to the patent such as GURT, which represents a technological alternative to the legal protection provided by patents. In fact, GURT takes much

of the control of traditional IP protection away from governments and places it directly within the agricultural seed and, therefore, within the hands of the inventor. The effects of this on industry structure cannot be forecast with any certainty.

Three interrelated developments have shaped structural changes in the GE seed industry thus far. The first is a combination of significant scientific breakthroughs in genetic engineering. The second is the evolution of business strategies to capture value from these changes. The third is the response of policymakers to these developments.²⁵⁷

Historically, the structural changes in this industry involved consolidation and concentration.²⁵⁸ These changes originated from a need for the seed companies to remain competitive in the face of increasing R&D costs and the rapid growth of IP rights associated with biotechnology-based inventions.²⁵⁹

An important consideration in understanding the evolution of this industry's structure is the significance of the upstream supply chain.²⁶⁰ In the GE seed industry, an example of an upstream supply chain component closely tied to innovation is the R&D firm that develops crop traits. This firm is a biotechnology company, and it can be an entirely separate firm, a subsidiary of the parent company, or a division of the seed company. The biotechnology firm then supplies the patented traits developed through R&D to the seed companies, which then incorporate them into the final seed product.

One way that firms in this industry acquire the assets, and in particular the IP assets, to access R&D is through mergers and acquisitions. These mergers and acquisitions can be horizontal [the acquisition of rival firms] or vertical [the acquisition of upstream firms] in nature. In 2000, Kesan reported that recent activity in the GE seed industry centres more on vertical integration of the supply chain that promotes the internalization of R&D (and the subsequent

²⁵⁷ Supra note 166 at 63-64.

²⁵⁸ Industry concentration refers to the number of firms in an industry and is a key factor in defining the structure of an industry. Industry consolidation refers to mergers and acquisitions within an industry both vertically and horizontally, which can also have the effect of increasing concentration within an industry. The vertical aspects of an industry involve the different levels of the supply chain. Horizontal aspects refer to rivals within the industry.

²⁵⁹ Supra note 166 at 65.

²⁶⁰ Upstream supply chain: the early portion of the various stages that ultimately result in bringing a product to market.

patents that result) within existing large seed firms.²⁶¹ This idea of R&D internalization harkens back to Chesbrough's description of the old closed innovation system.

Kesan's view of the results of vertical integration fits nicely with that of Schenkelaars et al. That is, that the greater the ownership within the vertical supply chain, the greater the number of sources from which a firm can appropriate value.²⁶² This value capture can be due to the vertical integration itself or the fact that with vertical integration comes the ownership of the IP that exists at the various levels of the supply chain. Patent ownership at various levels of an integrated supply chain can negate the need for licensing and the transaction costs associated with it.

However, Kesan suggests that patents can also lessen the need for vertical ownership by allowing firms of any size to capture value through those very same licensing agreements.²⁶³ Kesan sees this as a benefit of patenting. He notes that patenting can decrease the need for mergers and acquisitions, and increase the ability of small R&D firms to survive beside large firms as a source of licensed traits.²⁶⁴ However, as Kesan and Schenkelaars have both noted, mergers and acquisitions in this industry continue to occur. One may suggest that the reason for this continued activity is that a combination of patents and vertical ownership allows a firm to not only capture the value created by various levels of the supply chain but also to control the foundational knowledge used to create that value.

Like Kesan, Schenkelaars et al. write extensively about industry structure. Yet, they also are concerned specifically with seed industry structure and its relationship to innovation as well as some of the public sector concerns that that these issues might affect. In their study for the Commission on Genetic Modification (COGEM), Schenkelaars et al. (2011) wished to answer two crucial questions. First, has genetic engineering led to the global monopolization of the plant-breeding sector by large multinational enterprises? Second, if this has indeed occurred, how has this affected, and been affected by, innovation and innovation protection in this

²⁶¹ Kesan, supra note 2 at 468.

²⁶² Supra note 166 at 65.

²⁶³ Kesan, supra note 2 at 469.

²⁶⁴ Ibid.

sector?²⁶⁵ A further question that the study by Schenkelaars et al. raises is how the potential impact of patents on innovation has influenced attempts by regulators to redirect the focus of innovation to more positively affect two different but related public sector concerns, economic growth and global food security.

Some of the most useful information for the Schenkelaars et al. study is derived from industry executive interviews in which these executives speak out about a critical dilemma. They note that patents act as a dual edged sword. Patents incentivize R&D investment and innovation while at the same time they can hold back innovation if they prevent the exploitation of fundamental knowledge that may, for example, be essential in a process that allowed others to innovate.²⁶⁶ However, this argument is only partially valid since patent acquisition requires disclosure of the invention. As such, it is clear that patenting can also promote innovation by providing knowledge that would otherwise be secret. While these executives are concerned with the lack of diffusion of fundamental knowledge and consider it a hindrance to private sector innovation, they also have some apprehension over a public sector component to this problem. That component is the difficulty that national and international regulators have in regulating innovation promotion and protection to the satisfaction of both the private and public sectors.²⁶⁷ In the public sector, the fact that the potential monopolization of fundamental knowledge may hinder future innovation means that it may also thwart the ability of policymakers to achieve both their social benefit and economic growth goals. These are goals on which the patent system bargain between society and private sector is dependent.

Beyond the concern over the stifling of fundamental knowledge diffusion that Schenkelaars et al. found among the interviewed executives, other authors note another negative attribute of patents related to innovation. In their paper, “Trait Stacking, Licensing, and Seed Firm Acquisitions in Genetically Modified Grains: A Strategic Analysis” (2008), Wilson and Huso suggest that, while industry control has increased, agricultural biotechnology firms are still faced with major strategic decisions. These decisions focus on how to commercialize GE traits in

²⁶⁵ Supra note 166 at 5.

²⁶⁶ Ibid at 21,35. (Perhaps “foundational” knowledge is a better way to describe this knowledge because this term more accurately reflects the fact that the knowledge is a prerequisite to what comes next; that is, it acts as a foundation for the next innovative step.).

²⁶⁷ Ibid at 36.

the face of mounting transaction costs associated with patents.²⁶⁸

Two common commercialization methods successfully adapted to the GE seed industry originate from previously noted structural development issues in this industry. They are the licensing of traits to seed firms and the purchasing of rival seed firms [i.e. horizontal integration]. Both of these commercialization methods have been precursors to the creation of new varieties of crops incorporating proprietary traits.²⁶⁹ At their core, both of these techniques are dependent on the application of the current patent system and the support of the existing regulatory regimes that were developed to address the various features of the patent system. As such, these commercialization methods at once both benefit and suffer from the patent attributes that have framed the current GE seed industry structure.

As seed industry structure evolved, the strategies employed by the GE seed firms also evolved. The GE seed industry has used many traditional business strategies over the years in response to both opportunities and challenges. These strategies have ranged from closed innovation to private/public R&D alliances. Other common strategies have included product and geographic diversification and the pursuit of IPRs including through the cross-licensing²⁷⁰ of IP. As with mergers and acquisitions, these strategies have opened previously untapped markets and brought outside, protected technologies such as seed germplasm [the collection of genetic resources contained in seeds] to firms that may have otherwise never have had these resources and capabilities.²⁷¹ Still, these strategies ultimately depend on the users of patented products adhering to property rights established by those patents. And here the support of national governments the international community and the goodwill of the user must accompany the legal structures that exist.

Fernandez-Cornejo in, “The Seed Industry in U.S. Agriculture: An Exploration of Data and Information on Crop Seed Markets, Regulation, Industry Structure, and Research and

²⁶⁸ William Wilson & Scott R Huso, “Trait Stacking, Licensing, and Seed Firm Acquisitions in Genetically Modified Grains: A Strategic Analysis” (2008) 33:3 *Journal of Agricultural and Resource Economics* 382. (

²⁶⁹ *Ibid* at 384-386.

²⁷⁰ In its simplest form, cross-licensing involves the licensing of an important aspect (likely patented) of a product owned by one firm to a second firm in exchange for the licensing of an important aspect (likely patented) of another product belonging to the second firm. Cross-licensing involves the exchange of access to patented materials or processes among firms without the need for any financial exchange.

²⁷¹ *Supra* note 166 at 63-65.

Development” (2004), describes how these and other strategic issues have increased in complexity as the seed industry evolved from a *seeds* to a *seeds and traits* model.²⁷² While the issues themselves may be complex, the approach to appropriate answers has always had an algorithmic quality to it; innovation requires R&D; R&D requires capital; ongoing capital flow demands innovation protection; patents provide innovation protection; business requires patents.

As commercialization opportunities continue to present themselves to GE seed firms, Kalaitzandonakes and Bjornson (2010) believe that there will be an intensification of product development innovation strategies highlighting complementary assets such as “manufacturing capability, scale-up experience, marketing, and distribution networks”.²⁷³ These authors and others suggest that both new entrants and incumbents will determine their commercialization strategies based on their individual abilities to capture value and access complementary assets.²⁷⁴

However, in the GE seed industry, just as in other high technology industries, this is a struggle that is rarely won by small new entrants. The excessive costs and expertise required for commercialization and the high value of owned patents often encourages startup firms to harvest [cash out] their investment by selling to incumbents. See Appendix E re: industry structure and the threat of new entrants. This harvesting of value represents a legitimate means of value capture but leads to further industry consolidation, which then opens the door to increased regulatory action on the part of governments faced with competition issues that can lead to market failure based on monopolization.

As previously noted, the GE industry has relied heavily on M&As to acquire and protect IP. Wilson and Huso (2008) explain that because of the perceived need to control innovation throughout the supply chain, a tendency toward M&As occurred in the U.S. crop seed sector

²⁷² USDA, *The Seed Industry in U.S. Agriculture: An Exploration of Data and Information on Crop Seed Markets, Regulation, Industry Structure, and Research and Development* by Jorge Fernandez-Cornejo. (ERS-AIB786) (Washington D.C.: USDA, Economic Research Service, 2004), online: USDA, Economic Research Service< <http://www.ers.usda.gov/publications/aib-agricultural-information-bulletin/aib786.aspx>> at 28.

²⁷³ Nicholas Kalaitzandonakes, & Bruce Bjornson, “Vertical and Horizontal Coordination in the Agro-biotechnology Industry: Evidence and Implications” (1997) 29:1 *Journal of Agricultural and applied Economics* 129 at 131.

²⁷⁴ *Ibid*; David J Teece, “Profiting from Technological Innovation: Implications for Integration, collaboration, Licensing, and Public Policy” in David J Teece ed, *The Competitive Challenge* (Cambridge MA: Balinger Publishing Co., 1987) as cited in Nicholas Kalaitzandonakes, & Bruce Bjornson, *Vertical and Horizontal Coordination in the Agro-biotechnology Industry: Evidence and Implications* (1997) 29:1 *Journal of Agricultural and applied Economics* 131.

between 1995 and 1999.²⁷⁵ In their 1999 paper, “Intellectual Property and Market Structure in Agriculture”, Rausser et al. identify additional reasons for M&As in the crop seed sector. These include a need to exploit complementary assets and to internalize spillovers.²⁷⁶ However, the use of M&As came at a high cost to global seed companies as a result of government policy imperatives. To limit monopolization and a concentration of market power, several governmental enforcement actions based on competition and antitrust laws occurred in Europe and the U.S. These actions required the biotechnology segment of the seed industry to divest some seed germplasm assets before merger and/or acquisition approval was granted.²⁷⁷

From a business perspective, the existing literature notes and supports the strategic decision of these agricultural biotechnology firms to merge and/or acquire companies to help them internalize innovation as they grew. It is obvious that what these firms were specifically internalizing was patents for the protection of inventions that formed the basis for innovation. However, it was also probable that strategic patenting was taking place for the purpose of preventing innovation by rivals.

In contrast to Wilson and Huso’s positive view of M&As as a means of exploiting complementary assets, Kalaitzandonakes and Bjornson (1997) have serious reservations about the overall value of M&A activity for both the firms engaging in the activity and the effect of the activity on new entrants. In their 1997 paper, Kalaitzandonakes and Bjornson accurately predicted that the accrued technology base and complementary assets (supported by their associated patents) of existing firms would prevent new firms from entering the market.²⁷⁸ These authors proposed that, as patent accumulation for innovation protection became more prevalent, there would be fewer and fewer new players in this industry.²⁷⁹

Beyond M&As, licensing agreements represent a simpler and older method of utilizing patents for value capture. These agreements have become popular in the GE industry just as they

²⁷⁵ Supra note 268 at 385.

²⁷⁶ Gordon C Rausser, Suzanne Scotchmer & Leo K Simon, “Intellectual Property and Market Structure in Agriculture” Working Paper No 880 (1999) Berkley, CA: Department of Agricultural and Resource Economics at 16. (Internalizing spillover is a term used to describe the prevention of value loss that can result from innovative ideas leaving the control of the firm. Once again the old concept of closed innovation was paramount at this time.).

²⁷⁷ Supra note 166 at 65.

²⁷⁸ Supra note 273 at 137.

²⁷⁹ Ibid.

remain popular in the information technology and communication sectors. Licensing agreements are also methods with which regulators have long been familiar and, therefore, are comfortable in managing.

The literature clearly identifies the importance of licensing agreements [again supported by patents] in the GE seed industry.²⁸⁰ Their use is particularly noteworthy in business arrangements between agricultural biotechnology firms that develop seed traits and those firms and organizations that enable research and the follow-up commercialization of GE traits.²⁸¹ Wilson and Huso (2008) stress the fact that licensing agreements are currently considered to be the primary mechanisms to support the commercializing of GE seeds.²⁸² While international agreements protect this technique very well, it has high transaction costs associated with it, not the least of which involves the monitoring of compliance. After all, the value of these licenses is dependent on patented IP that forms the foundation of the license value. These transaction costs represent a source of potential market failure leading to some dissipation of value from the perspectives of both the industry and the consumers of the products.

The importance of potential market failure is that it can bring about hasty changes in the regulatory environment as regulators attempt to “correct” the failure; sometimes to prevent a failure that may never occur. The result is an inevitable tension between the public and private sectors as both attempt to maximize their respective value capture; the private sector for the benefit of the shareholders of the firms; and the public sector for the benefit of society as a whole.

Goldsmith et al in their 2005 paper titled, “Seed Biotechnology, Intellectual Property, and Global Agricultural Competitiveness” look at licensing from a different, but related perspective. They suggest that licensing is perceived to be an insecure strategy compared to direct investment in the high technology sectors in countries with weak IPRs. They propose that firms prefer foreign direct investment (FDI) to licensing when complex technologies and highly

²⁸⁰ Supra note 268 at 384; Peter D Goldsmith, DK Nauriyal & W Peng, “Seed Biotechnology, Intellectual Property, and Global Agricultural Competitiveness” (2005) in J Kesan ed, *Agricultural Biotechnology and Intellectual Property: Seeds of Change* (CAB International, 2007) 19 at 28 [Goldsmith]; supra note 200 at 12,18,22.

²⁸¹ Supra note 268 at 384.

²⁸² Ibid.

differentiated products are in play.²⁸³ In addition, FDI is preferred when, as is often the case, the transfer of technology through licensing is costly and local IPRs regimes are weak.²⁸⁴ FDI also lowers monitoring costs by giving firms a more hands-on direct control of their product. Of course, here we are comparing FDI to licensing. As noted earlier, multinational enterprises often hesitate to become involved with FDI in developing countries because of their lack of faith in the local legal system to protect their property rights.

Where Wilson and Huso see substantial benefits in the licensing of traits in the GE seed industry, Goldsmith et al. see difficulties. The latter authors stress that in developing countries with weak levels of IP protection, licensing represents a loss of control of the technology by the licensee. This again harkens back to the closed innovation paradigm that others, such as Chesbrough, despise for its lack of transformational potential. It also encourages firms to restrict access to GE seeds in weak IP environments and directly disrupts a key objective of international public innovation policy, the promotion of global food security.

There is another form of licensing, which Phillips and Gustafson discuss in their paper, “Patent Strategies in the Biotechnology Industry and Implications for Technology Diffusion” (2000) which leads into the discussion of innovation strategies in the public sector. Phillips and Gustafson discuss the previously mentioned concept of cross-licensing, first as a private sector solution to the problem of high transaction costs caused by the inevitable mix of patented technologies required for a single innovation in the agricultural biotechnology sector.²⁸⁵ According to Phillips and Gustafson, cross-licensing works well in the private sector but less well in the public sector.²⁸⁶ The question is why?

Phillips and Gustafson suggest that the reason for the difference is based on how the

²⁸³ Goldsmith, supra note 280 at 28;

²⁸⁴ WH Davidson & DG McFetridge, “International Technology Transactions and the Theory of the Firm” (1984) 32:3 *Journal of Industrial Economics* 253 at 262; WH Davidson & DG McFetridge, “Key Characteristics in the Choice of International Technology Transfer Mode” (1985) 16:2 *Journal of International Business Studies*, summer, 5 at 9,18; Ignatius Horstmann & James R Markusen, “Licensing Versus Direct Investment: A Model of Internalization by the Multinational Enterprise” (1987) 20:3 *Canadian Journal of Economics* 464 at 476; David J Teece, *The Multinational Corporation and the Resource Cost of International Technology Transfer* (Cambridge: Ballinger, 1996) as cited in Peter D Goldsmith, DK Nauriyal & W Peng, *Seed Biotechnology, Intellectual Property, and Global Agricultural Competitiveness* (2005) in J Kesan ed, *Agricultural Biotechnology and Intellectual Property: Seeds of Change* (CAB International, 2007) 19 at 28.

²⁸⁵ Supra note 171 at 16.

²⁸⁶ Ibid.

public and private sectors reward employees for the development of patented products or processes.²⁸⁷ These authors note that the private sector is more likely to use flat rate bonuses, stock options, or some other method of compensation that is not directly tied to the patented product or process. On the other hand, the public sector often rewards its researchers with a share of the royalties related to the specific technology patented. This method of public sector compensation makes cross-licensing in the public sector more difficult because of the problem in dealing with the researcher royalties as part of the transfer of the license to an outside firm or organization.²⁸⁸ The result is that the royalty payments required by this transfer from the public to the private sectors can be too costly for the private sector purchaser, leading to no transfer at all and, therefore, no innovation. While licensing is a major concern between firms, it also is relevant at the level of the farmer.

As previously mentioned, farmer-saved seed is a critical threat to the seed companies' ability to protect their IP. To deal with this threat companies have usually employed legal methods [license agreements] to prevent the unauthorized use of their property. These companies have also resorted to legal methods after the fact to punish those farmers who have illegally used patented GE seed. This issue is discussed at length during the research portion of this thesis where an assessment of the innovation protection capacity of patents occurs.

Overall, it is clear that the business strategies of the seed companies have been and continue to be focused on maximizing IP protection and that the acquisition of patents has been at the centre of this strategy. In fact, the evidence available in the literature reviewed supports the contention that patents have been the driving force establishing the structure and the strategies of the industry. That is all well and good for an industry-level discussion of patents and innovation protection, but as GE seeds grow in use exponentially, more and more emphasis on the protection of IP at the level of the farmer is inevitable.

In contrast to the legal avenues for innovation protection represented by the patent, a potential primarily technological method of protecting crop trait and maximizing value capture is the previously mentioned use of GURT. It is the potential introduction of GURT as a means of IP

²⁸⁷ Ibid.

²⁸⁸ Ibid.

protection at the farmer level that may alter the way that the GE seed industry interacts with the users of its products.

3.6 GURT and Technological Innovation Protection

Thus far, the literature review has addressed primarily the innovation protection and promotion of commercially available non-GURT patented GE seeds. Also, the literature review has situated this non-GURT alternative in a historical context while revealing the impacts or potential impacts on important stakeholders that various authors attribute to these patented only GE seeds. In this section, the alternative to patented GE seeds, GURT, is addressed in detail through the views of some of the same authors as well as from others.

GURT seed is an existing, although not commercialized, form of GE seed that has been patented by several agricultural biotechnology companies. An international moratorium on the commercialization of this technology is in place, and the standards established by some national and international regulators for lifting this moratorium suggest that this technology may not be commercialized in the future. As a result, many of the political, economic, and social benefits or costs associated with GURT usage are based on speculation.

The basis for the GURT moratorium was established at the UNEP/CBD “Fifth Meeting of the Conference of the Parties to the Convention on Biological Diversity” (COP 5 Decision V/5) in paragraph 23 where it recommends that,

...in the current absence of reliable data on genetic use restriction technologies, without which there is an inadequate basis on which to assess their potential risks, and in accordance with the precautionary approach, products incorporating such technologies should not be approved by Parties for field testing until appropriate scientific data can justify such testing, and for commercial use until appropriate, authorized and strictly controlled scientific assessments with regard to, inter alia, their ecological and socio-economic impacts and any adverse effects for biological diversity, food security and

human health have been carried out in a transparent manner and the conditions for their safe and beneficial use validated.²⁸⁹

One conclusion on which all sides agree is that the effect of GURT on IP protection in the GE seed industry would be to enhance this protection far beyond the level that could be achieved by patents alone.²⁹⁰

Louwaars et al. highlight investment protection for the GE seed industry as a key motive for the development of GURT. In addition, they see three other significant motives. The first is environmental and involves the prevention of outcrossing [gene spread to other plants in the environment]. The second is to encourage the promotion of research investment in major food crops.²⁹¹ The third is to provide farmers an ability to control traits to match economic needs and the environmental conditions in which crops grow.²⁹²

There is little doubt, as Endres and Goldsmith (2007) point out that, from a business strategy perspective, the GE seed industry considers that the industry cost savings from GURT would be substantial. The use of GURT could largely avoid the need for private monitoring and enforcement of IP rights through the court system in even the weakest of IP environments.²⁹³

It is important to understand that the use of GURT is not a completely patent-free solution. However, it does offer the potential to lessen the need to patent protect crop traits in weak IP environments where patent protection is least effective. One may rightly ask, if GURT

²⁸⁹ UNEP/CBD, *Agricultural biological diversity: review of phase I of the programme of work and adoption of a multi-year work programme*, (COP 5 Decision V/5) online: Convention on Biological Diversity <http://www.cbd.int/decision/cop/default.shtml?id=7147> at paragraph 23.

²⁹⁰ Niels P Louwaars, "Policy Response to Technological Developments: The Case of GURTs" (2002) 4:1-2 *Journal of New Seeds* 89 at 91-92 [Louwaars]; C Oguamanam, "Genetic Use Restriction (or 'Terminator') Technologies (GURTs) in Agricultural Biotechnology: The Limits of Technological Alternatives to Intellectual Property" (2005) 4:1 *Canadian Journal of Law and Technology* 59 at 60 [Oguamanam]; Sina Muscati, "Terminator Technology: Protection of Patents or a Threat to the Patent System" (2005) 45:4 *IDEA – The Journal of Law and Technology* 477 at 481 [Muscati]; Guanming Shi, "Intellectual Property Rights, Genetic Use Restriction Technologies (GURTs), and Strategic Behavior" (2006), a paper (No. 156058) prepared for presentation at the American Agricultural Economics Association Annual Meeting (Long Beach, California, July 23-26, 2006) at 19 [Shi].

²⁹¹ Louwaars, *supra* note 290 at 92.

²⁹² *Ibid* at 93.

²⁹³ *Supra* note 200 at 37; Louwaars, *supra* note 290 at 91; Oguamanam, *supra* note 290 at 64; Muscati, *supra* note 290 at 482; Shi, *supra* note 290 at 16.

provides a technological barrier that prevents farmers from unauthorized access to a desired crop trait, why would a patent be required at all? The answer is that there is still some need for IP protection to prevent invention appropriation by rival firms. Also, there is the previously discussed common practice of strategic patenting as a method of blocking rivals from innovating.

Building on the importance of IP protection, Oguamanam, whose paper “Genetic Use Restriction (or “Terminator”) Technologies (GURTs) in Agricultural Biotechnology” seems to have an overall anti-GURT slant, highlights two significant GURT papers that concur with Louwaars et al. Oguamanam notes that Cullen Pendleton argues in “The Peculiar Case of ‘Terminator’ Technology: Agricultural Biotechnology and Intellectual Property Protection at the Crossroads of the Third Green Revolution” that the ease with which IP can be appropriated restricts GE seed firm investments in advanced crops.²⁹⁴ Adding support for the potential of GURT to promote value capture and to encourage R&D expenditures, Oguamanam reports on findings by Srinivasan and Thirtle. These authors determined that value capture would increase significantly with the application of GURT technology to self-pollinating crops.²⁹⁵ In fact, a reading of their study confirms that a four-fold R&D increase is possible.²⁹⁶ This is an increase that matches that from the use of hybrid crops that represent an long established non-legal technological means of IP protection. Hybrid crops provide an important source of comparison to GURT that is addressed later in this thesis.

Finally, Sina Muscati concurs that GURT maximizes IP protection while noting the disadvantages of traditional patent protection, such as the previously discussed monitoring

²⁹⁴ CN Pendleton, “The peculiar case of “terminator” technology: agricultural biotechnology and intellectual property protection at the crossroads of the third green revolution” (2004) 23 *Biotechnology Law Report* 1 as cited in C Oguamanam, *Genetic Use Restriction (or ‘Terminator’) Technologies (GURTs) in Agricultural Biotechnology: The Limits of Technological Alternatives to Intellectual Property* (2005) 4:1 *Canadian Journal of Law and Technology* at 68.

²⁹⁵ Chittur S Srinivasan & Colin G Thirtle, “Impact of terminator technologies in developing countries: A framework for economic analysis in RE Evenson, V Santaniello, & D Zilberman eds, *Economic and Social Issues in Agricultural Biotechnology* (Wallingford, UK: CABI Publishing, 2002) 159 as cited in C Oguamanam, “Genetic Use Restriction (or ‘Terminator’) Technologies (GURTs) in Agricultural Biotechnology: The Limits of Technological Alternatives to Intellectual Property” (2005) 4:1 *Canadian Journal of Law and Technology* at 68.

²⁹⁶ Chittur S Srinivasan & Colin G Thirtle, “Impact of terminator technologies in developing countries: A framework for economic analysis in RE Evenson, V Santaniello, & D Zilberman eds, *Economic and Social Issues in Agricultural Biotechnology* (Wallingford, UK: CABI Publishing, 2002) at 167.

requirements for patent infringement; high transaction costs; and the issues related to weak IP environments.²⁹⁷

The question then becomes, could GURT act as a technological alternative to patenting for securing value for the seed companies? At first glance, GURT appears to accommodate business concerns over IP protection, but Oguamanam (2004) quite rightly asks whether this technology will adapt to the public policy considerations that have been established with patents.²⁹⁸ Here Oguamanam briefly asks one of the core questions in my thesis. He reflects on some of what I label as the “viability” issues with respect to GURT and how these viability issues compare when applied to patents.

Virtual unanimity exists in the area of IP protection maximization associated with GURT; its ability to contain transgenes; and to some degree its R&D enhancement potential. However, this unanimity breaks down when one assesses the potential costs associated with GURT. Various authors place varying degrees of emphasis on some of the risks and potential costs of GURT. Some of these are concerns over outcrossing; limited access and higher costs of genetic material for breeders; degrees of regulation required; potential for environmental damage; health risks; higher seed costs for farmers; monopolization of agriculture by corporations; lack of invention disclosure if not patented; and the effects of GURT on biodiversity.²⁹⁹

Oguamanam asks whether, as is the case with patents, GURT would balance the interests of innovators with those of society concerning the promotion, diffusion and dissemination of knowledge?³⁰⁰ He points out public policy deficiencies of GURT usage as he suggests that, unlike patents, GURT has no lasting agricultural value or compulsory disclosure requirement.³⁰¹ While it is true that GURT has no compulsory disclosure requirement, the fact remains that each company that has developed GURT seeds has patented them and, therefore, has fulfilled the disclosure requirement.

More importantly, to state as he does that GURT has no lasting agricultural value is to

²⁹⁷ Muscati, *supra* note 290 at 482.

²⁹⁸ Oguamanam, *supra* note 290 at 68.

²⁹⁹ Louwaars, *supra* note 290; Oguamanam, *supra* note 290 at 67; Muscati, *supra* note 290 at 483; Shi, *supra* note 290 at 18-22.

³⁰⁰ Oguamanam, *supra* note 290 at 68-69.

³⁰¹ *Ibid* at 60.

close one's mind to future scientific discovery and innovation. For example, GURT seeds can prevent the unwanted spread of GE traits to fields where those traits are not wanted by the farmers. Oguamanam goes on to state that this technology also has no built-in "mechanism for balancing the interests of innovators and those of the public domain".³⁰² Again here, Oguamanam limits his understanding of GURT to a static model rather than one that is continuing its dynamic progression beyond the current state of knowledge even as he wrote his paper. GURT does not require a built in balancing mechanism. What may be needed is an added newly developed regulatory mechanism; one that is as dynamic as the invention itself.

One particular GURT concern highlighted by Oguamanem is that the technological protection offered by GURT may result in a firm acquiring a permanent monopoly.³⁰³ Shi (2006) also makes the point that there is no expiration date on GURT protection, even after patent expiration, and that this will further strengthen the monopoly position of the seed companies.³⁰⁴ But this is at least partially a strawman argument because there is nothing to prevent a regulatory solution to this issue. In fact, current competition laws could have an effect on this issue without the need for additional regulation. Furthermore, there is no requirement that farmers use GURT seeds. There are many alternatives available that are currently being used. In fact, today no seed is a GURT seed. However, if a farmer wishes to use a GURT seed, there is some validity in Shi's assertion at the farmer level of the discussion. In this case, a permanent monopoly could have significant financial and economic repercussions for the farmer if GURT is commercialized without changes to the regulatory environment.

Muscata goes farther than Oguamanem when he suggests that one might argue that GURT involves patent misuse because the technology unlawfully lengthens patent rights.³⁰⁵ The problem with this contention is that the seed companies are not using a legal device to extend the patent term; rather it is the technology itself that accomplishes this goal, and the technology does not need to be patented for this to occur. In fact, since GURT is patented, it is subject to disclosure and patent expiration. The disclosure issue would only be a knowledge diffusion issue

³⁰² Ibid at 71.

³⁰³ Ibid at 68.

³⁰⁴ Shi, supra note 290 at 19.

³⁰⁵ Muscati, supra note 290 at 484.

if this technology is not patented and there are no new regulatory solutions implemented to address this concern. The extension of GURT technological protection beyond patent expiration would also only be relevant without the implementation of new regulatory solutions to overcome this problem.

Oguamanam is quite adamant in concluding that the *purpose* of this technology is to inhibit knowledge diffusion and to *impede* the promotion of improved agricultural benefits.³⁰⁶ The fact that GURT is patented makes the former contention a stretch since there is no GURT that is not patented and although the need for patenting GURT is secondary, it is unlikely to be eliminated as an important business strategy to deal with rivals.

The latter contention concerning impeding the promotion of improved agricultural benefits simply goes against good business sense. If the conclusion by Srinivasan and Thirtle that expenditures on R&D will grow because of the innovation protection that GURT affords to innovators is valid, it seems likely that GE seed firms will find it worthwhile to develop new useful seed traits secure in the knowledge that GURT will protect their investments. The controversy over the effect of GURT on R&D opens up an area where further investigation is needed and where this thesis attempts to inject further understanding.

Endres and Goldsmith, who have much to say about the effects of GE seeds on the seed industry, also weigh in on the effects of GURT on farmers. They acknowledge that although GURT technology is feasible and is at the cusp of commercialization, a strategy employing it remains a long-term vision because of social, political and environmental concerns.³⁰⁷ One obvious concern is its effect on farmers in developing countries. These farmers have historically depended on the ability to plant harvested seeds as a means of growing a new seasonal crop without the added cost of repurchasing seed.³⁰⁸ The sterility of harvested V-GURT seeds is one reason that many farmers and NGOs oppose GURT and one reason this technology is currently blocked from commercialization at the international level. However, the sterility issue is only relevant to one of the two types of GURT. It is only V-GURT that produces second-generation sterile seeds. T-GURT seeds are not sterile.

³⁰⁶ Oguamanam, *supra* note 290 at 70.

³⁰⁷ *Supra* note 200 at 38.

³⁰⁸ *Supra* note 194 at 55-59.

As Kesan (2000) rightly notes, it is up to farmers to decide whether they wish to use conventional or GE patented seeds of which GURT seeds is a subset. Those opposed to GE seeds, and specifically GURT, claim that to survive farmers have no choice but to use these products as they become available. Farmers are further encouraged to use these new products since the seed companies heavily market their GE seeds.³⁰⁹ Louwaars et al. argue along the same lines as Kesan that the farmers employing GURT will become more dependent on seed suppliers as the in-demand traits made available by GURT reduce farmer saved seed as a viable option.³¹⁰ This latter contention by Louwaars et al. reflects upon the actual situation that exists today with hybrid seeds, which have a technological protective mechanism built-in. Hybrid seeds have been a runaway success in agriculture, and there is little complaint heard about the dependence of farmers on their use. The reason is simple enough. Hybrid seeds produce higher quality crops and the benefits associated with them outweigh the costs for farmers. The case of GE seeds has a similar dynamic to these hybrid seeds. In fact, James (2011) provides abundant statistical data to show that it is developing world farmers [those who one would expect to be the poorest] who seem to benefit the most and who have been at the forefront of GE seed adoption.³¹¹

Currently, regulators have kicked the GURT problem down the road, but eventually they will have to deal with GURT either proactively or reactively. When they do, it may be global food security and the potential for increased yields on previously poor agricultural land that will be foremost on their minds.

An evaluation of the effect of GURT on global food security requires a more detailed analysis than seems to be currently available. Determining the viability of GURT from a public sector perspective must address the specific relevant dimensions of food security. How will GURT affect food availability, access and stability?

Muscati sees a potential food security and biodiversity threat from GURT that would impact farmers and consumers in developing nations.³¹² He suggests that GURT will lead to a decrease in biodiversity because the technology would emphasize only major crops and direct

³⁰⁹ Kesan, *supra* note 2 at 497.

³¹⁰ Louwaars, *supra* note 290 at 91.

³¹¹ *Supra* note 93 at 7.

³¹² Muscati, *supra* note 290 at 483.

farmers in developing countries away from traditional local crops.³¹³ In contrast, Shi notes that Collins and Kreuger (2003) argue exactly the opposite position concerning diversity. They see greater diversity as competition among seed companies increases.³¹⁴ That competition would encourage seed companies to diversify their product lines to attract particular segments of the farm sector that may grow specialized, higher value crops.

So where do these issues leave national and international policy considerations? Louwaars et al. identify three policy options for dealing with GURT. GURT technology can be promoted, regulated or prohibited. Louwaars et al. identify the problem of differing policy objectives internationally, nationally and even within different ministries within national governments.³¹⁵ Of course, this creates another problem that is highlighted by the contrasting policy approaches to GE seeds and GE food that occurs in North America and Europe (e.g. the Precautionary Principle v the substantial equivalence approaches to GE food labelling). Situations such as this cannot help but complicate a uniform international approach to policy development. Furthermore, the long-established international patent regime that balances private and public sector needs would be rendered virtually meaningless in a GURT agricultural world if that regime were left unaltered. This represents another area where this thesis intends to further the discussion.

Muscati also takes another policy tack in response to GURT. He suggests either an absolute or limited prohibition on patenting of GURT or, more specifically, the requirement for compulsory non-sterilization [i.e. no V-GURT allowed]. In the former situation, for example, the GE traits are only technologically protected for a limited period of time (e.g 20 years as with patents) and then the protection is deactivated through the application of an inducer chemical or agent. This would occur when a patent expires. In this way, Muscati sees a method of

³¹³ Ibid.

³¹⁴ Collins, HB & RW Krueger. "Potential Impact of GURTs on Smallholder Farmers, Indigenous & Local Communities and Farmers Rights: The Benefits of GURTs." (2003) Paper made available to the CBD's Ad Hoc Technical Expert Group on the Impact of GURTs on Smallholder Farmers, Indigenous People and Local Communities, February 19-21 as cited in Guanming Shi, *Intellectual Property Rights, Genetic Use Restriction Technologies (GURTs), and Strategic Behavior* (2006), a paper (No. 156058) prepared for presentation at the American Agricultural Economics Association Annual Meeting (Long Beach, California, July 23-26, 2006) at 14.

³¹⁵ Louwaars, supra note 290 at 96.

accommodating GURT within the current IP system.³¹⁶ In this suggestion, Muscati is striving to think beyond the static model of GURT to embrace what I would suggest is dynamic thinking for a dynamic product.

One can see from the GURT discussion above that the issues surrounding this technology are being hotly debated before its potential introduction as a commercial product and that the issues involved are both complex and often highly speculative yet appropriate.

GURT represents a technological alternative to the traditional use of patents as a means of promoting and protecting innovation in the GE seed industry. However, it is not the only non-patent method of attaining the goal of innovation protection. At the other end of the non-patent spectrum of innovation protection is the trade secret. The existing literature also takes this method of IP protection under consideration.

The protection provided by a trade secret entirely eliminates the need for patenting. In fact, if one wishes to avoid the disclosure that accompanies a patent application, keeping the invention as a trade secret is an often-used method. Endres and Goldsmith provide some insight into the trade secret as one particularly useful non-patent method of protecting innovation while suggesting that it could have applicability to agricultural biotechnology. Trade secrets protect information that: “(1) has an independent economic value as a result of it not being generally known or ascertainable, (2) is subject to reasonable efforts to maintain the secrecy.”³¹⁷ However, one may question whether this is a viable alternative to the use of patents in the GE seed industry as Endres and Goldberg suggest. Endres and Goldberg note the long-term success in maintaining the Coca-Cola formula as a trade secret and suggest that this method of property protection, rather than patents, may have value in agricultural biotechnology.³¹⁸ They indicate that the trade secret has been useful as a means of protection for the hybrid corn seed but they do not even speculate beyond that particular indication. An interesting question is, why is the trade secret effective in protecting hybrid corn IP?

Hybrid plants are currently in use and have been used for many years. One drawback of hybrids is that the resulting hybrid plant may contain unwanted or unneeded characteristics

³¹⁶ Muscati, *supra* note 290 at 508.

³¹⁷ *Supra* note 200 at 19.

³¹⁸ *Ibid.*

because these plants are essentially the result of breeding. Pure non-GE hybridization is not able to add only the specific traits desired to the final plant without potentially adding other unneeded traits.

Hybrid corn is the result of cross-pollination of two parent seed lines with enhanced characteristics.³¹⁹ Therefore, this technique is limited to sexually rather than asexually reproducing crops. A key feature of the hybrid is that the next generation offspring no longer retains 100% of the high quality enhanced characteristics of the original hybrid. Significantly, these genetic characteristics are undetectable through examination of the hybrid plant. The result is that it is necessary to cross-pollinate the two parent plants to produce a hybrid every time. In this way, the breeder can preserve the secrecy of the parent lines' genetic makeup.³²⁰

This method of protection for hybrid corn appears similar to GURT technology in that the *source* of the original innovation is protected [hybrid corn by trade secret; GURT by a patent], but the released product is protected by its biotechnological attributes rather than by legal means. This latter form of protection is crucial since it prevents the unauthorized use of progeny seeds by farmers. In the case of hybrids, the plant will grow but with weakened traits. In the case of v-GURT, the plant will not grow. In the case of T-GURT, the plant will grow but without its enhanced traits. As previously noted, it is at the farmer level where the primary value leakage occurs.

The trade secret technique discussed by Endres and Goldsmith may be an effective means of innovation protection for hybrid crops such as corn, but it has one critical disadvantage when dealing with non-GURT GE seeds. That disadvantage is the problem of the harvested seed. The trade secret technique can be used to protect the initial non-GURT GE seed, but it becomes irrelevant to the protection of the harvested non-GURT GE seed since that seed is out of the seed firm's direct control. For these seeds, secrecy loses all of its value since it is the ability of farmers to use and replicate the product (the GE seed) that is of concern to the GE seed companies. Unlike harvested hybrid seeds, the harvested non-GURT GE seed can produce a GE plant that is identical to the original plant. The ability to create a duplicate plant makes the use of

³¹⁹ Ibid.

³²⁰ Ibid.

the trade secret useless as a method of innovation protection for non-GURT GE seeds.

One might consider from a review of the literature, that the primary discussion around the protection and promotion of innovation in GE seeds is the private sector. This, however, is not the case. The literature also addresses GURT from a public sector perspective.

On the surface, GURT does appear to address a key public sector concern associated with GE seeds. That concern is the potential escape of genetic material into the wild. GURT by its nature represents a biotechnological solution to this problem in that this technology promotes the containment of GE traits. Louwaars et al, Muscati, Shi and others all note this key benefit of GURT.

3.7 Public Sector Strategies/Private Sector Impacts

Agricultural biotechnology firms develop and implement strategies that are heavily dependent on innovation and its protection to maximize their return on investment. However, innovation strategies are not unique to the private sector. Schenkelaars et al. point out that governmental science and technology (S&T) policies have long overseen public R&D in plant sciences.³²¹ In fact, it was only after the 1980s that private R&D investment in plant breeding overtook that of the public sector. Still, the public sector remains a prominent R&D player in agricultural biotechnology.³²² As with the private sector, the public sector is looking for a return on its investment, but that return is guided by goals, such as national economic growth, that are unique to the public sector.

The OECD, whose aim is “to promote policies that will improve the economic and social well-being of people around the world”³²³ is well positioned to provide useful data related to IP and innovation promotion and protection. As early as 1963, the OECD was linking science policy to economic objectives through the relationship of these two considerations with IP.³²⁴ As such, this organization has been at the forefront of policy development for the promotion of

³²¹ Supra note 166 at 64.

³²² Ibid at 89, 92, 93.

³²³ *About the OECD*, online: OECD <<http://www.oecd.org/about/>>.

³²⁴ Bengt-Ake Lundvall & Susana Borrás, “Science, Technology and Innovation Policy” (2005) in Jan Fagerberg, David C. Mowery & Richard R. Nelson eds, *The Oxford Handbook of Innovation* (Oxford University Press, 2005) 599 at 603.

innovation through research and IP protection. As a result of the research carried out by the OECD to further these goals, this organization is a leading source of science, technology, and innovation data. In addition the OECD has been stressing the importance of innovation in agriculture for many years. Many publications produced by this organization, such as “Patents and Innovation: Trends and Policy Challenges”(2004); “Genetic Inventions, IPRs and Licensing Practices: Evidence and Policies” (2003); and “Turning Science into Business: Patenting and Licensing at Public Research Organizations” (2003) demonstrate how important the OECD considers patent use to be as a means of protecting innovation both nationally and internationally.

In spite of public sector success in agricultural biotechnology innovation, Phillips & Dierker (2001) see three existing or potential problems with innovation in this sector. First is the decrease in publicly funded basic research needed to promote the continued development of new technologies. Second, the poor quality of IP systems and strategies in the public systems may hinder technology exploitation. Third, a decrease in the number of independent researchers due to the integration of public/private research will reduce consumer confidence in the safety and usefulness of the new technologies.³²⁵ This idea of consumer confidence plays a large roll as a viability issue in comparing patented non-GURT GE seeds and GURT seeds in the viability section of this thesis.

The decrease in publically funded basic research is significant because, as Phillips & Dierker point out, the public research that is taking place is directed more and more to patentable technologies rather than the “know-why” research that is often most useful for pointing research in new directions and toward new potential innovations.³²⁶ It is this “know-why” research that leads to innovations such as GURT. Phillips and Dierker allude to the importance of private/public partnerships as one reason behind this trend. I would add that another reason for the focus on patentable technologies is that public institutions are looking for self-sustaining funding sources. As governments are finding it more and more difficult to find funding for basics

³²⁵ Peter WB Phillips & D Dierker, “Public good and private greed: Strategies for realizing public benefits from a privatized global agri-food research effort” (2001) in Philip G Pardey ed, *The Future of Food: Biotechnology Markets and Policies in an International Setting* (Washington D.C.: International Food Policy Research Institute, 2001) at 134.

³²⁶ Ibid.

such as health care and social security, “luxuries” such as fundamental research become easy targets for budget cutting.

As to the second problem of poor public sector IP strategies, Phillips & Dierker note that increasingly the public sector acts much like the private sector by filing patents that have limited appropriable value in the real world. The increasing tendency of the public sector to act in a highly proprietary manner, rather than releasing patents to the public domain, can impede commercialization by others who might find value in these patents.³²⁷ This interference with commercialization is somewhat like the previously mentioned “strategic patenting” that takes place in the private sector except that one would expect the public sector to encourage rather than stifle innovation. To some degree, it seems that the public sector is also heavily wedded to the old closed innovation model.

Also, these authors report an increasing tendency of public institutions to license widely primarily those innovations that have the potential to return the greatest public good. In many cases, these innovations require additional investment before commercialization is possible. Unfortunately, the competitive environment established by the widespread licensing of an innovation by public institutions deters private investors from funding these projects. This occurs because the high level of induced competition reduces the ability of private firms to recoup ongoing R&D investment.³²⁸

Although Phillips and Dierker question the quality of IP strategies in the public sector, Granstrand (2005) argues that public sector IP strategies are not a deciding factor for innovation promotion. He identifies studies that show that a strong patent system has not been necessary for the industrialization of economic growth at the country level.³²⁹ Granstrand suggests that this growth occurred irrespective of patenting. The previously referred to Lerner (2001) study also finds that national policy changes that increase patent protection have a limited effect on patenting although it also notes that there is a greater effect on patenting by foreigners than by domestic entities. Granstrand concludes that the IPR system in general and patents, in particular, have been neither necessary nor sufficient for significant technical and/or economic progress at

³²⁷ Ibid at 134-135.

³²⁸ Ibid at 135.

³²⁹ Supra note 134 at 283.

the national level. He reviews the evidence and notes that the scholarly literature indicates that the patent system has led to technical progress but that for this progress the importance of the patent system is secondary to that of other institutional developments such as general property rights.³³⁰ This assertion by Granstrand is general in nature and not specifically related to the private/public involvement in GE seeds.

However, Granstrand does provide an inkling of the potential for industries such as the GE seed industry to dramatically impact economic growth at a national level. He points out that the “pro-patent era” that has developed since the 1980s is dependent on knowledge, innovation and intellectual capital.³³¹ He argues that the increasing global activism for IP from industrialized countries culminating in the TRIPS agreement can be seen as an attempt by these countries to maximize value capture from R&D at the expense of developing nations.³³² Unlike the previous general patent system assertions by Granstrand, the reference to TRIPS brings the GE seed industry and its regulatory environment into the cross hairs of international innovation policy discussions.

Pertaining to the third problem of consumer buy-in, Phillips & Dierker argue that the strategy of public institutions partnering with private sector entities enhances consumer belief that regulatory capture will occur and will negatively affect the safety and effectiveness of new innovations in agricultural biotechnology.³³³ This is a well-established anti-business belief that suggests that firms are willing to maximize profit at the expense of corporate social responsibility. While there are numerous industry examples of this regulatory capture in the U.S. [oil industry, rail industry, coal industry], the manifestation of such a belief could be a slowing of GE crop adoption and a decline in agricultural biotechnology investment leading to a decrease in innovation in this sector.

The three problems discussed above overlap three types of public sector policy areas that are unique to high technology industries such as agricultural biotechnology. These areas are science policy, technology policy and innovation policy. The evolution from science policy

³³⁰ Ibid at 284.

³³¹ Ibid at 285.

³³² Ibid at 284.

³³³ Supra note 325 at 138-139.

through to innovation policy in the U.S. began with the post-WWII Vannevar Bush report, “Science: The Endless Frontier” which defines the “task for science policy as contributing to national security, health and economic growth.”³³⁴ The science policy and public R&D advancement likely had much to do with the manner in which WWII³³⁵ ended.³³⁶ At that time, national security was a priority but an unintended consequence was economic growth. As Lundvall and Borrás intimate, the overlap of national security and economic growth also resulted in an overlap between private and public innovation.³³⁷

Fast-forward to the 1990s and we see that since the early part of that decade, there has been a constant push on the part of politicians for a science policy that returns *value for money*. That search for *value for money* is very much how the private sector develops its policies as well. Lundvall, Borrás and Sharp argue that this short-term attitude disregards some essential aspects of science policy such as the training of scientists and technicians, and the development of knowledge capabilities in areas where uncertainty is so high that private investors lack incentives.³³⁸

Politicians are often accused of looking at the short-term as a means of obtaining political advantage, but the public sector also involves public research organizations (PROs) that may have more of a long-term focus. As such, they may address the type of innovation that creates long-term benefits.

Phillips and Gustafson also highlight the short-term/long-term innovation dilemma. They note that PROs, especially in Canada and other developed countries, are more likely to focus on the development of innovative processes rather than innovative products. Innovative processes tend to be more of a long-term prospect than innovative products.³³⁹ In the case of GURT, for

³³⁴ Supra note 324 at 605.

³³⁵ The war in the Pacific (World War II) was brought to a close primarily through the success of the Los Alamos project in developing the atom bomb.

³³⁶ Supra note 324 at 605.

³³⁷ Ibid.

³³⁸ Ibid at 607; Margaret Sharp, “The UK-Experiment: Science, Technology and Industrial Policy in Britain 1979-2000” (2003) in Peter Biegelbauer & Susana Borrás eds, *Innovation Policies in Europe and the US. The New Agenda*, Aldershot: Ashgate, 17-43 as cited in Bengt-Ake Lundvall & Susana Borrás, *Science, Technology and Innovation Policy* (2005) in Jan Fagerberg, David C Mowery & Richard R Nelson eds, *The Oxford Handbook of Innovation* (Oxford University Press, 2005) at 607.

³³⁹ Supra note 171 at 10.

example, it is the process used to identify, isolate and transfer traits that provides the long-term benefit for innovation. The traits that represent the products are simply a short-term source of profit. However, at this level of technology and cost, it is the private sector where the bulk of the research activity takes place.

And what about measuring innovation success? PROs, more so than private organizations, are more likely to measure success by the resulting economic development that the innovation promotes.³⁴⁰ One shortcoming of Phillips and Gustafson's study is that it is based primarily on public sector data sourced in Canada. However, the private sector data obtained and used is related to multinational enterprises and can, therefore, provide some valid global implications based on international innovation attitudes.

Phillips and Gustafson also point out that public agencies tend to operate nationally, and the resulting policy goals of public agencies also tend to be national in character.³⁴¹ For this discussion, the examination of Canadian public agencies by Phillips and Gustafson seems adaptable to the U.S. given the close ties between Canada and the U.S. in trade (NAFTA) and the high degree to which both of these countries have adopted GE crops.³⁴² The two countries also have very similar attitudes toward the safety and labelling of GE foods. For example, as previously noted, unlike Europe, Canada and the U.S. only require the labelling of GM food if the product is substantially different from its conventional counterparts; that is if the product itself rather than the process involved in creating it is different.³⁴³

Reviewing the numerous academic papers in the Oxford Handbook of Innovation,³⁴⁴ it seems that in the discussion of the evolution in policy focus from science to technology to innovation, science policy is rarely discussed in terms of its direct economic value. In contrast technology policy specifically addresses science-based technologies, such as genetic engineering, as core elements of economic growth. These technologies, with their high rate of

³⁴⁰ Ibid.

³⁴¹ Ibid at 5.

³⁴² Supra note 93at 11-15.

³⁴³ Supra note 190 at 103.

³⁴⁴ Jan Fagerberg, David C Mowery and Richard R Nelson eds, *The Oxford Handbook of Innovation* (Oxford University Press, 2005).

innovation, are meant to satisfy expanding markets.³⁴⁵ However, without an effective science policy, there is less foundational material for an effective technology policy leading ultimately to a stagnation of innovation.

The key elements of the innovation system that form the basis of technology policy remain universities, research institutions, technological institutes, and R&D labs. However, Lundvall and Borrás in their paper, ‘Science, Technology and Innovation Policy’ (2005), have described how attention has shifted from the institutions themselves toward how they link with industry.³⁴⁶ This shift in focus has highlighted the private/public tensions in the agricultural biotechnology sector; tensions that are much like those that exist among many high technology industries and public institutions and policy makers. Reasons for this tension include differing goals, responsibilities, expectations and oversight responsibilities. These are tensions that organizations such as the OECD attempt to mitigate by providing a forum that allows governments and businesses to meet and to discuss issues of mutual concern such as how to handle the issue of global food security.

The tie in with the specific issue of global food security is one that both the public and private sectors can influence. That influence is particularly relevant because of the importance that the genetic engineering of seeds holds for agriculture. Science policy and technology policy are vital components in the advancement of the GE seed industry, however, innovation policy is where commercialization occurs; and commercialization is what allows for both private and public sector benefits to accrue.

Innovation policies in the public sector take a step beyond that which is required to promote science and technology. Here, innovation policies attempt to address the private/public tensions in the GE seed industry. Lundvall and Borrás consider innovation policy to have two versions. The first, what they refer to as the *laissez-faire* version, emphasizes non-intervention and deems the market and competition as essential prerequisites for innovation. The second systemic version suggests that most major policy fields need to be considered in light of how they contribute to innovation. In this latter version, competition is still important but so is

³⁴⁵ Supra note 324 at 612.

³⁴⁶ Ibid at 608-609.

cooperation vertically among users and producers and horizontally among competitors.³⁴⁷ This idea of cooperation vertically and horizontally fits nicely with Chesbrough's concept of open innovation where a firm can bolster its success through the success of its rivals. Interestingly, however, it contrasts with the structural evolution of the GE seed industry where consolidation rather than cooperation is occurring vertically and horizontally.

Schenkelaars et al. take a practical view of the policy issues involved by pinpointing the policy dilemma that they see in agricultural biotechnology; that is in managing innovation for societal benefit versus private sector viability. These authors emphasize the pursuit by governments around the world of policy development directed primarily toward growth in agricultural productivity. Schenkelaars et al. are convinced that science and technology policies and IP laws address policy-based incentives for innovation. For example, biosafety and GE organism regulations deal with food and environmental safety concerns and competition and antitrust laws handle market risks.³⁴⁸ But this line of thinking does not seem to provide a space for GURT technology, which exists away from the traditional realm of IP "control". Its strength for innovation protection may lie in private sector control but with public sector oversight.

Unfortunately, struggling to meet the high cost of compliance with rules and regulations in agriculture can create difficulties. It creates market entry challenges for small firms; incentivizes existing GE seed companies to protect innovation through growth; and increases the financial and legal risks of innovation leading to an increased need to protect investments through IP assets. It is evident from this that policy issues related to agricultural biotechnology represent a significant and controversial area of discussion in its own right.

Summarizing their paper Lundvall & Borrás (2011) come to three broad conclusions each of which links overall innovation policy, as the product of science policy and technology policy, to private sector concerns. First, they suggest that economic performance is closely tied to science and technology and, therefore, ultimately to innovation. Second, the authors tighten the connection of innovation policy to the private sector by stating that a joint concern in an era where innovation policy dominates is how to coordinate policies affecting innovation. Finally,

³⁴⁷ Ibid at 608.

³⁴⁸ Supra note 166 at 5.

the authors propose that a comparison of successful international and domestic innovation systems is the best way to design an effective innovation policy.³⁴⁹

The long term use of patents to protect and promote innovation is well understood and the ability for patents to protect and promote innovation in the GE seed industry can be researched based on a mountain of qualitative and quantitative data. However, how does one accurately compare an existing primarily legal method of innovation protection and promotion with a non-legal method, such as GURT, which does not yet commercially exist?

3.8 Literature Review Conclusion

The literature clearly identifies patents as one of the most important, if not the most important, current means of innovation protection in the GE seed industry. Through this protection, patents provide an incentive for innovation promotion rather than acting as a specific source of innovation. Many sources of innovation have been noted, such as inventions, R&D, business strategies, resources, capabilities, etc. These sources of innovation are important in the GE seed industry and require protection, but it is protection not necessarily related to patents, which specifically protect inventions. For example, disguising their nature from competitors can protect business strategies. Contracts with the owners or outright purchase can protect resources such as raw materials. Capabilities and tacit knowledge can be protected by properly rewarding, for the purpose of retaining, key employees who possess those vital sources of innovation. These sources of innovation require protection for what they embrace rather than for what they are.

On the other hand, the value of a patent for the protection of innovation is based on what it excludes. The patent excludes those, other than the inventor, from making, using, or selling an invention that may be a source of the innovation. For most inventions, all three of these restriction rights are vital. In some cases, creating the invention is not difficult and not costly and, therefore, these factors do not act as a barrier to imitation. In such circumstances, a patent is a vital legal source of protection for an inventor. In other cases, creating the invention is complex and costly, and a patent is less relevant to the inventor because these attributes make it somewhat self-protective.

³⁴⁹ Supra note 324 at 613-614.

The literature review notes that in the GE seed industry, the invention as a source of innovation is vital. The process required to create this invention is complex and costly and demands highly specialized abilities and knowledge to be successful. However, this is only the case with the first iteration of the invention; the first GE seed. Here a patent is useful in protecting the original invention from appropriation by other biotechnology firms that have the capability [financial and knowledge-based] to copy the GE seed creative process. However, rival firms are not the only or even the primary source of potential value leakage from the GE seed invention.

It is the second iteration of the invention [the seeds produced by the initial GE plant] where the difficulty in protecting the invention becomes a serious issue for the GE seed companies. Here the pressing concern for these firms is that the invention can be easily reproduced without any knowledge and at virtually no cost. One need only plant the initial seed, and the invention is copied by creating a new plant that will produce seeds that are an exact genetic copy of the original. For this reason, a good argument can be made that the chief threat to the GE seed industry is not rival GE seed firms, but rather the farmers who purchase the initial seed from the GE seed company and can easily save and replant second-generation seeds if they choose to do so.

The use of progeny seeds by farmers is where the critical problem with IP associated with GE seeds actually lies. This is because of the difficulty and cost of employing strictly legal avenues for IP protection on a worldwide scale where the regulatory environment is variable. Although the literature notes this farmer issue, it does not seem to be considered as a significant threat to the industry by many authors. This thesis proposes that the lack of emphasis on this industry threat is one of the inadequacies of the current literature.

The same issue is relevant in the public sector even though most of the commercialization in the GE seed industry occurs in the private sector. However, a significant amount of basic research takes place at PROs. If the private sector is unable to protect its IP and to profit from it, what incentive beyond the quest for knowledge for its own sake would there be for the public sector to carry out pre-commercialization research? There would certainly be no incentive for the private sector to partner with the public sector. As a result, innovation in this area of

biotechnology would likely be severely diminished.

Currently, the private sector uses contracts with farmers to prevent the unauthorized use of seeds. This method of protection is technically problematic and costly to monitor because of the millions of farmers all over the world using GE seeds and the variations in national IP regimes. This difficulty suggests that it is worthwhile to search for an alternative to the traditional use of patents to protect GE seed biotechnology that might eliminate some of the problems associated with patents. At least, it would appear to be worthwhile from the perspective of the GE seed companies as the stakeholders responsible for much of the innovation/commercialization in this field.

The identification of the farmer as the weak point in GE seed protection is crucial to this thesis. It narrows the choice of alternatives for invention protection and, therefore, innovation protection and promotion to those methods that are relevant to this problem area in this industry sector.

A number of GE seed industry and public institution innovation protection and promotion strategies are identified in the literature. Appendix F is a diagrammatic representation of the general alternative landscape for the protection and promotion of innovation so that the positions of the two most distinct alternatives are readily apparent.

The chief difficulty in delineating alternatives for this thesis is the fact that many potential alternatives can often operate through multiple mechanisms that overlap. For example, a strategic mechanism for innovation protection at the firm level is vertical integration of the business. While this strategy enhances innovation protection by internalizing the supply chain, one of its key goals is also to internalize and, therefore, control the patents within that supply chain. This highlights the fact that alternatives may present themselves at various levels of “purity.” In the case of vertical integration, the core protection mechanism is the acquisition of patented inventions, and the vertical integration of the business is the means of attaining this goal.

Another example is the licensing of seed products by the GE seed firms. Licensing is the overt mechanism by which the GE seed firms protect their invention-based innovation. However, without the patenting of the GE seeds, the licensee would have no incentive to pay for the

license. As such, patents can be thought of as a foundation for the current licensing protocol used by GE seed firms.

In another example, patents can also be an essential component of structural mechanisms of innovation enhancement, such as mergers and acquisitions. Mergers and acquisitions represent a higher-level application of the benefits of patents as these structural mechanisms often occur for the purpose of acquiring existing patents in addition to the obvious industry consolidation that results. The acquisition of patents was described earlier as one of the chief reasons behind the structural evolution of this industry in its formative years. The influence of patents is also evident in the strategic mechanisms that affect the course of innovation. For example, as previously discussed, the patenting of inventions can occur as a purely blocking mechanism to prevent rivals from innovating.

Most business strategies in the GE seed industry rely on the legal protection of IP, to some degree, to be successful. Even an open innovation model, which was discussed earlier, often depends on the use of patents for it to function effectively. That use of patents may be more novel in an open innovation system than that employed in a closed innovation system but at some point in the process of open innovation, the patent influences the overall process. In fact, the failure of the open innovation system occurs primarily at the point of greatest concern in this industry, the farmer. Any potential success of an open innovation system at the industry or public sector level is overshadowed by its total failure to address the protection of innovation at the farmer level. This is because open innovation is an industry level concept about how to promote innovation. It is not about protecting innovation, but rather it is about taking advantage of protected innovation whether it is internally or externally generated. It cannot be overemphasized that the primary concern in the GE seed industry is not firm-to-firm interaction or even firm-to-public sector interaction. Rather, the primary issue is firm-to-farmer interaction and who retains control of the product that the industry produces.

What the above discussion suggests is that one of the main alternatives to be evaluated on the basis of the established criteria in Chapter 4 is, in fact, the patent. The various ways in which the patent is used, and there are many, are significant but ultimately these uses depend on the legal attributes of the patent itself to make them valuable.

When all is said and done, there are only two basic categories of alternatives for the protection and promotion of innovation in the GE seed industry. These alternatives involve either primarily legal mechanisms or involve primarily non-legal mechanisms. In addition to the utility patent, potential legal mechanisms include the trade secret, the Patent Act (or international equivalent) and the Plant Variety Protection Act (or international equivalent).

It is well understood, and it has been clearly shown, that the Patent Act and the Plant Variety Protection Act do not offer legal protection to the same degree as the utility patent. This is why the utility patent has become the primary source of IP protection in the GE seed industry. A re-evaluation of the Patent Act and the Plant Variety Protection Act would not offer anything new to this discussion, and they will not be addressed further.

The other legal possibility is the trade secret, which is of limited value in any situation where reverse engineering is possible. This is because once an invention is reverse engineered, the secret is “out” and the protection offered by this mechanism ceases. The trade secret in the GE seed industry does not offer dependable protection, but for a reason other than the ability to reverse engineer the product (seed). In the case of GE seeds, the “secret” exists within the product, the DNA of the seed, and this secret does not need to be revealed for someone to profit from its appropriation. All that is required is the ability to grow the seed to produce more seeds.

At this time, GE seed companies monitor farmers’ fields to prevent the illegal use of proprietary seeds and they must expend a great deal of effort to accomplish this goal [i.e. regularly check farmers’ crops for the illegal use of GE seeds]. The only real alternative to this is to develop a method in which monitoring is unnecessary. GURT has the potential to do this and could render legal protection mechanisms of secondary importance, if not redundant. The other technological method of protection is the use of hybrids, but hybridization is limited by its lack of specificity as noted earlier.

An important question that arises out of the enhanced control that GURT offers to GE seed firms is what effect would this have on key stakeholders such as farmers, national governments and international regulatory agencies. These areas require investigation when judging the viability of GURT as an alternative to patents.

One clear conclusion evident from the literature review is that the promotion of

innovation requires protection for the invention behind that innovation. Another conclusion is that the maximization of innovation promotion requires technological and knowledge diffusion. The literature notes that patents can have both a positive and a negative effect on innovation depending on the characteristics of the technology being patented and the patent regime that is designed by policymakers. In fact, the effects of patents on innovation and diffusion depend on addressing specific concerns about some patent regime features. These features include the determination of patent subject matter, patenting requirements and patent breadth.

On the subject of viability of the two alternatives, patents and GURT, the literature review tends to address some viability criteria within isolated silos. There is scant comparative analysis to lead to a determination as to the superiority of one alternative over the other. One major effort of this thesis is to make that comparison.

Chapter 4

Research Methodology, Design and Questions

Chapter 4 represents Step 4 in the thesis path. Its contents are heavily influenced by the literature review, which sets the stage for the research to come. The research design, methodology and methods are detailed as follows:

- 1) The foundation for the research design is established.
- 2) The thesis question is revisited and scrutinized to eliminate any ambiguity about the research focus and direction. This has been influenced by the availability and quality of relevant material available for and analyzed in the literature review.
- 3) The innovation protection and promotion criteria are established.
- 4) The viability criteria are identified and described. These criteria required completion of the literature review in order to determine where the literature review authors placed their emphasis.
- 5) Data sources and data gathering methods are outlined.

In the research and analysis sections of this thesis that follows this chapter, both patents and GURT, the two most distinct alternatives with widespread potential usefulness, will be tested for their ability to protect and promote innovation. One, patents, has a long history of use and the other, GURT, has not yet been commercialized but exists on the edge of commercialization.

After assessment for innovation protection and promotion, patents and GURTs are tested for their viability. These tests involve their evaluation based on criteria centred on the concerns presented in the literature review and described in the research methodology and methods portion of this thesis. Not only are these alternatives evaluated in isolation but they are also directly compared with each other.

The viability determination is based on the attributes of the alternatives (patents and GURT) rather than on the question of whether GE seeds themselves represent a viable alternative to traditional non-GE seeds. This latter question is not at issue in this thesis. The viability criteria must be specifically those that are related to the similarities or differences between alternatives. So, for example, how is the viability criterion identified as “global food security” addressed in this thesis? The effect of GE seeds on global food security is a legitimate debate. However, that

is not the focus of this thesis. In this thesis, the question is put forward as, how does the patenting of GE seeds compare with GURT in their potential effects on global food security? In the case of both alternatives, GE seeds themselves are a constant.

4.0 Foundation for the Research Design

A good starting point for establishing a solid foundation for the research design is an explanation of the methodology and methods selection. The type of research to be outlined in the following chapters is applied research since the purpose of the research is to search for practical solutions to a specific set of identified problems. This research is a combination of analytical research, exploratory research and explanatory research. The analytical portion of the research critically evaluates the innovation protection and promotion features and viability criteria of patents and GURT as a basis for responding to the research question. The exploratory nature of the research involves the pursuit of new sources for insights and increased knowledge into the protection and promotion of innovation in the GE seed industry. The explanatory aspect of the research looks to clarify and evaluate the viability of the two unique alternatives, patents and GURT, for the protection and promotion of innovation in GE agriculture. In this way, this thesis fulfills a fundamental goal of research, and that is to create a foundation from which sound predictions can be made.

In this research, the methods employed are the specific tools of the investigation that are used to accomplish tasks in a logical, orderly manner. The primary method involves Internet searches for contemporary and historical data and information produced by national and international organizations and experts in the field. The information (quantitative and qualitative) is obtained from publically available government, business and international organization reports, analyses, databases and policy papers. This thesis uses a mixed methods design and will stress data analysis, expert opinion and policy analysis. The motivation for mixing methods is that no single method alone is adequate to capture the trends, details and complexity of the interrelationships among the IP protection methods chosen (patents and GURT), innovation, and private and public sector strategies for the promotion and protection of innovation.

Often, when one discusses policy analysis, it is in relation to public sector institutions or organizations. In the context of this research, the term policy analysis has a broader context. Here

the term is used from the perspective of both the public and private sectors. That is, for private and public stakeholders, policy analysis will pose questions such as: what decisions are made; why are these decisions made; and how do these decisions affect the goals of the stakeholder in question? The theoretical research design flowchart is found in Appendix G.

Since GURT seeds have not been commercialized, there are limited avenues available to predict the outcome of various scenarios that might occur if that commercialization had taken place. Comparisons with existing similar technologies are one method to overcome this problem.

For example, a comparison is made with hybrid corn, and this comparison draws on many of the known existing attributes of hybrid corn that are the same or similar to GURT seeds. The use of expert opinion is another method, and this involves resources from individuals and national and international organizations. Also, the use of GURT attributes, both known and predicted, are used to create a GURT product that can be compared to a patented GE seed.

However, these techniques provide only part of the GURT seed analysis model. Counterfactual thinking is an integral part of this thesis specifically because GURT GE seeds exist but have not been commercialized. To understand how GURT might impact various scenarios, it is essential to commercialize GURT in what one might call a type of “virtual reality” existence. For example, there are four short case studies presented that deal with historically important GE seed IP issues (Schmeiser, Bowman, OSGATA, and Argentina). Included are the outcomes of those cases. These actual cases are followed by “What if...” scenarios that are then presented as if a GURT commercialized world existed. The outcomes of these scenarios are then forecast based on this counterfactual world. These scenarios are certainly contrary to fact but they are not contrary to logical possibilities. In this thesis such counterfactuals are used in the absence of empirical evidence since there is limited empirical evidence for some aspects of the GURT analysis.

4.1 Revisiting the Thesis Question

The literature review provides a depiction of the current status of innovation protection and promotion with an emphasis on genetic engineering in agriculture. It also identifies controversies and gaps in the literature through my active engagement with the authors as their positions were identified. In addition, the literature review explores issues, which this thesis

represents as viability issues. With this information at hand, the thesis question can now be revisited and an approach to addressing this question can be developed.

The thesis question is:

Is Genetic Use Restriction Technology (GURT) a viable alternative to the conventional use of utility patents to protect and promote innovation associated with the genetic engineering of agricultural seeds?

Answering the thesis question involves operationalizing its three key concepts so that they can be properly evaluated. Those three crucial concepts are: 1) *protection* (of innovation) 2) *promotion* (of innovation) and 3) *viability* (of the alternatives). Operationalizing these concepts involves the identification and evaluation of one or more indicators that represent criteria pertinent to the appraisal of each concept. The indicators must have a direct link to their respective concept in order for their evaluation to be relevant.

A combination of qualitative and quantitative research is carried out for this thesis, although the emphasis is on qualitative research. As such, whenever both quantitative and qualitative data is employed to evaluate a criterion, the conclusion is qualitative.

It is clear from the earlier background and foundational preparation and the literature review that patents and GURT both protect and promote innovation. The question is whether one choice is superior to the other and the degree of viability that each of these alternatives possesses.

Viability is the second concept in the thesis question, even though it appears near the beginning of the question. The viability of an alternative depends on a number of conditions (criteria), which collectively are sufficient, but individually may not be sufficient to create a circumstance of overall viability.

The difficulty with the term *viable* is that, as a concept, viability is a perception that varies among individuals as is demonstrated by the differing opinions of authors in the literature review given an identical set of circumstances or facts. Often, it appears that these perceptions are based on subjective impressions. To give meaning to the thesis question, it is necessary to establish specific criteria for viability. An example of a viability criterion is (global) food security. That is, does the selected alternative promote or hinder food security and to what

degree. As described earlier, food security is judged by its attributes as articulated by the U.N. FAO: access, availability, stability and utilization.

To summarize, the establishment of a mixture of qualitative and quantitative criteria operationalizes the concepts of *viability* and the *promotion and protection of innovation*. The final determination of whether a given alternative (patents or GURT) is viable and promotes and protects innovation, and the degree to which it does or does not do so, is a qualitative one.

The long-standing use of patents, as a means of innovation protection and promotion, necessitates that patents serve two purposes in this thesis. Patents not only represent one of the two alternatives but also act as a *control* against which to judge GURT.

In the GE seed industry, the key to protecting innovation, although not the only means of doing so, is to protect the primary source of innovation, which is the invention. If the alternative protects invention, it will also go a long way toward protecting innovation. Protecting innovation enhances value capture, and this incentivizes innovation.

The innovation promotion, protection, and viability criteria used to compare non-GURT patented GE seeds and GURT seeds have been determined based on the those criteria most heavily emphasized in the literature review and on the agricultural biotechnology concerns raised in papers produced by the following UN specialized agencies, programs, related organizations, and international organizations:

United Nations Group

United Nations Food and Agriculture Organization (UNFAO)

United Nations Environmental Program (UNEP)

Convention on Biological Diversity (CBD)

World Intellectual Property Organization (WIPO)

United Nations Conference on Trade and Development (UNCTAD)

Non-United Nations Group

Organization for Economic Co-operation and Development (OECD)

International Consortium on Applied Bioeconomy Research (ICBAR)

International Union for the Protection of New Varieties of Plants (UPOV)

Commission on Genetic Modification (COGEM)

A substantive question that must be addressed is how best to demonstrate or measure innovation protection. This thesis measures innovation protection qualitatively by answering the question, “Does the alternative offer effective physical, technological, legal, or strategic protection against appropriation?” Although there may be quantitative aspects involved in answering this question, the ultimate answer to each element of this question is a qualitative range between the two extremes of *absolutely yes* and *absolutely no*.

On the other hand, to determine if the alternative promotes innovation we need to identify one or more key measures of innovation and then assess how the alternative affects the measures. There are many measures of innovation promotion that appear in the literature. They include number of patents issued, GDP, GDP per capita, R&D spending, knowledge diffusion, commercialization, important inventions per person per year, etc. Three of these measures are more applicable to the research presented here that is specific to the GE seed industry: R&D, knowledge diffusion, and commercialization. These areas are frequently and repeatedly noted in the literature review.

A very significant and easily accessible measure is R&D effort and this is the key measure used. That it applies to both the public and private sectors is one reason for the high quality of the R&D measure. In addition, this measure reflects the motivation and resource allocation employed to strive for successful innovation promotion.

Another measure that is less quantifiable but one with undeniable importance is the capacity for knowledge diffusion. Knowledge diffusion helps to generate the spark for others to innovate. Finally, successful commercialization is the source of return on investment (ROI), and this criterion promotes further innovation.

Once the protection and promotion of innovation conclusions are established for each alternative, the first hurdle for alternative selection is crossed. That is, the necessary condition for the alternative has been established. The next step is to determine if the alternative meets the criteria for viability.

The viability criteria are examined for each relevant stakeholder to determine if the alternative is indeed a viable alternative. Because of the contrasting nature of the two alternatives, the degree of criterion emphasis may vary among stakeholders. For example, a GE

seed firm may give added weight to an alternative that maximizes profits whereas an environmental activist may give added weight to maintaining biodiversity. In such a case, an alternative that stresses firm profits over biodiversity is more viable for a GE seed firm than it is for an environmental activist.

Throughout the research, it is essential that the viability criteria for the two alternatives be judged with an understanding that the common comparison starting point is the GE seed.

4.2 Innovation Criteria, Measurement and Questions

The innovation criteria and measurement aspect of the research portion of this thesis is represented diagrammatically in Appendix H.

4.2.1 Criteria for Innovation Protection

Patents

The qualitative questions posed with respect to patents to test their ability to *protect* innovation [primarily through the protection of invention] in the GE seed industry are:

- 1) Do patents exclude those, other than the inventor, from making the invention?
- 2) Do patents exclude those, other than the inventor, from using the invention?
- 3) Do patents exclude those, other than the inventor, from selling the invention?

These three questions can be summarized as: **Do patents offer effective physical, technological, legal, and strategic protection against appropriation?**

GURT

The qualitative questions posed with respect to GURT to test its ability to *protect* innovation [primarily through the protection of invention] in the GE seed industry are:

- 1) Will/can GURT exclude those, other than the inventor, from making the invention?
- 2) Will/can GURT exclude those, other than the inventor, from using the invention?
- 3) Will/can GURT exclude those, other than the inventor, from selling the invention?

These three questions can be summarized as: **Will GURT offer effective physical, technological, legal, and strategic protection against appropriation?** The next question is then: **How does this protection compare to that provided by patents?**

4.2.2 Criteria for Innovation Promotion

Based on the literature review, the criteria selected as indicators of innovation promotion are: R&D (private and public expenditures and focus); the diffusion of fundamental knowledge; and the creation of economic value [specifically public benefit and in the private sector, successful commercialization].

Patents

The qualitative questions posed with respect to the patent's ability to *promote* innovation are:

- 1) Do patents increase private and/or public sector R&D expenditures?
- 2) Do patents increase the diffusion of fundamental knowledge?
- 3) Do patents increase economic value through commercialization of products developed in the public and private sectors? (i.e. public benefit and commercialization)?

GURTS

The qualitative questions that will be posed with respect to GURTS as to their ability to *promote* innovation are:

- 1) Will/can GURT increase private and/or public sector R&D expenditures?
- 2) Will/can GURT increase the diffusion of fundamental knowledge (e.g. through an increase in publications)?
- 3) Will/can GURT increase economic value through commercialization of products developed in the public and private sectors? (i.e. public benefit and commercialization)?

4.3 Viability Criteria, Measurement and Questions

The viability criteria and measurement aspect of the thesis is represented diagrammatically in Appendix I.

Both qualitative and quantitative indicators represent the viability criteria. However, the overall viability determination of an alternative is qualitative just as is the case for the innovation protection and promotion determination. Only those viability criteria that are most relevant to the most important stakeholders as detailed in the literature review are addressed [i.e. GE seed firms, farmers, governments (regulators and policymakers), consumers]. These stakeholders are also those who would be most dramatically affected by the difference between GE seeds protected by patents and those protected by GURT.

The criteria employed in this thesis to test viability are global food security; the environment, biosecurity and biodiversity; economic well-being of firms and farmers; policy and regulation; and consumer acceptance. Each one has one or more useful qualitative or quantitative variables associated with it. Some of these variables may have current quantitative and/or qualitative data available whereas others require forward-looking estimates based on historical or current data. Although each criterion can have numerous variables that could be evaluated, only the most significant will be addressed to create a reasonable boundary within which the goals of this thesis can be accomplished.

Each viability criterion may be relevant to one or more stakeholder. As a practical example of why this is so, we can examine one viability criterion, the global food security indicator. The issue of global food security affects GE seed firms, farmers, consumers and national and international policy-makers. However, the impact varies among these stakeholders. For example, firms and farmers, through their actions, affect the level of global food security whereas consumers are affected by those decisions and are subject to the consequences of the level of global food security.

A general question to be asked for each of these criteria is: **How do patents and GURT affect the specific criterion in question? More specifically, does one alternative have a more positive effect [or less of a negative effect] on a viability criterion than the other alternative?**

1) Global Food Security

Global food security is high on the list of goals for the U.N. Food and Agriculture Organization. Initially, measurement of this indicator will be based on the three most relevant of the four previously noted dimensions of food security: availability, access, and stability. How do patents and GURT affect each of these dimensions of food security? The utilization dimension is overly dependent on factors outside of the scope of this thesis and is therefore not considered.

2) The Environment, Biosecurity and Biodiversity

Some of the greatest concerns associated with the introduction of GE seeds into mainstream agriculture are the effects that they may have on the environment. As noted in the background and literature review sections of this thesis, the scientific consensus is that the possibility of harm to health from food crops produced from genetically engineered seeds is no greater than that found with conventional crops. More controversial are the potential effects on the environment of the various methods of protecting and promoting innovation in GE seeds. For example, patents provide strong legal innovation protection for firms. This encourages firms to innovate in this field, and the result is the development of ever more specialized crops which become the standard in the industry. The result is that specific crops are planted, and other naturally occurring or traditionally bred varieties are eliminated. The question then becomes, is there a difference in how GURT and non-GURT GE seeds affect biodiversity?

Questions about patents and GURT should also inquire about environmental consequences.

- Do patents and will/can GURT negatively affect the environment and to what degree?
- Is inadvertent outcrossing (uncontrolled cross breeding) more or less likely from these IP protective mechanisms? (i.e. the escape of transgenes)
- Do patents and will/can GURT act as a method of environmental protection?
- Do patents and will/can GURT affect human health?

3) Economic Well-being

This criterion is addressed in a number of subcategories.

- **GE Seed Firm Success and Industry Structure**

To a large degree, seed firm success is determined by GE seed company profitability (i.e. net profit margin (NPM), return on equity (ROE), return on assets (ROA) etc.). However, although one can assess the current profitability of GE seed firms, profitability associated with GURT seeds is speculative. Another way to approach the problem of determining the potential for GURT profitability is to compare the specific profitability determinants that are associated with GURT GE seeds that are not present with non-GURT GE seeds. Those determinants are: the consequences that arise from the “patent cliff”³⁵⁰; the effect that GURT may have on industry structure [i.e. vertical and horizontal integration and the effect on barriers to new entrants]; product acceptance by both users [farmers] and consumers; and the potential for increased regulatory costs associated with GURT commercialization.

- **Farmers and Formal Seed Systems**

This subcategory looks at both developed and developing nations from the point of view of the farmer who represents one of the key stakeholders in this industry. This subcategory includes potential changes in farm income based on the use of patents or GURT. The analysis of the effect of patents and GURT on farming systems include questions such as:

- Do they or will/can they affect the intensification of farming systems and how? [e.g. increased intensification leads to greater use of inputs (fertilizer, pesticides, etc.) to maximize outputs(crops)]
- What are the repercussions of a change from patents to GURT, should it occur?
- Does the level of protection provided by patents and GURT benefit or harm farmers in developing countries; what about farmers in developed countries?

³⁵⁰ Patent cliff refers to a significant drop in firm revenues due to patent expiration for a product, and the resulting production of the once patented product much more cheaply by the firm’s competitors.

Formal seed systems taken as a whole include seed production, seed control, and seed distribution activities carried out by the public and commercial sector. Questions that can be posed for the seed system analysis provide qualitative answers and include:

- Do patents and will/can GURT increase or decrease the likelihood of seed diversity?
- Do patents and will/can GURT lead to more or less breeding?
- Do patents and will/can GURT affect the cost of other types of seeds i.e. non-GE or hybrid seeds?
- Do patents and will/can GURT increase or decrease the dependence on external seed sources? How do these two alternatives affect dependence on seed suppliers?
- Do patents and will/can GURT lead to monopolization of gene pools [the stock of different genes in an interbreeding population]?

4) Regulation and Policy

- Are there current economic policies and regulations in place to deal with the implementation and consequences of patents and GURT? If they are in place, can they effectively deal with these protection mechanisms or do these policies and regulations have to be modified. If they are not in place, can they easily be put in place? If not what are the consequences of this inability?
- Do patents and will/can GURT alter public agricultural research as a result of its private sector impact? e.g. If they negatively affect resource-poor farmers, will public sector agricultural research have to compensate for this by redirecting efforts to mitigate these negative affects?
- Do patents and will/can GURT weaken or alter a government's ability to use existing regulations as policy instruments?

Well-established national and international organizations exist that assess, regulate, modify, and manage IP associated with the genetic engineering of agricultural seeds. At the

national level, organizations such as the United States Patent Office (USPO) and the European Patent Office (EPO) play a crucial role in patent evolution to meet the challenges of the new biotechnologies. Internationally, WIPO, the OECD, and other organizations play a similar policy development role.

- How do patents and will/can GURT affect these organizations and their ability to manage the IP system?
- Will the evolution of patents and GURT diminish or enhance their influence over the biotechnological IP landscape?

This IP system category has a connection to the innovation portion of the thesis question. It reflects back on whether patents and GURT protect and promote innovation. Here is where the viability and innovation portions of the thesis question link together and provide some cohesiveness to the question.

- How do patents and how will/can GURT affect the scope of innovation protection?
- For the GE seed industry, the primary source of innovation is the invention for which an arguably successful patent model for protection currently exists. How do patents and how will/can GURT affect the viability of the IP system going forward?
- Currently, innovation can be protected by legal means employing various mechanisms or strategies and also by physical (technological) means. Do patents and will GURT accomplish their protective function and if so how? Does it matter how protection occurs? If so, why does it matter?
- Is the innovation protection and promotion of patents and GURT viable?

5) Consumer Acceptance

Consumer acceptance of a product is the ultimate deciding factor in whether a product is viable. For consumers, the end product is GE food that results from the growth of GE seeds. One might imagine that how the seed is protected would be irrelevant to whether the consumer accepts the end product. After all the end product is essentially the same whether the GE seed is

protected by a patent or by GURT. However, evaluation of the end product may not necessarily be the way in which consumers would differentiate the products that result from the two alternatives. Today many consumers place a great deal of emphasis on the ethics associated with a product. Part of that discussion involves how the product is produced and whether consumers “believe” that the production process has adverse consequences.

To determine consumer attitudes internationally respected surveys such as the EU “Eurobarometer Biotechnology Report of 2010” and the “Pew Research Center Study of 2015 on Public and Scientists’ Views on Science and Society” in the U.S. are used. Relevant portions of the results of these surveys are extrapolated to examine consumer attitudes to GE foods and biotechnology to predict how consumers might react to GURT foods. Other surveys are also used and the justification for their use is discussed when they are brought into the conversation. In addition, some current events are included to provide a snapshot into the public opinion debate into GE foods that continues unabated.

4.4 Data Gathering Summary

The specific sources of data for this thesis are found in Appendix J.

While public sector information on GE seed policy, strategy and innovation concerns and development is readily accessible online, this is not the case, to the same degree, in the private sector. The realization that some of the information that private firms use to develop business strategies is not available to those outside of the firms suggests that creative ways of understanding firm strategy and its effects on IP policy development is necessary.

I use business documents from international business organizations, government databases, and company filings to relate the patent/innovation aspect of the research to the business strategy discussion.

Company documents filed with regulatory agencies such as the U.S. Securities and Exchange Commission are valuable in determining firm strategy. Filings with these types of government agencies provide raw material for determining current and future firm strategy.

Finally, primary documents produced by international organizations, governments, research institutes, advocacy groups and corporations are significant sources of research materials especially in the area of the interrelationship between patents and innovation in the

private and public sectors. Academic institutions involved in agricultural biotechnology research are particularly useful since they are most in tune with current activity in the field. A careful examination of the potential biases of these entities to determine the value of these documents for this thesis is imperative. The fact that biases exist does not in and of itself eliminate any particular piece of information as long as that bias is noted.

Chapter 5

Research and Analysis: Part 1

Innovation Protection and Promotion: Patents v. GURT

5.0 Introduction to Innovation Protection: Patents and GURT

Historically, patents have demonstrated the capacity to provide a level of innovation protection that encourages plant innovators to seek out this form of protection. Writings by Janis, Kesan, Graff, Straus, Cullet, Haugen et al. and many others described in the literature review bear this out. Although there is no existing innovation protection track record for GURT, the technology on which GURT depends provides GURT-based plants with innovation protection.

One question that is under consideration in this thesis is how do patents and GURT compare in their ability to effectively accomplish this goal and at what cost? To make this determination one should examine and compare the protective attributes of patents and GURT that exclude those other than the inventor from making, using, copying or selling the patented or technologically protected invention. That is, to what degree do these two alternatives exclude someone other than the inventor from appropriating value from the GE seed invention? If patents and GURTS can accomplish this goal, then these two alternatives will protect the invention that is the key source this innovation. What will affect the characteristics of that innovation is whether this protection is physical, legal or a combination of the two. Furthermore, the basis of the protection will also affect the viability of the particular method of IP protection.

As previously noted, a “traditional” non-GURT GE seed can be grown by anyone. There is no specialized knowledge required. In this sense, a GE seed is no different from a non-GE seed. As such, there is no physical or technological barrier to the appropriation of value from a basic GE seed.

Although anyone can physically grow the GE seed and thereby appropriate its value, this is not the only way to appropriate GE seed IP. For example, rival firms can copy and sell the invention by imitating the biotechnological IP contained within the GE seed DNA. As much as this can be problematic for the inventor, there are well-established often-employed legal mechanisms in the marketplace to settle firm-to-firm disputes.

The high cost of R&D and product commercialization in the GE seed industry results in a relatively few large GE seed firms in this industry that have the capability and resources to produce the GE seed product from first principles. In contrast, as relatively small players, farmers can often fly under the radar if they attempt to appropriate value associated with patented GE seeds. This farmer appropriation takes the form of simply growing the GE seed and harvesting the result for replanting. This is a problem for GE seed firms particularly in developing countries with large numbers of often remotely situated farmers where firm monitoring of agricultural fields is more difficult.

Of the GE seed firms, biotechnology firms, and combined seed and biotechnology firms in existence today, the largest and arguably most controversial in this industry is Monsanto. Monsanto's major competitors are listed in Table 2.

Table 2: Monsanto's Major Competitors³⁵¹

Monsanto Competitors
BASF Aktiengesellschaft
FMC Corporation
Nissan Chemical Industries, Ltd.
Chemtura Corporation
Bayer CropScience Limited
Syngenta AG
E.I. du Pont de Nemours & Company
Tyratech Inc
CF Industries Holdings, Inc.
Groupe Limagrain Holdings S.A.
KWS AG
The Scotts Miracle-Gro Company

Based on industry statistics in 2007, Monsanto GE seeds (including those licensed to other companies) accounted for 87% of the total GE crops planted worldwide.³⁵² At that time,

³⁵¹ *Monsanto Company, Company Profile* (2014) online: Advantage Marketline <<http://advantage.marketline.com.ezproxy.library.yorku.ca/Product?pid=68BBC79A-483A-41B1-AAB1-A2F43AAF5BF8>> at 32.

73% of the global commercial seed was controlled by the top ten companies.³⁵³ Just three companies controlled more than half (53%) of the global commercial market for seed.³⁵⁴ Monsanto currently controls 27% of the commercial seed market.³⁵⁵ In addition, this company is involved in extensive international activities involving all aspects of agricultural biotechnology including R&D.

As the largest company in the industry, it is not surprising that Monsanto is involved in many of the most significant GE seed controversies and significant IP protection cases in this industry. Two of these cases are discussed in more detail in the portion of this thesis dealing with the evaluation of patents as a means of innovation protection. These two cases are: *Monsanto v. Schmeiser*, a case that was decided by the Supreme Court of Canada in 2004 and *Monsanto v. Bowman*, a case that was decided by the U.S. Supreme Court in 2013.

Because of Monsanto's involvement in precedent-setting cases in this industry, this company is highlighted in many of the national and international activities identified and analyzed in this thesis. The fact that many of the internationally significant court cases and other disputes occur in the U.S. or are in some way connected to the GE seed industry in the U.S., directs significant portions of this thesis to this largest GE seed market in the world. As with many industry sectors, what takes place in the U.S. seed market often has a tremendous influence on the international seed market.

The innovation protection section of this research chapter begins with an investigation of how patents can protect GE seed IP. This is followed by an analysis of the use and effectiveness of the Monsanto Technology/Stewardship Agreement that is similar to that used by other seed firms and that farmers using Monsanto GE seed must sign. This leads directly into an analysis of four specific Monsanto cases that highlight the effort required to protect patented GE seeds.

Hybridization, as an existing commercialized, technologically based method of IP protection is then assessed as a possible predictor of the success of GURT for the protection of GE seed IP. Finally, the four Monsanto cases previously analyzed are evaluated to predict how

³⁵² *Factoids: Just 3 companies control more than half (53%) of the global commercial market for seed.* (2014) online: ETC Group <<http://www.etcgroup.org/factoids>>.

³⁵³ *Ibid.*

³⁵⁴ *Ibid.*

³⁵⁵ *Ibid.*

GURT may have affected the outcomes of these cases if this technology, rather than patents, had been the primary method of IP protection at that time.

5.0.1 Patents: Innovation Protection for GE Seeds

A patent strives to legally protect the GE seed by providing the inventor with legal recourse should someone attempt to use illegally, copy, or sell the patented GE seed. Should this occur, the patent holder might sue for patent infringement. If successful, there are several remedies available to the plaintiff depending on the jurisdiction where the infraction occurs. Damages to compensate for losses are one of the most common remedies. While a lost patent infringement case and the ensuing damages can have a significant economic effect on a losing firm, the demand for damages can have more serious consequences on farmers who lose such cases. The limited resources available to many farmers cannot only hinder their ability to fight patent infringement cases but also devastate their assets should they lose these cases.

In the best-case scenario for GE seed firms, simply the existence of a patent will successfully protect the invention from patent infringement by farmers. The well-known consequences associated with the loss of such a case may be enough to prevent the infringement. However, even in this best-case scenario, the GE seed firm must in some way monitor seed users to know whether any illegal activity is taking place. There is a cost in time and money involved in monitoring farmers. Documents may need to be examined; interviews may need to take place; fields may need to be examined and crops tested. However, this may not be the only cost to seed firms. Another cost may be to their reputations from a potential “David vs. Goliath” spectacle of a large, wealthy, multinational corporation financially squeezing a “poor” farmer. The fact that the firm might have a strong legal position and the farmer a poor one may be of little value to the firm in the court of public opinion. Just the act of monitoring a farmer’s field for infringement can potentially set off a flurry of negative publicity for the GE seed firm as the spectacle of strangers lurking in farmers fields presents itself. The Center for Food Safety, an influential anti-GE crop NGO, is well known for its documentation of farmer “abuse” by large agricultural biotechnology firms.³⁵⁶

³⁵⁶ *Seed Giants vs. U.S. Farmers*, (2013) online: Center for Food Safety

The next best-case scenario from the perspective of the GE seed firm is that if infringement by the farmer occurs, the firm sues the farmer and either the farmer settles out of court or the seed firm wins in court. The difference between this scenario and the previous one is that costs involved in monitoring are magnified by the additional cost of beginning formal court proceedings. Once again, the reputational optics of this scenario is problematic for the seed firms.

The worst-case scenario for the seed firm is that they are unsuccessful in court in legally defending their patent against infringement by farmers. In this situation, the firms risk losing their GE seed monopoly position because of the precedent set by this loss. The firm also takes a financial hit from the loss of their R&D investment in the invention as well as the costs involved in commercializing the invention. In this scenario, the societal bargain in which the firm's invention disclosure is exchanged for a time-limited monopoly has failed, and the result might be that the firm is reluctant to invest in future innovation. GE seed firms are therefore concerned that patents should have features that make this form of IP protection effective.

There are a number of patent features that should exist for the effective protection of a GE seed invention and, therefore, the protection of the resulting innovation. First, as with the protection of any invention, the patent should have sufficient quality and breadth to protect the important components of the invention. Of course, it is vital that the patent is also supported by a legal system that respects and defends the value of IP. Furthermore, effectiveness dictates that all members of society support the property rights decisions of the legal system whether they agree with a specific decision or not. In addition, the remedies for patent infringement provided by the legal system should act as a deterrent to those who may consider infringing on the patent. Finally, the patent holder must have a mechanism to determine if patent infringement is occurring.

Developed nations such as the U.S., Canada, and the member states of the EU all have a well-established IP regime with strong IP rights. In contrast, developing countries such as those in Central and South America and Asia generally are known for having relatively weak IP regimes. As a result, in an attempt to improve IP rights in developing nations, TRIPS was

<<http://www.centerforfoodsafety.org/reports/1770/seed-giants-vs-us-farmers#>>.

included in the WTO negotiations in 1995. TRIPS is discussed earlier in this thesis as an attempt to create an IP standard and a degree of international respect for IP in developing countries. The lack of IP protection in the developing world had been a long-standing irritant for large multinational firms.³⁵⁷

One of these large biotechnology firms, Monsanto, provides an excellent example of the successful use of patents to protect IP in developed countries with strong IP regimes. The techniques employed by Monsanto to maximize its GE seed and trait IP in North America is useful in assessing the ability of patents to protect this innovation in the company's important developed-world market. These techniques also serve as a contrast to the difficulty that still exists in the application of patent protection in developing countries and why there is an incentive for firms to search for an alternative method of IP protection that would provide superior IP protection than that available from patents.

First, it is instructive to assess how Monsanto and other GE seed firms establish the conditions under which farmers are able to use their patented GE seeds. The primary method that Monsanto employs is to use a contract known as a Technology/Stewardship Agreement (TSA). The most recent version of this agreement is the 2014 Monsanto TSA. (See Appendices K and L for a copy of this agreement) This agreement is an example of a patent license common in the GE seed industry. This one is a contract between the patent holder [Monsanto] and the plant grower [farmer] that gives the farmer the right to use the patented invention [the patented GE seed] under limited conditions specified in the contract by the patent holder. A review of the key sections of this license shows that, to no one's surprise, its terms and conditions are heavily weighted in favour of the company. The key points in the agreement, examined below, demonstrate that this agreement is constructed to ensure that the farmer undertakes all of the risks. One reason that it is important to assess this document is that it is the entry point for the transaction costs that the GE seed firm must incur with its customers. Another consideration is that because the GE seed that Monsanto sells is patented, a farmer wanting to use the seed legally would have no alternative but to agree to the terms of the TSA.

³⁵⁷ Supra note 228 at 1076-1078; supra note 227.

Understanding Important Sections of the 2014 Monsanto TSA³⁵⁸

a) Section 3, Page 1

This section states that any farmer lawsuit against Monsanto must be filed in the Eastern Division of the U.S. District Court for the Eastern District of Missouri. Monsanto headquarters is located in St. Louis, Missouri and the company has a large workforce and a longstanding relationship with this community. As a result, it is reasonable to suggest that the company would consider this court to be the most favourable it could find and as a result Monsanto often sues in this court. The use of this court raises farmers' legal costs by adding travel and living expenses for farmers who must travel from other areas of the country as well as the costs of any witnesses or experts that farmers may wish to call to support their position. This added cost, might act as a disincentive for farmers wishing to defend patent infringement lawsuits brought by the seed company.

One consequence of this potential increased litigation cost to farmers is that they may determine that their best course of action is to settle out-of-court. Out-of-court settlements are in fact common in Monsanto's dealings with farmers, as noted in the *Monsanto v. U.S. Farmers 2012 Update* produced by the Center for Food Safety.³⁵⁹ In this Update, The Center for Food Safety using no longer available documents from Monsanto's 2006 website, noted that in the U.S., Monsanto began between 2,391 and 4,531 investigations for farmer illegal use of patented Monsanto seed. These are cases in which no lawsuits were filed. The outcome of these matters was the payment to Monsanto of an estimated \$85M to \$160M by farmers.³⁶⁰

b) Section 4, Subsection a, Page 1

This section notes that farmers taking over land on which Monsanto seed is growing and on which a previous owner has signed a Monsanto TSA, must continue to accept the previous owner's obligations under the TSA. A potential consequence of this provision is that it may limit a farmer's ability sell or lease his land to another farmer if that other farmer is unwilling to abide by the terms of the Monsanto license agreement.

³⁵⁸ *2014 Monsanto Technology/Stewardship Agreement* (2014), online: Monsanto Web Site <<http://www.monsanto.com/sitecollectiondocuments/technology-use-guide.pdf>> at 32.

³⁵⁹ *Monsanto v. U.S. Farmers Update 2012 (2012)*, online: Center for Food Safety <<http://www.centerforfoodsafety.org/reports/1780/monsanto-vs-us-farmers-2012-update>>.

³⁶⁰ *Ibid* at Appendix I.

c) Section 4, Subsection d, Page 1

In this section, Monsanto limits where farmers may purchase GE seed for their fields. Farmers may only acquire seed from Monsanto licensed sellers. This subsection prevents farmers from acquiring seed from other farmers, seed cleaners [seed cleaning is described in Paragraph (d) below] or grain elevators. This section also prevents farmers from obtaining the seed for free.

d) Section 4, Subsection g, Page 1

In this section the license agreement becomes very precise about farmers' responsibilities. Farmers must agree *not to save or clean³⁶¹ seed produced from their Monsanto crop or to supply it to anyone else for planting*. In the past, Monsanto sued an individual named Moe Parr who operated a seed cleaning business in which he convinced soybean farmers to save seed that he then cleaned for them for the purpose of replanting.³⁶² In this case the outcome was a permanent injunction from the U.S. District Court in Lafayette, Indiana that barred Mr. Parr from cleaning Monsanto patented soybeans.³⁶³

This section makes it clear that unless the farmer is selling seed to a licensed Monsanto seed company under a seed production contract, the farmer can only use or sell seed as a food product and not for the purpose of planting a new crop. This inability to save seed has been a sore point for many developing world farmers who depend on the ability to save seed as a cost saving mechanism.

e) Section 4, Subsection j, Page 1

This section focuses on the concept of *fair use* for research that is a common feature of patented inventions. Specifically, this section places limits on that research by stating that farmers cannot conduct research or provide the crop for research other than for their own personal yield or comparative research. The bad publicity associated with this aspect of the TSA has led Monsanto to make some adjustments to its research policy although the wording within

³⁶¹ Saving seed is self-explanatory however seed cleaning requires some further explanation. Cleaning seed involves preparing raw seed so that it will be able to be used effectively in mechanical planting machinery. This is a common procedure in agriculture especially in the developed world where agriculture tends to be highly mechanized. It is also common in the developing world on large farms.

³⁶² *Moe Parr*, (2014) online: Monsanto < <http://www.monsanto.com/newsviews/pages/moe-parr.aspx>>.

³⁶³ *Monsanto Company and Monsanto Technology, LLC v. Maurice Parr*, No. 4:07CV0008AS, Memorandum Opinion and Order for Permanent Injunction (N.D. Ind. April 22, 2008).

the TSA has not changed. This feature of the TSA has implications for R&D, which is an important aspect of innovation promotion to be addressed later in this thesis.

f) Section 4, Subsection n, Page 2

The intrusiveness of the TSA becomes abundantly clear in this section. It states that growers of Monsanto GE seed must be willing to produce extensive documentation of *any* [my emphasis] information that Monsanto considers relevant to the grower's [farmer's] compliance with the agreement within seven days of a written request by Monsanto. This open-ended requirement demonstrates the degree to which the company is willing to go to protect its patents. This point is emphasized by the Center for Food Safety as one of its many criticisms of the large, multinational seed companies. For example, the Center notes that Monsanto could, and has in the past, asked for seed receipts from farmers so that the acreage planted can be compared to the quantity of seed purchased to identify whether the acreage exceeds the seed purchases. If the acreage were excessive, it would indicate that a portion of the crop originated from "illegal" seed acquisition.³⁶⁴ The heavy handedness on the part of Monsanto demonstrated in this section may be understandable from a business perspective, but it does have somewhat of a quality of presumed guilt associated with it.

g) Section 4, Subsection o, Page 2

Growers of Monsanto GE seed must allow physical access to farmed land by Monsanto to inspect the land and the crops within seven days of written notice of inspection by the company. This section has been a bone of contention for numerous farmers who claim that inspectors have simply appeared on their land and acted in a heavy-handed manner. Examples of interviews with farmers claiming that Monsanto inspectors acted inappropriately can be found in "Seed Giants vs. U.S. Farmers", another publication of the Center for Food Safety.³⁶⁵ Monsanto, however, denies that it has in any way acted inappropriately. On the Monsanto website, the company indicates that seed inspections occur only when the company has cause to believe that patent infringement or a breach of contract is taking place.³⁶⁶

³⁶⁴ Supra note 356 at 23.

³⁶⁵ Supra note 356.

³⁶⁶ *Monsanto's Commitment: Farmers and Patents*, (2014) online: Monsanto <<http://www.monsanto.com/newsviews/pages/commitment-farmers-patents.aspx>>.

One can imagine that the cost of monitoring farmers in this way is costly and difficult in a strong IP environment such as exists in North America. Internationally, dealing with the millions of farmers in developing countries in this way would be virtually impossible.

h) Section 8, Page 2

This section states that any violation of the terms of the agreement terminates all of the grower's rights but leaves intact the grower's responsibilities to Monsanto. Since the grower's rights are minor, but their responsibilities are onerous, the contract becomes more one-sided in favour of the company *after* termination of the contract.

i) Section 9, Page 2

The TSA becomes still more burdensome on farmers in this section. Here it states that if the grower has been found to infringe on Monsanto's patents or to breach the TSA, the grower is responsible for Monsanto's attorney fees and costs. This added burden on farmers is another bone of contention brought forward by the Center for Food Safety. They report that farmers have found themselves under severe financial distress simply as a result of an accusation by Monsanto that they have breached their contract.³⁶⁷ Monsanto has deep pockets whereas, in most cases, farmers do not. The high cost of defending themselves is one of the primary reasons that many farmers have settled with Monsanto before trial.

j) Section 12, Page 2

The only remedy the grower [farmer] has in this agreement is Monsanto's limited liability equal to seed replacement costs for damages from the use or handling of the seed. According to the USDA Economic Research Service, the average cost per acre of soybean seed planted in the U.S. is approximately \$59 USD per acre.³⁶⁸ GE soybeans represent 93% of all soybeans grown in the U.S. Based on a 100-acre crop, Monsanto's liability to the farmer would be limited to \$5900.00 USD.

It is clear that this TSA is designed so that the farmer takes all of the risk and in return is essentially leasing the technology from Monsanto. However, the company's position in keeping a tight rein on its IP would be supported by many of the voices whose positions on patents

³⁶⁷ Supra note 356 at 26.

³⁶⁸ USDA, *Soybean Production Costs and Returns per Acre Planted* (USDA, Economics Research Service, 2013), online: USDA <www.ers.usda.gov/datafiles/.../csoyb.xls>.

clearly supported their use in this industry. Kesan sees strong agricultural biotechnology protection as a key source of innovation.³⁶⁹ Grandstrand cites Kenneth Arrow's (author of "Economic Welfare and the Allocation of Resources for Invention") worries over underinvestment in R&D that could result without the ability to strongly protect IP.³⁷⁰ Mansfield would see the Monsanto TSA as little more than the result of an industry that closely resembles other high technology industries such as the pharmaceutical industry where patenting is frequent and protecting those patents imperative for commercialization success.³⁷¹

The question at the heart of the matter is, does this TSA and Monsanto's seed patents effectively protect the company's IP? In theory it should accomplish this goal. The best way to assess the practical effects of the TSA and Monsanto's patents is to look at specific court cases in which decisions have set precedents of importance for the entire GE seed industry.

According to the Monsanto website, the company has filed 145 lawsuits against U.S. farmers.³⁷² This number is largely corroborated by the Center for Food Safety. In an update to their 2005 publication titled "Monsanto v. U.S. Farmers" the Center for Food Safety reports that, as of November 28, 2014, Monsanto has filed 142 lawsuits against U.S. farmers.³⁷³ This is from a pool of over 250,000 U.S. farmers that are Monsanto customers.³⁷⁴ The number of farmers sued represents no more than 0.058% of Monsanto's U.S. farmer base.

The company states that of the 145 cases that it reports on, only 11 proceeded to trial.³⁷⁵ To date, Monsanto has not lost a single patent infringement case against a North American farmer.³⁷⁶ The company also notes that 700 "matters" in total have been settled out of court.³⁷⁷

³⁶⁹ Kesan, *supra* note 2 at 466.

³⁷⁰ Kenneth J Arrow, "Economic Welfare and the Allocation of Resources for Invention" (1962) in Richard R Nelson ed, *The Rate and Direction of Inventive Activity: Economic and Social Factors* (Princeton: Princeton University Press for the National Bureau of Economic Research, 1962) 609 as cited in Ove Granstrand, *Innovation and Intellectual Property Rights*" in Jan Fagerberg, David C Mowery & Richard R. Nelson eds, *The Oxford Handbook of Innovation* (Oxford University Press, 2005) 266 at 279.

³⁷¹ *Supra* note 140 at 174, 175, 176.

³⁷² *Saved Seed and Farmer Lawsuits* (2015), online: Monsanto Web Site <<http://www.monsanto.com/newsviews/pages/saved-seed-farmer-lawsuits.aspx>>.

³⁷³ *Supra* note 359.

³⁷⁴ *Supra* note 372.

³⁷⁵ *Ibid.*

³⁷⁶ *Ibid.*

Monsanto notes that the, “primary reason for enforcing its patents is to ensure a level playing field for the vast majority of honest farmers who abide by their agreements, and to discourage using technology illegally to gain an unfair advantage.”³⁷⁸ It would not be a stretch to suggest that the company realizes that if it does not actively protect its patents, there would be a financial incentive on the part of farmers to disregard them. The resulting financial loss to Monsanto from value leakage would be substantial.

On their website, Monsanto also makes a very important claim, which was highly relevant in the case of Organic Seed Growers and Trade Association (OSGATA) v. Monsanto, which is discussed later in this thesis. Here the company outlines its policy toward farmers when investigating potential seed infringement cases. Of particular importance is item number ten, which states that “It has never been, nor will it be Monsanto policy to exercise its patent rights where trace amounts of our patented seed or traits are present in farmer's fields as a result of inadvertent means.”³⁷⁹ The issue of Monsanto supposedly suing farmers whose fields have been subject to inadvertent contamination is an ongoing concern in the anti-GE seed online community and is an often-repeated complaint against the GE seed industry. A review of the various court cases involving Monsanto appears to back the company’s position that it does not target instances of inadvertent GE seed contamination on farmland. In cases where farmers have claimed this, such as in *Monsanto v Schmeiser*, the court documents reveal that the “contamination” has not been inadvertent but rather intentional on the part of the farmer. Nevertheless, online articles and websites continue to repeat this fallacy. A good example of this erroneous repetition comes from the Center for Food Safety. In one of its most recent publications, “Seed Giants v. US Farmers (2013)” it states on page 37 that, “farmers may still be prosecuted even if protected seed varieties inadvertently pollute their crop.”³⁸⁰ This misstatement is repeated many times in this booklet. Each example provided by this publication describing farmer prosecution/persecution for inadvertent GE seed field contamination fails to stand up to scrutiny of the facts.

³⁷⁷ *Settling the Matter –Part 5*. (2008) online: Monsanto <<http://www.monsanto.com/newsviews/pages/settling-the-matter-part-5.aspx>>.

³⁷⁸ Supra note 372.

³⁷⁹ Supra note 366.

³⁸⁰ Supra note 356 at 37.

Four cases are particularly noteworthy in establishing the degree of the GE seed IP protection afforded by the traditional patent system. Three of these cases show how the patent system has successfully protected innovation through the protection of the invention in GE seeds: 1) *Monsanto v Schmeiser*, 2) *OSGATA v Monsanto* and 3) *Monsanto v Bowman*. The fourth case, dealing with cornmeal exports to Europe from Argentina, demonstrates how the patent system fails to afford the level of protection that the GE seed companies may desire. This fourth case involves GE seed issues related to international trade between a developing country (Argentina) and a developed group of countries, the EU.

*i) Monsanto Canada Inc. v. Schmeiser*³⁸¹

This case is an early example of Monsanto successfully defending a GE seed patent against infringement by a farmer in a developed country. The case involves a Canadian farmer, Percy Schmeiser, who claimed that the canola plants on his property were a result of inadvertent contamination by GE canola seeds from surrounding fields. These surrounding fields were the property of other farmers who were legally growing Monsanto patented GE canola seeds. The facts of the case show that in 1997 Schmeiser realized that the canola plants along the border of his property were glyphosate resistant. This indicated that these plants originated from proprietary GE seeds.³⁸² Schmeiser applied this herbicide to his plants, killing all non-GE plants. He then saved the herbicide-resistant seeds and grew a full crop of these patented seeds the following year (1998) without permission from the patent holder, Monsanto.³⁸³ Schmeiser had not signed Monsanto's TSA and was, therefore, not subject to its terms and conditions. However, this would not excuse Schmeiser from abiding by the patent that protected the GE seeds.

Monsanto sued Schmeiser for patent infringement, and the company was successful in the initial Federal Court of Canada case.³⁸⁴ The Federal Court of Appeal upheld this decision.³⁸⁵ In the initial case, the Court stated in its conclusion that, "I find on a balance of probabilities that

³⁸¹ *Monsanto Canada Inc. v. Schmeiser* [2004] 1 S.C.R. 902, 2004 SCC 34.

³⁸² Monsanto's Roundup Ready herbicide contains glyphosate as its key ingredient. Resistance to this chemical is the specific GE value-added trait that allows these plants to survive when exposed to this herbicide.

³⁸³ *Supra* note 381 at para 6.

³⁸⁴ *Monsanto Canada Inc. v. Schmeiser* [2001] FCT 256 (Fed court).

³⁸⁵ *Monsanto Canada Inc. v. Schmeiser (C.A.)* [2003] 2 F.C. 165 (Fed Court of App).

the growing by the defendants in 1998 of canola on nine fields, from seed saved in 1997 which was known or ought to have been known by them to be Roundup tolerant, and the harvesting and sale of that canola crop, infringed upon the plaintiffs' exclusive rights under Canadian patent number 1,313,830 in particular claims 1, 2, 5, 6, 22, 23, 27, 28 and 45 of the patent.”³⁸⁶

In the Federal Court of Appeal case, the court emphasized, “In this case, Mr. Schmeiser cultivated glyphosate resistant canola plants. His 1998 canola crop was mostly glyphosate resistant, and it came from seed that Mr. Schmeiser had saved from his own fields and the adjacent road allowances in 1997....”³⁸⁷ The trial judge concluded that Mr. Schmeiser either knew or should have known that the plants he grew in 1998 were glyphosate resistant because of the manner in which he saved their seeds in 1997.³⁸⁸ This 1998 planting by Schmeiser put him at risk of a claim of patent infringement by Monsanto.

At the Supreme Court of Canada (SCC) appeal, the case centred on whether the growing of the GE canola in 1998 involved “use” of the patented invention. Schmeiser had not applied the Roundup herbicide [containing the glyphosate] to the canola plants involved in the 1998 crop. These canola plants were genetically engineered to resist this chemical, and by not applying it to the 1998 crop, Schmeiser claimed that he had not “used” the invention.³⁸⁹ There is some logic to this contention. Schmeiser could argue that if the GE seed trait that made this seed patentable was not taken advantage of, then this GE seed is no different than a non-GE seed. Of course, the question then becomes, if the seed is no different than a non-GE seed why would someone go to the trouble of isolating these GE seeds and growing a full crop with them?

Monsanto prevailed at the SCC where the Court noted that a machine with a patented part cannot be used without infringing on the patent of that part. In the same way as this machine, a canola plant cannot be grown without using the patented gene [trait] contained within the plant and thereby infringing on the patent of the gene. Specifically, the SCC noted, “...where a defendant’s commercial or business activity involves a thing of which a patented part is a

³⁸⁶ Ibid at para 146.

³⁸⁷ Ibid at para 58.

³⁸⁸ Ibid at para 120, 125.

³⁸⁹ Supra note 381 para 28,40,74,81.

significant or important component, infringement is established. It is no defense to say that the thing actually used was not patented, but only one of its components.”³⁹⁰

The outcome of the *Monsanto v. Schmeiser* case strengthened the IP protection of agricultural biotechnology for GE seed companies and sent a strong signal to farmers that the seed companies, with the support of the Canadian legal system, would challenge the *deliberate* illegal use of patented GE technologies. Although no monetary damages resulted from this case, the precedent set by the case has been referred to in other GE seed patent cases including those in the U.S. The result of this case has also been noted in broader agricultural circles and thus may act as a deterrent to those who may contemplate GE seed patent infringement. The extensive coverage that this case has received on the FAO website demonstrates its potential worldwide influence on this industry.³⁹¹ This case establishes that the protection of GE seed IP is effective in the developed world where a strong IP environment exists. However, it also shows the importance of field monitoring by GE seed companies in order to catch infringers “in the act”.

The first court decision in the *Monsanto v. Schmeiser* case occurred in 2001. At that point in time, GE crops had been commercially available for approximately six years. In 2011, another landmark case involving Monsanto began (i.e. *Monsanto Co. v. Bowman*) at the United States District Court for the Southern District of Indiana (case no. 07-CV-0283, Judge Richard L. Young). This case also involves patent infringement and was ultimately decided by the U.S. Supreme Court in May 2013.

ii) *Monsanto v. Bowman*³⁹²

One might imagine that the decision in the *Schmeiser* case would be enough to prevent farmers from directly attempting to infringe on GE seed patents, however, this has not been the case. The issue of infringement of patented GE seeds has continued to be before the courts.

³⁹⁰ Supra note 381 at para 78.

³⁹¹ UNFAO, *Search Results for Schmeiser* (2014) online: UNFAO<
[³⁹² *Bowman v. Monsanto Co.*, 569 U.S.__\(2013\).](http://www.fao.org/search/en/?cx=018170620143701104933%3Aqq82jsfba7w&q=schmeiser&cof=FORID%3A9&siteurl=www.fao.org%2Fhome%2Fen%2F&ref=www.google.ca%2Furl%3Fsa%3Dt%26rct%3Dj%26q%3D%26esc%3Ds%26source%3Dweb%26cd%3D1%26sqi%3D2%26ved%3D0CBwQFjAA%26url%3Dhttp%253A%252F%252Fwww.fao.org%252F%26ei%3DQHC9U7_nD4ji8AWfyIHADg%26usg%3DAFQjCNFN0FJRtsVrfnxh2u66Un8onLMaSw%26bvm%3Dbv.70138588%2Cd.dGc&ss=2264j838114j9>.</p></div><div data-bbox=)

In the *Monsanto v. Bowman* case, the U.S Supreme Court *unanimously* affirmed that Indiana farmer Vernon Bowman had infringed on Monsanto's GE soybean patent when he planted the patented seeds without buying them from the company or a Monsanto-authorized seller.³⁹³ This decision strengthened the patent-law related to GE seeds but also addressed the complex issue of self-replicating technology. The latter issue is significant because this aspect of the decision addresses the difficulty alluded to earlier in this thesis when the straightforward patenting of a non-replicating toaster was compared to the complexity of self-replicating seeds.

The facts of the case indicate that Bowman was a satisfied and legal user of Monsanto GE soybean seeds.³⁹⁴ He had signed the Monsanto TSA and so was aware of Monsanto's terms and conditions and his responsibilities under this agreement. Bowman decided that he did not wish to pay the high cost charged for Monsanto GE soybean seeds when it came time to plant an additional, riskier late-season crop.³⁹⁵ To obtain seeds for planting, Bowman went to a grain elevator to purchase "commodity soybeans" which can only be used for consumption by animals or humans as indicated under U.S. federal and state law (7 U. S. C. §1571(Federal Seed Act); Indiana Code §§ 15-15-1-32 to 43. For example, Section 15-15-1-40 of the Indiana Code prohibits distribution of agricultural seed within Indiana without a label indicating variety and maturity information. A grain elevator storing commodity soybeans is not able to provide this information since the elevator receives seed from many sources. A crop from these seeds is a mixture of varieties. If farmers plan to sell their crop, they would be better off purchasing traditional seeds for planting because this would result in a uniform crop.

One further point is that the purchase of commodity seed, even if it contains some GE seeds, does not require the signing of a license agreement, such as Monsanto's TSA discussed earlier, since the seeds are not intended for planting. Furthermore, the seed would be a mixture of both GE seed and non-GE seed in unknown proportions. The TSA that Bowman would have signed with Monsanto for his regular legal GE soybean crop is the standard Monsanto TSA that all growers must sign in order to be allowed to use Monsanto GE seed. This agreement does not

³⁹³ Ibid at 10.

³⁹⁴ Ibid at 2.

³⁹⁵ Ibid.

explicitly mention “commodity seed.”³⁹⁶ (See Appendix K) Bowman may have surmised that this loophole could be used to circumvent the requirement to pay Monsanto for their patented seed.

Knowing that most of the farmers in the area used Monsanto patented Roundup Ready soybean seeds, Bowman apparently concluded that it was likely that most of the seed he purchased from the local grain elevator would contain those GE seeds. He purchased and planted the commodity seed, grew the crop and applied the Roundup Ready herbicide to the plants knowing that those that survived must contain Monsanto patented technology. Bowman saved these Monsanto seeds and replanted them for eight years. In this way, Bowman was reaping the advantage of Monsanto GE technology without paying for the license to use the patented invention.³⁹⁷

Monsanto sued Bowman for patent infringement to which Bowman claimed patent exhaustion as a defense. The principle of patent exhaustion states that once a patented product is purchased, all patent rights to the [*specific*] item cease and the owner can do with it as he wishes [i.e. one can use it and/or one can sell it]. Bowman argued that his GE seed use was non-infringing because the first sale of the patented seeds had been by other farmers to the grain elevator and that this represented a valid first sale after which patent rights are exhausted. The District Court did not support Bowman’s defense and awarded damages to Monsanto. The Federal Circuit affirmed this decision noting that by growing new seeds for planting Bowman had “created a newly infringing article” (657 F. 3d, at 1348).³⁹⁸

In their questioning of the lawyers for the petitioner [Bowman], the justices of the U.S. Supreme Court seemed to be sympathetic to Monsanto’s position. During the arguments, a comparison was made to the copying of a DVD. It was agreed that, with the purchase of the original DVD, the exhaustion principle holds for that DVD. However, the simple technique of copying the DVD creates new versions that are legally protected. The petitioner made the interesting argument that the two situations were not analogous since the copied DVDs are not created in the course of using the DVD as intended, whereas the copied GE seeds are derived by

³⁹⁶ Supra note 358.

³⁹⁷ Supra note 392 at 3.

³⁹⁸ Ibid.

using the GE seeds as they are intended to be used; that is by growing them. This argument did not convince the court to side with the petitioner. [Bowman v. Monsanto Co., 569 U.S.__(2013) (Oral Arguments, Bowman) online: SCOTUS <http://www.supremecourt.gov/oral_arguments/argument_transcripts.aspx>.]

After reviewing the case, the U.S. Supreme Court unanimously decided the Bowman v. Monsanto case on May 13, 2013. The court held that, “Patent exhaustion does not permit a farmer to reproduce patented seeds through planting and harvesting without the patent holder’s permission. Pp. 4–10.”³⁹⁹

The Court noted that the purchaser had already been rewarded for the initial purchase, and that if he could endlessly reproduce the invention, it would be worthless to the inventor after the sale of the first seed.⁴⁰⁰ The Court specifically noted that the source of the seeds was not relevant.⁴⁰¹

Justice Elena Kagan wrote the Court’s decision and she summarized the decision very succinctly when she wrote that, "In the case at hand, Bowman planted Monsanto's patented soybeans solely to make and market replicas of them, thus depriving the company of the reward patent law provides for the sale of each article. Patent exhaustion provides no haven for that conduct. We accordingly affirm the judgment of the Court of Appeals for the Federal Circuit."⁴⁰²

By stressing that Bowman carefully isolated the GE soybean seeds, the Court concluded that Bowman’s intent was to deliberately infringe on Monsanto’s seed patent. An interesting aspect of this emphasis by the Court is that usually intent is not a factor in determining patent infringement cases and by noting intent the Court may have inadvertently weakened patents in self-replicating technologies. The reason is that if GE seeds are grown without knowing that patented seeds are being used [such as in the case of field contamination by GE seeds], would the lack of intent result in a situation where patent infringement could be claimed? This question then leads directly into a third important case that further clarifies the protective ability of patents

³⁹⁹ Ibid at 1.

⁴⁰⁰ Ibid at 5.

⁴⁰¹ Ibid.

⁴⁰² Ibid at 10.

for the protection of GE seed innovation, *Monsanto Co. v. OSGATA* (Organic Seed Growers and Trade Association; a U.S. based organization). This case ended in 2013.

iii) OSGATA et al. v. Monsanto Co.

The significance of this case is that, by not allowing the case to proceed, the court is challenging the misinformation, promoted in the media and specifically by the OSGATA, that Monsanto, or any GE seed company, uses its patent-provided monopoly to sue farmers for accidental contamination of their fields with GE plants. This idea, which has permeated the popular media and various NGO websites, represents a source of continuing reputational concern for GE seed companies. As a result, this mistaken belief adds to the negative impression that the patenting of GE seeds inevitably harms small farmers through no fault of their own.

This case once again involves Monsanto. The Appeals Court decision occurred one month after the Bowman/SCOTUS final decision and the result again supports Monsanto's position.

The Organic Seed Growers and Trade Association [OSGATA] case began in 2011 with OSGATA claiming that organic farmers were afraid to grow organic crops because of the threat from Monsanto to sue them if Monsanto patented seeds accidentally contaminated the organic farmers' crops. OSGATA was asking the court for the Southern District of New York to direct Monsanto to "expressly waive any claim for patent infringement [Monsanto] may ever have against [appellants] and memorialize that waiver by providing a written covenant not to sue."⁴⁰³

It seems that Monsanto's explicit web-based promise not to sue farmers whose fields are inadvertently contaminated by the company's GE seeds was not a sufficient for OSGATA. Monsanto's promise is clearly stated on the company's website in, "Monsanto's Commitment: Farmers and Patents" as item (x) where it states that, "It has never been, nor will it be Monsanto policy to exercise its patent rights where trace amounts of our patented seed or traits are present in farmer's fields as a result of inadvertent means."⁴⁰⁴

⁴⁰³ *Organic Seed Growers & Trade Ass'n v Monsanto Company and Monsanto Technology LLC*, No. 11 Civ. 2163 (NRB) (S.D.N.Y. 24 February 2012) at 18.

⁴⁰⁴ *Supra* note 366.

In the original suit, the judge threw out the case based on Monsanto's clear statement not to sue farmers whose fields are accidentally contaminated with trace amounts of GE seeds. The judge stated that, "these circumstances do not amount to a substantial controversy and . . . there has been no injury traceable to defendants."⁴⁰⁵ At the United States Court of Appeals for the Federal Circuit, OSGATA admitted that they had never been a threat by Monsanto to sue them or their members for inadvertent field contamination. One might suggest that the fear of being sued by Monsanto for accidental field contamination is based on the fact that patent infringement does not require intent [although I have noted in the Bowman case, that intent seemed to play an important part in the decision] and that even the presence of a small amount of patented material could establish patent infringement. However, the Appeals Court concluded, "that Monsanto has disclaimed any intent to sue inadvertent users or sellers of seeds that are inadvertently contaminated with up to 1% [Monsanto did not contest that "trace amounts" of contamination must mean about 1%] of seeds with Monsanto's patented traits."⁴⁰⁶ The court ruling concluded with, "the appellants have alleged no concrete plans or activities to use or sell greater than trace amounts of modified seed, and accordingly fail to show any risk of suit on that basis. The appellants therefore lack an essential element of standing."⁴⁰⁷

This case presents a classic picture of the intricacies involved in patent use for protecting innovation. It demonstrates the strength that patents have in protecting innovation in a strong IP environment while also highlighting the difficulty of applying traditional patents to non-traditional inventions such as self-replication.

The above three cases have all occurred in the developed world, however, patenting for innovation protection has also been an issue in the developing world. The Argentina case that follows is a recent example of the difficulties in GE seed IP protection that can arise from the disparity in national patent regimes.

The above three cases clearly demonstrate that in the developed world where the IP regimes are well established and fairly uniform, and the rule of law is effective and responsive,

⁴⁰⁵ Supra note 403 at 23.

⁴⁰⁶ *Organic Seed Growers & Trade Ass'n v Monsanto Company and Monsanto Technology LLC*, Appeal from the United States District Court for the Southern District of New York in No. 11 Civ. 2163 (NRB) (U.S. Court of Appeals for the Federal Circuit 10 June 2013) at 16.

⁴⁰⁷ *Ibid* at 21.

patents will successfully protect innovation; that is, when infringement is discovered. Unfortunately, the costs of this protection to GE seed firms are high in both time and money.⁴⁰⁸ Although monitoring and other patent enforcement costs are not separated out in Monsanto's financial statements, the vigour with which the company monitors and legally defends its patents suggests that the cost of doing so and the potential losses of not doing so are significant.⁴⁰⁹ Cost is not only an issue for firms attempting to protect innovation but also for farmers with limited resources who may find themselves defending against a patent infringement accusation.

As high as the cost of protecting innovation through patents may be, it seems that the self-replicating capacity of this biotechnology makes protection vital at almost any cost in order to sustain the IP value. From an innovation protection perspective, patents seem to be able to effectively protect innovation in GE seeds in the developed world where a strong IP environment exists and a means to monitor compliance is available.

iv) The Argentina Case: Protection in the Developing World

As much as the legal protection offered by patents appears to be effective as a GE seed and crop IP protection method in developed countries, developing countries present challenges to this method of IP protection that may not be easily overcome. Developing countries present environments where the potential for significant value leakage is great due to nationally skewed, lax or ineffective IP regimes or international agreements such as TRIPS [Article 27] that allow developing countries some leeway in IP protection. While this leeway is not necessarily a negative feature of these agreements, it does act as a wedge that encourages the loosening of IP protection.⁴¹⁰

A noteworthy example of IP protection problems, from a firm perspective, is the case of Argentinian soybeans. The IP surrounding these soybeans, which was already a bone of contention between Monsanto and the Argentine government, became an international issue in 2005 when soy meal made from these soybeans was exported to the EU.

⁴⁰⁸ *Monsanto Company, Form 10K – 2013*, online: U.S. Securities and Exchange Commission <<http://www.sec.gov/Archives/edgar/data/1110783/000111078313000205/mon-20130831x10k.htm>> at 7.

⁴⁰⁹ *Ibid.*

⁴¹⁰ *Supra* note 194 at 53; *supra* note 76 at 25.

This case has its origins in the way that Monsanto's Roundup Ready gene in GE soybeans initially entered Argentina. The entry occurred as a result of an agreement between Asgrow Seed Company and Monsanto by which Asgrow was granted use of the gene in its Argentinian operations. (Asgrow is now a seed brand of Monsanto). Nidera, an Argentinian biotechnology firm, then purchased Asgrow. This gave Nidera access to the Roundup Ready gene, which the company widely distributed in Argentina. At this point, the gene was patented in the U.S. but not in Argentina. Nidera was unable to patent the gene in Argentina because the company was not the creator [inventor]. Monsanto attempted to patent the gene in Argentina, but because the gene was already widely released and therefore was no longer considered to be "novel," Argentinian patent law prohibited the patenting at this point.⁴¹¹ As a result of Monsanto's ultimate inability to patent the soybean GE seed gene in Argentina, the use of Monsanto's GE soybean seed in Argentina became a free-for-all.⁴¹²

This situation is an example of a lack of consistency across jurisdictions in the international patent system. Three characteristics of the patent system are responsible for this problem. First, it is a voluntary system and not automatic, so that inventors have a choice whether to apply for a patent. This means that strategic miscalculations and unusual circumstances, as happened in this case, concerning when or if to patent can lead to costly and irreversible consequences such as a lost opportunity to patent an invention. Second, the patent system is territorial in nature so that a patent is only enforceable where it has been obtained.⁴¹³ This can lead to a patented product in one jurisdiction becoming an unpatented product simply by crossing an international border. Third, once the invention is in the public domain in those countries where no patent application has been made, the inventor may lose the ability to obtain a patent. The inventor would then have no ability to prevent others from exploiting the invention.

As a result of Monsanto's inability to patent the Roundup Ready soybean gene in Argentina, it was freely available, leaving Monsanto with no legally binding method of capturing

⁴¹¹ Mauricio Antonio Lopes et al, "Approaching Biotechnology: Experiences from Brazil and Argentina" (2005) in Ricardo Melendez-Ortiz & Vicente Sanchez eds, *Trading In Genes: Development Perspectives On Biotechnology, Trade and Sustainability* (Sterling, Virginia, USA: Earthscan, 2005) at 100.

⁴¹² Ibid.

⁴¹³ David Vaver, *Intellectual Property Law: Copyright, Patents, Trade-marks* 2nd ed. (Toronto: Irwin Law Inc., 2011) at 25.

the value from its invention in Argentina. To make matters worse for Monsanto, GE soybeans then became a major crop in Argentina making up approximately 80% of the total area of biotech crops in that country.⁴¹⁴ The significance of this is dramatic when one considers two points. First, GE soybeans account for 47% of all GE crop acreage worldwide. Second, in 2012, 81% of the GE soybeans grown were Roundup Ready (Monsanto) soybeans. Finally, in 2012, Argentina grew about 25% of all the world's soybeans and virtually all of them were Roundup Ready soybeans.⁴¹⁵ The amount of value leakage for Monsanto in this situation was virtually 100% as the company was not able to charge a seasonal per-use technology fee or to in any way restrict the use of the GE soybean seeds by Argentinian farmers.⁴¹⁶

As a value capture attempt, Monsanto told Argentine exporters of soy meal that the company would levy a \$15-per-ton fee on soybean exports. If these terms were not accepted, the company threatened to sue the exporters in the courts of European countries where the patent was recognized and to which the soy meal was exported. The Argentine government on behalf of the exporters resisted this threat.⁴¹⁷

Ultimately, Monsanto filed a lawsuit in a Dutch court after the company discovered trace amounts of its proprietary DNA in soy meal that had been exported from Argentina to the Netherlands in 2005 and 2006.⁴¹⁸ Monsanto in Europe had patented the Roundup Ready soybean gene and the company seemed to be placing its hopes for the success of the lawsuit on this fact. The Dutch court asked that the European Court of Justice rule on the matter and on July 6, 2010, the Court provided an opinion. Specifically, the Court of Justice was being asked whether the presence of a European patent-protected DNA sequence in the imported soy meal

⁴¹⁴ UNFAO, FAOSTAT (2014) online: UNFAO
<<http://faostat.fao.org/DesktopDefault.aspx?PageID=339&lang=en&country=9>>.

⁴¹⁵ Clive James, "Global status of commercialized biotech/GM crops: 2012 – ISAAA Brief No 44" (2013) online: ISAAA <<http://www.isaaa.org>> at 211.

⁴¹⁶ Supra note 411 at 104.

⁴¹⁷ Taos Turner, "Argentina Slams Monsanto For "Attitude" On GMO Royalties", *Dow Jones Newswires* (17 March 2005) online: Dow Jones Newswires
<<http://www.connectotel.com/gmfood/dj170305.txt>>.

⁴¹⁸ Eliot Marshall, "European Ruling Curbs Monsanto's Claims on GM Crops", *Science/AAAS* (7 July 2010) online: *Science/AAAS* <<http://www.sciencemag.org/news/2010/07/european-ruling-curbs-monsantos-claims-gm-crops>>.

constituted patent infringement.⁴¹⁹

The Court of Justice concluded that the patented genetic material in a product must be able to perform its function in that product for it to be protected. Specifically, “Article 9 [Article 9 of Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions (OJ 1998 L 213, p. 13)], contained in Chapter II, entitled ‘Scope of protection’, provides: ‘The protection conferred by a patent on a product containing or consisting of genetic information shall extend to all material ... in which the product is incorporated and in which the genetic information is contained and performs its function.’”⁴²⁰ In this case, the Court found that the function of the genetic information is to protect the soybean plant against the effects of the herbicide glyphosate and that after processing, soy meal no longer performs that function. The Judgement stated, “As follows from paragraph 37 of this judgment, a DNA sequence such as that at issue in the main proceedings is not able to perform its function when it is incorporated in a dead material such as soy meal.”⁴²¹

In summary, the Court of Justice ruled, “Article 9 of Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions is to be interpreted as not conferring patent right protection in circumstances such as those of the case in the main proceedings, in which the patented product is contained in the soy meal, where it does not perform the function for which it is patented.”⁴²²

As a result of this ruling, Monsanto was unable to prevail in this case and, therefore, could not prevent Argentina from shipping soy meal that originated from the company’s patented [outside of Argentina] Roundup Ready soybean gene.

This case demonstrates a serious shortcoming of the patent system as an IP protective mechanism for GE seeds and/or traits from the perspective of the inventing firm. A strategic error in failing to patent promptly in one country can have serious consequences that can lead to

⁴¹⁹ Ibid.

⁴²⁰ ECJ *Monsanto Technology LLC v Cefetra BV and Others*, C-428/08, [2010] ECR I-6765 Reference for a preliminary ruling: Rechtbank 's-Gravenhage - Netherlands. Industrial and commercial property - Legal protection of biotechnological inventions - Directive 98/44/EC - Article 9 - Patent protecting a product containing or consisting of genetic information - Material incorporating the product - Protection – Conditions para 12.

⁴²¹ Ibid para 48.

⁴²² Ibid at C234/7.

an inability to ever file that patent in that country. As in this case, the result is a massive loss of value capture capability. This matter does not even take into account the fact that the absence of a singular global patent system means that even those countries subject to the TRIPS Agreement have wide latitude in determining what is or is not an invention and therefore what may or may not be protected. This flexibility originates in Article 27.3(b) of the TRIPS Agreement where it states that, “members may exclude from patentability, plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes.”⁴²³ In the case of developing countries such as Argentina, this allows for more stringent regulations on the patenting of genetic resources leaving some inventions unpatentable.

For GE seed companies such as Monsanto, the less than ironclad protective characteristics of international patenting and the peculiarities of national patent systems can encourage strategic litigation [litigation with a motive other than for the purpose of obtaining a final judgement] as a means to create some value from a bad situation. Professor Carlos Correa, who is the Director of the Centre for Interdisciplinary Studies on Industrial Property and Economics Law at the University of Buenos Aires (Argentina), suggests that Monsanto’s litigation of the soy meal case was, in fact, a case of strategic litigation. He proposes that Monsanto used this litigation, not to obtain a favourable final judgment, but rather to create an uncertain environment in which the targeted parties [the Argentine government and farmers] are forced to compromise to meet commercial conditions on the ground. In this way, all parties can supposedly avoid the cost and uncertainty of a long drawn out litigation.⁴²⁴ The problem with strategic litigation is that there is no guarantee of strategic success. However, there is a guarantee that it will be costly and possibly time consuming, and it may distract the firm from the achievement of other important more immediate goals.

One other interesting consequence of this Argentina soybean situation is that it resulted in the bootlegging of GE soybean seeds across the border into Brazil where the seeds are patented.

⁴²³ Supra note 10 at Article 27.3(b).

⁴²⁴ Carlos M Correa, “The Monsanto vs. Argentina dispute on GMO soybean” (2007) 203/204 Third World Resurgence, online: Biosafety Information Centre
<www.biosafety-info.net/file_dir/795538734c5116c822abe.doc> at 6.

Farmers in Brazil were able to obtain cheaper Argentinian GE soybean seeds illegally.⁴²⁵ This led to a substantial decrease in the sale of legal Monsanto patented GE seeds in Brazil.⁴²⁶ This situation is discussed further in the next section of this thesis dealing with innovation.

The issues presented by this case highlight the problems of depending on legal mechanisms, such as patents, for the protection of GE seed IP. These include an inability to implement the legal mechanism; the high cost of implementing those mechanisms; the high cost of enforcement; and negative public perception of the firms involved.

5.0.2 GURT v. Patents and Innovation Protection

Based on the earlier description of GURT, this technology appears to be the ideal method of protecting GE seed inventions in both developing and developed countries because it is capable of protecting *itself* from unauthorized exploitation. However, because GURT has not been commercialized, any prediction regarding its innovation protective capacity is to some degree speculative. One must look for additional ways beyond its advertised technological attributes to evaluate the innovation protective capacity of this untried technology.

One possibility is to examine the potential attributes of GURT and from them to predict the degree of IP protection that they may offer under modelled real world conditions. In addition, one can look at important patent infringement cases, such as those described in the previous section, and judge how the existence of GURT might influence those cases. Finally, one can search for other technological means of innovation protection in agriculture and evaluate how well they have accomplished this goal.

The first possibility, the theoretical examination of GURTS, is described in the foundational section of this thesis. While useful, it does not provide any definitive results on which one can arrive at a conclusion. This is because while the science is convincing, it cannot be looked at in isolation. There are too many practical, external factors that can influence the application of this technology for innovation protection. These factors include the quality, dependability and access to inducers in the case of T-GURTS; and the uniformity, availability

⁴²⁵ Ibid at 3.

⁴²⁶ Ibid.

and environmental dispersal of sterile seeds in the case of V-GURTS. As this possibility has been discussed there is no need to further dwell on the scientific theory of GURT.

The second possibility involves hypothesizing how existing GE seed patent infringement cases would have fared had GURT technology been available as an enhanced feature of GE seed technology. In fact, one could ask whether the situations on which these cases were based would have occurred at all and if so what would have been the possible outcome.

The third possibility of comparing the protective capacity of GURT with another existing technological method of protection that has been in place for many years could be especially useful in examining the impact of technological protection over the long term. Hybrid corn represents a current and well-established technological means of innovation protection that first appeared in the U.S. corn belt in the 1930s.

This section begins with this third possibility by evaluating how hybrid corn has fared as a technological IP protective alternative to patents using specific examples in the U.S. [a developed country] and Argentina and Brazil [developing countries]. This is followed by an assessment of the second possibility in which a re-examination of the four cases previously discussed takes place to see how they might have developed with GURT as the IP protective model.

Hybrid corn is the closest practical example of large-scale technological protection of agricultural IP and, therefore, provides some insight into the potential use of GURT as a technological alternative to patents for IP protection. Hybrid corn is patented to protect it from exploitation primarily by rival firms, however, it is its ability to technologically protect itself from exploitation by farmers without the permission of the developer that makes this product so useful in assessing the protective potential of GURT.

i) The Case of Hybrid Corn

The key question for hybrid corn is whether the technology of hybridization has protected innovation in corn agriculture. Specifically, does the hybridization of corn exclude others from making, using or copying corn so as to capture value from this technology?

Corn hybrids were first developed and commercialized in the U.S. in the 1930s.⁴²⁷ In the U.S., most hybrid corn plants are crossbred from two inbred lines. “Inbred lines are developed by selfing [self-pollinating] plants from a source population. Source populations could include open pollinated varieties, synthetics, or crosses from two or more inbred lines. The source population is then self-pollinated [selfed] for seven to eight generations, with several hundred selfed families being selected and advanced during each selfed generation.”⁴²⁸

The best lines from the selfed families, “are advanced to further “selfing” generations and recrossed onto additional tester hybrids to produce new hybrids to evaluate. As the families are selfed, each generation becomes more and more homozygous [inbred]... [This results in new inbred lines that are extensively evaluated]... over two to three years before a... few are released as new commercial hybrids. The above process requires eight to ten generations of selfing... over three to five concurrent years of hybrid testing.”⁴²⁹ The result of this long and complex process is two inbred lines whose genetic makeup is known only to the creator of the lines. The vigour [genetic quality] of these lines begins to deteriorate after the initial planting if seeds are saved and replanted.⁴³⁰

The key feature of hybridization that encourages its comparison with GURT is that in both cases farmers are discouraged from saving seed for replanting. This is significant because this thesis has identified the farmer’s use of saved patented seed as the primary source of value leakage faced by the GE seed firms. In the case of GURT, the reason that seed saving would not take place is that either the second-generation seeds are sterile (V-GURT), or the value-added GE traits require activation by the seed firm (T-GURT). Alternately, in the case of T-GURT, the seeds can be grown without the activation of the value-added trait but the result is a plant without the value-added trait. In the case of hybridization, the second-generation seeds, while fertile,

⁴²⁷ A Forrest Troyer, “Development of Hybrid Corn and the Seed Corn Industry” (2009) in Jeff Bennetzen & Sarah Hake Springer eds, *Handbook of Maize – Volume II: Genetics and Genomics* (New York: Science + Business Media LLC, 2009)87 at 87.

⁴²⁸ Vernon Gracen, “How Intellectual Property and Plant Breeding Come Together: Corn as a Case Study for Breeders and Research Managers” (2007), online: MIHR/PIPRA ipHandbook<
http://www.pipra.org/Resources/en/IP/ipHandbook_Volume_2.pdf at 1820.

⁴²⁹ Ibid.

⁴³⁰ Ibid at 1824.

produce a lower quality [i.e. genetically inferior] crop.⁴³¹ Today, hybrid crops can be genetically engineered with additional traits which can be further protected by patents which creates a crop with both strong technological as well as legal IP protection. However, the useful comparison here remains non-GE seed hybridization and GURT.

Hybrid corn is grown in both the developed and developing world and its innovation protection capacity in the developed world is identical to that in the developing world. That is, unlike patent protection, hybrid protection is a technological protection that is not dependent on national or international regulatory influences of patent regimes.

Hybrid Corn in the U.S.

Initially, the attractiveness of hybrid corn in the U.S. was related to what was thought to be its potential for increasing corn yield. U.S. Field tests of hybrid corn in the 1920s did demonstrate significant increases in yield. Because it can take many crop generations to transfer a trait to an elite strain of the desired plant through breeding, it took 25 years of research before hybrid corn was finally introduced in the 1930s.⁴³² Even so, it took another 30 years for hybrid corn to reach a 95% adoption rate in the U.S.⁴³³ Differences in adoption rate can be influenced by factors such as marketing intensity; availability of new farming techniques to maximize the potential of the new varieties; and the degree of increased benefit to the farmer that the new variety represents.⁴³⁴

An examination of the changes in U.S. corn yield over a long period demonstrates that there has been a significant increase in yield since the introduction of hybrid corn. This increase in yield is cited frequently as the reason for the rapid adoption of hybrid corn in the U.S. (See following graph Figure 2).

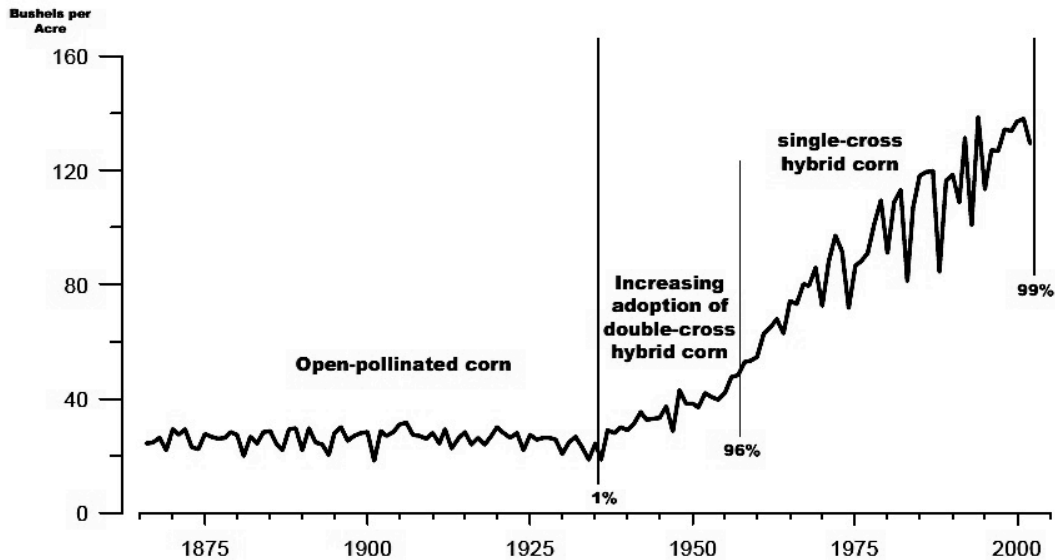
⁴³¹ Goeschl, Timo & Timothy Swanson. "The development impact of genetic use restriction technologies: a forecast based on the hybrid crop experience" (2003) 8 *Environment and Development Economics* 149
online:<<http://journals.cambridge.org/action/displayFulltext?type=1&fid=136438&jid=EDE&volumeId=8&issueId=01&aid=136437>> 149 at 151;

⁴³² *Supra* note 272 at 1.

⁴³³ *Ibid* at 2.

⁴³⁴ *Ibid* at 61.

Figure 2: U.S. Corn Yields 1866 – 2002⁴³⁵

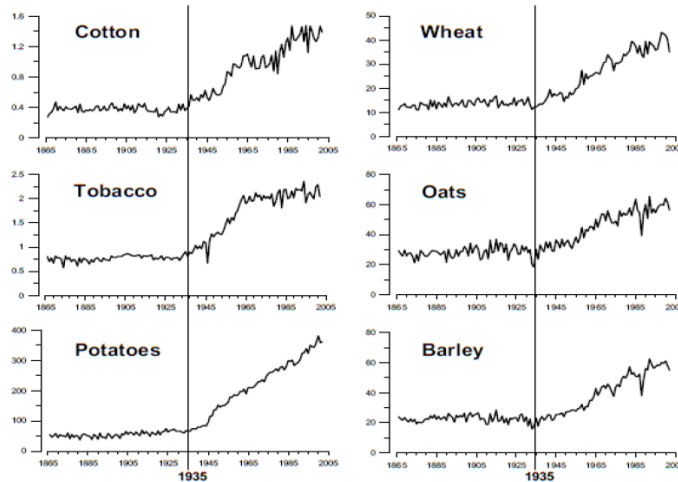


Source: Susan B. Carter et al, Editors, *Historical Statistics of the United States*, Cambridge University Press, 2006, Series Da693-694. United States National Agricultural Statistics Service, *Field Crops: Final Estimates, 1997-2002*, Statistical Bulletin Number 982a, March 2004, pp. 7 & 9.

A casual observer might suggest that this increase in corn productivity at the time of the introduction of hybrid corn represents more than a correlation. However, graphs of other non-hybrid crops show a similar yield configuration to that of hybrid corn, suggesting that there are other factors at play that have led to a general level of productivity increase. (See following graph Figure 3)

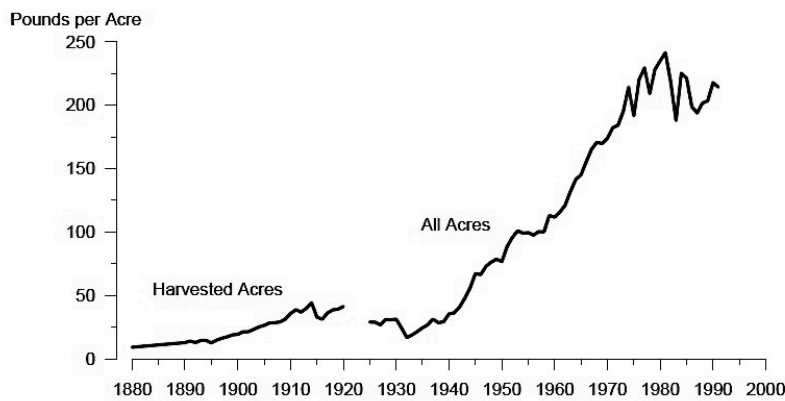
⁴³⁵ Richard C Sutch, "Henry Agard Wallace, the Iowa Corn Yield Tests, and the Adoption of Hybrid Corn", National Bureau of Economic Research Working Papers 14141 (2008)
Online: National Bureau of Economic Research<<http://www.nber.org/papers/w14141>> at Appendix, Figure 3.

Figure 3: U.S. Major Crop Yield 1865 - 2005⁴³⁶



One of these factors is fertilizer use. The graph below (Figure 4), which maps fertilizer use, is strikingly similar in configuration to the other graphs. Note that the increase in fertilizer use closely corresponds to crop productivity in the previous graphs.

Figure 4: U.S. Commercial Fertilizer Use per Acre of Cropland⁴³⁷



Source: Susan Carter et al, Editors, *Historical Statistics of the United States*, Cambridge University Press, 2006, Series Da20 and Da644

According to Richard Sutch in his National Bureau of Economics paper, “Henry Agard Wallace, the Iowa Corn Yield Tests, and the Adoption of Hybrid Corn,” there is no indication

⁴³⁶ Ibid at Appendix, Figure 10.

⁴³⁷ Ibid at Appendix, Figure 11.

that the introduction of hybridization was the primary cause of the increased productivity of corn. In addition to fertilizer use, other factors such as the introduction of plant breeding programs; the use of more proficient experimental procedures; government actions to improve inbred lines; and improvements in mechanization all played a part in the productivity gains.⁴³⁸ Sutch does identify subsequent improvements in hybrid corn varieties as a source of increased productivity in the same way as improvements in traditional breeding improved non-hybrid crops. In addition, Sutch notes that improvements in farming technology helped all types of crops.⁴³⁹

The point is that hybrid corn became the standard for the industry and, perhaps not coincidentally, hybrid corn offered the industry a method of highly effective technologically based value capture.

Similarly, GURT is not necessarily intended as a method of increasing productivity. According to Eaton and Tongeren, developers of GURT are looking for two benefits from this technological innovation. In their Agricultural Research Institute (The Hague) paper, “Genetic Use Restriction Technologies (GURTs) Potential Economic Impacts at national and international levels”, these authors state that the primary benefit is an increase in value capture. The secondary benefit is an improvement in transgenic containment. These authors stress that it is the appropriation issue that is particularly relevant to both national and international public and private sectors especially around the issues of IPRs and competition.⁴⁴⁰

Productivity may increase if GURT is commercialized, however, any productivity gains would be due to GE traits that can exist irrespective of embedded restriction technology. Simply, the same traits that can lead to increased productivity in technologically IP protected GURT exist in traditional patent protected GE crops.

It is important to consider why so many farmers were willing to purchase hybrid corn seed even **before** hybrids offered them a clear economic advantage. Robert Sutch describes how, in 1936, there was no absolute economic advantage of hybrid corn over traditional open-

⁴³⁸ Ibid at 4.

⁴³⁹ Ibid.

⁴⁴⁰ DFJ Eaton & FW van Tongeren, “Genetic use restriction technologies (GURTs) Potential economic impacts at national and international” (The Hague: Agricultural Economics Research Institute (LEI), 2002) at 15.

pollinated varieties.⁴⁴¹ The switch to hybrid corn began when Pioneer Hi-Bred and other seed companies launched very aggressive marketing campaigns directed at potential adopters. This campaign was supported by the U.S. Department of Agriculture. At that time, the Secretary of Agriculture was Henry A. Wallace who was also co-founder of Pioneer Hi-Bred, the first and largest hybrid seed producer.⁴⁴² The apparent conflict of interest between Wallace's financial interest in Pioneer and his promotion of the company's product through the government agency that he controlled was not, however, sufficient to overwhelmingly tip the balance away from open-pollinated corn toward hybrid corn.⁴⁴³

Sutch goes on to state that it was, in fact, the major droughts of 1936 and 1938 that turned the tide in favour of hybrid corn. The reason is that while the absolute yields of corn were greatly reduced during the droughts, the relative yield of hybrid corn was higher than that for the open-pollinated varieties. In fact, the relative yield of hybrid corn in relation to the absolute yield of the entire corn crop was greatest when the absolute yields of corn were down.⁴⁴⁴ This led to a dramatic increase in demand for hybrid corn.⁴⁴⁵

As hybrid seed corn became a profitable industry, R&D by industry and public scientists rapidly increased corn yield potential, creating a momentum away from open-pollinated breeding efforts. The profitability of hybrid corn attracted private capital that advanced seed production, distribution technologies and infrastructure. Lastly, the uniformity of hybrid corn made it a good fit with early mechanical harvesting equipment.⁴⁴⁶

Best of all, from the seed firm's perspective, the loss of crop quality from the replanting of saved hybrid corn seeds forced farmers to purchase new hybrid corn seed each growing season to be certain that the quality of the hybrid was maintained. Once most farmers were locked into using hybrid corn [U.S. adoption rates hit 96% in the 1950s - see Figure 2: U.S. Corn Yields graph above], seed firms were able to retain their price premium over that of open-

⁴⁴¹ Supra note 435 at 5.

⁴⁴² Ibid at 11.

⁴⁴³ Ibid at 12.

⁴⁴⁴ Ibid at 16-17.

⁴⁴⁵ Ibid at 17.

⁴⁴⁶ Ibid at 8.

pollinated corn.⁴⁴⁷

Although hybrid corn was an obvious benefit to seed firms because farmers had to purchase seed for each planting, there was also a benefit for farmers that would encourage firms to maintain a high level of R&D for this product. That farmer benefit was the high quality of a product that contained genetic improvements necessary to maintain product demand.

It would appear that in the case of GURT, the benefit to the seed firm would be very much the same as occurred in the case of hybrid corn. The question is, what is the farmer level benefit that would initiate significant increases in R&D should this technology be commercialized? One farmer benefit is that GURT will prevent or at least limit the spread of transgenes. However, this is only really a benefit for farmers who do not wish their crops to be contaminated by GE crops. It is not an advantage for farmers using the GURT seeds.

A more financially beneficial attribute of GURT for farmers using the product could be associated with T-GURT seeds. The ability to turn GE traits on or off depending on weather and soil conditions or the requirements of the market for particular nutrient content could be the “killer app”⁴⁴⁸ that T-GURT represents.

Hybrid Corn in Argentina/Brazil : A developing world contrast

An examination of a unique situation in which two valuable crops compete for production acreage in Argentina is used here to demonstrate the innovation protection attributes of hybridization. That comparison is between soybeans and hybrid corn both grown in Argentina and Brazil. As was discussed earlier, Monsanto was unable to patent soybeans in Argentina. As a result, farmers there can save valuable GE soybean seed for replanting. In the U.S. where GE soybeans are patented, this replanting of saved seed is specifically prohibited by the TSA that

⁴⁴⁷ Ibid at 19.

⁴⁴⁸ “Killer app” is a term that originated in the early days of the personal computer industry. The term suggests that a new technology, no matter how brilliant or sophisticated will not gain widespread adoption unless there is a specific use to which it can be put. Therefore, in the early days of the personal computer industry, there was a need for a specific use for the personal computer before it would gain widespread acceptance. In the case of the computer industry, that “killer app” was the Lotus 123 accounting software that allowed a spreadsheet to completely update all of its entries when a single entry was altered. In agriculture, the consumer (farmer) has a need that may be the ability to access a specific trait such as drought resistance, and T-GURT technology may allow the farmer to fulfill that need giving the technology widespread acceptance.

farmers sign in addition to the fact that doing so infringes on the seed patent. According to Goldsmith et al. in “A Tale of Two Businesses: Intellectual Property Rights and the Marketing of Agricultural Biotechnology”, this has led to an unusual situation in which the soybean industry in Argentina has grown tremendously since the introduction of Roundup Ready (Monsanto) soybeans in 1996 (when 5.9 million hectares of soybeans were grown) while the soybean *seed* industry that developed the seeds has struggled.⁴⁴⁹

In 1998, 6.9 million hectares of soybeans were planted in Argentina as unpatented GE soybeans began to take over the industry. This increased to 17.6 million hectares in 2012.⁴⁵⁰ In contrast, 3.2 million hectares of hybrid corn was planted in Argentina in 1998 and in 2012, the figure was 3.7 million hectares.⁴⁵¹ Both of these crops are valuable and represent two of the most important crops grown in Argentina and around the world. However, corn is technologically protected by its hybrid attributes that later were enhanced with GE traits, and GE soybeans are not protected because of the inability of Monsanto to patent the value-added GE trait in Argentina.

Argentinian farmers were growing soybeans in exponentially increasing amounts to the point that the soybean seed market became three times that of the corn seed market. However the seed industry was not benefiting from this growth because of the lack of IP protection for its product as described earlier in the Monsanto/Argentina/EU.⁴⁵²

It is not just Monsanto that had this problem. Dupont Pioneer Seed Company also produces GE soybean seeds. However, there appears to be very little profit to be had in Argentina because the Monsanto GE soybeans can be saved at no cost for future plantings. Interestingly, Dupont also produces technologically protected hybrid corn.

In 2001, Dupont Pioneer had total annual sales in Argentina of \$35 million dollars. Soybean seed sales for the company were 33 times lower than corn seed sales even though the market for soybeans was one-third the size of the market for corn. The reason for this difference

⁴⁴⁹ Peter D Goldsmith, Gabriel Ramos & Carlos Steiger, “A Tale of Two Businesses: Intellectual Property Rights and the Marketing of Agricultural Biotechnology”, *Choices Magazine* (3d Quarter 2003) online: Choices Magazine<<http://www.farmdoc.illinois.edu/policy/choices/20033/2003-3-05.pdf>>.

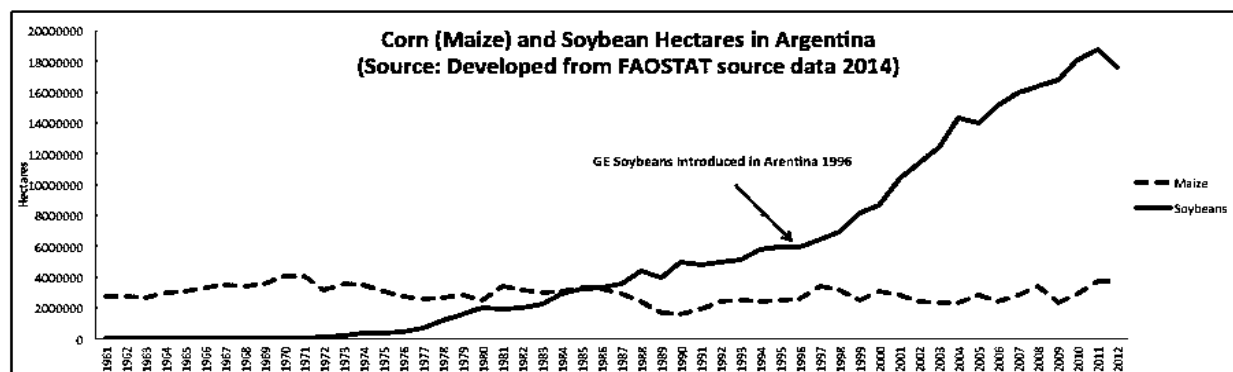
⁴⁵⁰ Supra note 414.

⁴⁵¹ Ibid.

⁴⁵² Ibid.

appears to be related to the effectiveness of the innovation protective ability of the hybrid corn seeds and the total lack of protection for the soybean seeds. Pioneer has both a soybean and a corn division in Argentina. In 2001, Pioneer controlled 18% of the corn seed market in Argentina. In spite of this small market share, corn seed earned 15 times the net profit of the soybean division even though the soybean hectares planted was over 5 times that of corn.⁴⁵³ This high level of profitability could be attributed to the technological protective capacity of hybridization and occurred while the overall acreage of corn in Argentina was steady. A graphical comparison of the crop areas of corn and soybeans is shown in Figure 5. In 2001, Argentina grew 10.4 million hectares of soybeans and in 2012 this increased to 17.6 million hectares. The corresponding values for maize were 2001: 2.8 million hectares and 2012: 3.7 million hectares.⁴⁵⁴

Figure 5: Corn and Soybean Hectares in Argentina⁴⁵⁵



The tremendous growth in the soybean crop in Argentina is the result of many factors. Certainly, the increasing demand for soy is one major factor. However, one would be hard-pressed to minimize the fact that during the period of analysis, GE soybean seeds in Argentina could be saved. Saving seed for subsequent replanting eliminates the need for farmers to purchase seed and, therefore, reduces farmer costs of production while at the same time reducing the seed firms' profitability.

⁴⁵³ Supra note 449.

⁴⁵⁴ Supra note 414.

⁴⁵⁵ Ibid.

The cost to grow a hectare (2.5 acres) of hybrid corn in Argentina is approximately \$490 USD, compared with \$320 USD per hectare for unprotected (non-patented) GE soybeans. The cost of seeds and fertilizers is much higher for corn than it is for GE soybeans in Argentina at least partially because of the use of saved GE soybeans.⁴⁵⁶ It is little wonder that Argentinian farmers are more apt to prefer planting soybeans to corn if there is a good market for both commodities. Why then do Argentine farmers not give up on the hybrid corn crops and switch to soybeans, which are freely available. According to the graph in Figure 5, growth in hybrid corn acreage seems to be stagnant. Considering that GE soybean seeds can be saved for future planting, one might expect hybrid corn planting acreage to decrease. However, this has not occurred. Part of the answer could be that while the acreage has not changed the value of the crop has increased in part because of dramatic yield increases as hybrid corn has been improved through breeding and genetic engineering. An example of this improvement in hybrid corn can be seen in Figure 6. This graph shows average corn yield in the U.S. from the Civil War era to 2005.

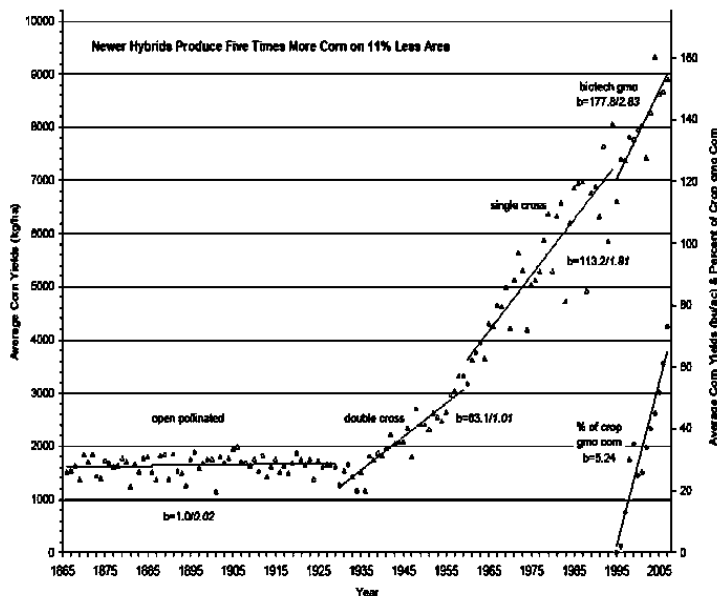


Figure 6: Average U. S. Corn Yields and Kinds of Corn, Civil War to 2007⁴⁵⁷

Periods dominated by open pollinated varieties, four parent hybrids, two parent hybrids, and genetically modified hybrids are shown. “b” values (regressions) are yield gain per year (kg/bu). USDA data compiled by E. Wellin and F. Troyer.

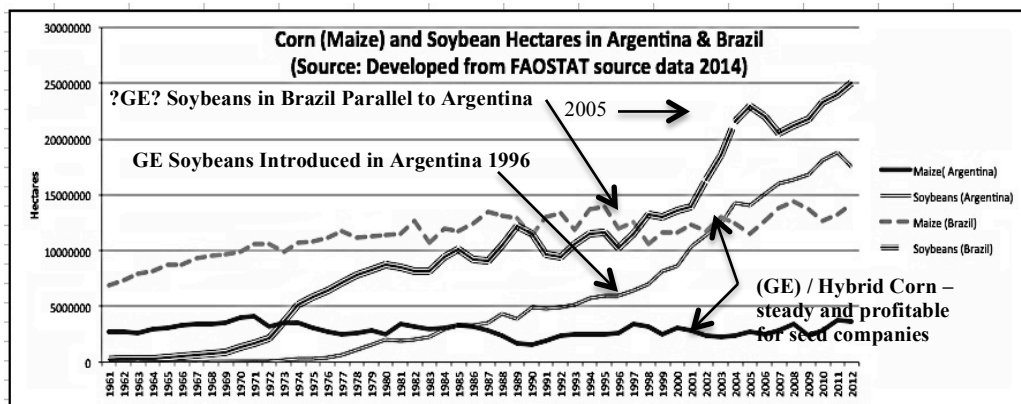
One might surmise that

⁴⁵⁶ Hugh Bronstein, “Analysis: Argentine farms to shun corn as costs rise, crop prices fall”, *Reuters* (9 April 2013) online: Reuters <<http://www.reuters.com/article/2013/04/09/us-argentina-corn-idUSBRE9380NO20130409>>.

⁴⁵⁷ Supra note 427 at 88.

perhaps the method of crop selection outlined above is unique to Argentina. To test this possibility a good choice for comparison is Brazil, a country that is also a major grower of GE soybeans and GE hybrid corn and a close neighbor of Argentina. Other than the fact that Brazil grows even greater amounts of both crops [Brazil ranks second to the U.S. in GE crop production]⁴⁵⁸ the key difference between the two countries is that GE soybeans are patented in Brazil and have been legal there since 2005.⁴⁵⁹ Interestingly, this legalization was encouraged by the realization that three-quarters of the soybeans grown in the Brazilian state of Rio Grande do Sol were from GE seeds illegally obtained from Argentina [where farmers could save seed due to the absence of a patent on the GE soybean seeds].⁴⁶⁰ In the graph below, two features stand out.

Figure 7: Corn and Soybean Hectares, Argentina and Brazil⁴⁶¹



First, both of the curves for corn and soybeans for both countries run parallel to each other for the most part. Up until 2005, the growth of GE soybeans in both countries was the equivalent of growing patent-free GE seeds. When Brazil introduced the patenting of GE soybeans in 2005 [indicated in Figure 7 as “2005”], there was a significant dip in GE soybean acreage for the next two to three years after which the curves begin to parallel each other again.

⁴⁵⁸ Supra note 415 at 11.

⁴⁵⁹ Luisa Massarani, “Monsanto may lose GM soya royalties throughout Brazil”, *Nature: International Weekly Journal of Science* (15 June 2012) online: Nature <<http://www.nature.com/news/monsanto-may-lose-gm-soya-royalties-throughout-brazil-1.10837>>.

⁴⁶⁰ Ibid.

⁴⁶¹ Supra note 414.

It is estimated that 30% of GE soybean farmers in Brazil still use illegal seed smuggled in from Argentina.⁴⁶² So, while GE soybeans are flourishing in Brazil just as they are in Argentina, the value leakage to the seed companies of the 30% illegal GE seed use in Brazil is significant. Once again, this does not occur in hybrid corn seeds whether they are genetically engineered or not, simply because the IP protective capacity of the hybrid corn is built into the seed.

In Argentina, corn represents the equivalent of a strong IPR environment even though the IP protection is technologically based. In contrast, the soybean industry exists in a weak IPR environment [for GE soybeans] The difference in innovation protection between these two crops could not be more apparent nor could the consequences of this difference be more important to the firms and the farmers involved. The innovation protective capacity of the technologically protected hybrid corn strongly resembles that which could result from the use of GURT should it ever be commercialized. In fact, GURT would not only be technologically protective but also that protection could be more absolute and more easily molded to the needs of the multinational seed firms that develop these seeds because of the previously noted very specific control that T-GURT offers to the seed companies.

Goldsmith et al. go on to conclude that Dupont Pioneer chose to invest in corn rather than soybeans because the superior IP protection available made corn seed sales significantly more profitable for the company. This case demonstrates how the level of IP protection available was an important deciding factor in determining firm behavior.⁴⁶³

The case of corn and soybeans in Argentina highlights the problem faced by the seed industry when it comes to value capture in a weak IP environment. In Argentina, the farmers have captured virtually all of the value created by GE traits in soybeans. Clearly, the industry suffers financially within Argentina while, in contrast, farming GE soybeans has become exceedingly profitable for farmers. Add to this the high international demand for soybeans and the result is that farmers in Argentina have a leg up in the soybeans business over those in developed countries where a more stringent IP environment for patented GE soybeans exists. The result is that Argentina can export soybean products at a cost that is difficult for developed

⁴⁶² Supra note 459.

⁴⁶³ Supra note 449.

country farmers to match. In contrast, the seed industry in Argentina profits very well from hybrid corn in large part because of the absolute technological protection that hybridization provides.

One can surmise that if this same technological protection were provided to GE soybeans through GURT, the industry profitability in Argentina would be significantly improved. However, there is no guarantee that the value capture from GURT GE soybeans would be more fairly distributed between the industry and the farmers.

In Argentina, a consequence of the disparity in industry value capture from GE soybeans and hybrid corn can be seen in a difference in innovation taking place in these two important crops. This assertion is defended and elaborated upon in the innovation promotion section of this thesis.

ii) GURT, Innovation Protection and the Four Example Cases

A New Paradigm

As can be seen in the Schmeiser and Bowman cases described earlier, innovation protection through the use of patents in the GE seed industry requires monitoring on the part of the patent holder. It also may require intervention by the legal system to enforce patent rights. GURT technologies, on the other hand, do not require either monitoring or intervention by the legal system. Both V-GURTS and T-GURTS employ built-in biotechnological mechanisms that eliminate the need for these costly activities on the part of the patent holder or the legal system that upholds patent rights.

In fact, the sterilization of second-generation seeds that would result from planting V-GURT seeds results in a product that is the equivalent of fully enforced, airtight patent protection. Similarly, but to a somewhat lesser extent, significant IP protection results from the absolute requirement for the use of an inducer/promoter for the activation of T-GURT traits.

GURT's prevention of seed saving for replanting is almost the equivalent of a "perfect" application of a patent. In fact, GURT would surpass the perfect application of a patent in that GURT IP protection would be both permanent and not subject to user cooperation. In a GURT-related expert paper written for the UNEP, Richard Jefferson et al. distinguish between patent and GURT IP protection by noting that unlike a patent, which has a finite term after which the

invention enters the public domain, V-GURT protection is infinite. The authors stress that this protection would be independent of any costly and irregularly applied legal requirements.⁴⁶⁴ In fact, V-GURT technology would make legal IPR protection for GE seeds redundant, at the level of the seed user [i.e. the farmer].⁴⁶⁵ As noted in the literature review, both the advocates and the opponents of GURT agree that GURT would create a level of GE seed IP protection beyond the level that could be achieved by patents alone.⁴⁶⁶

One could also legitimately conclude that the unregulated use of GURT could provide a permanent monopoly at the farmer level. One can imagine a traditional twenty-year GE seed patent coming to an end at which time the farmer may save and grow those once patented GE seed without the fear of patent infringement. At this point, there is no longer a reason for a farmer to contract with a GE seed company by signing that company's TSA. Such a contract could prevent the farmer from saving seed since this agreement explicitly prohibits this action. The result is that the off-patent GE seed is no longer a profit source for the seed firm.

In the case of GURT with this very same patent, the farmer could still not save seed when the GURT patent expires since, in the case of "terminator" seeds the seeds are sterile and will not grow. This can result in a difficult public policy situation since the social contract that permits the temporary monopoly on the patented seeds no longer exists with the permanent monopoly that results from GURT. This issue is addressed later in the thesis as a viability consideration for GURT as it compares to patents.

The existence of a patent for GURT is irrelevant to the farmer using GURT. The built-in protection provided by V-GURT would make any recourse to legal protection unnecessary at the farmer level.⁴⁶⁷

Companies with the technical ability to duplicate the self-protected seeds through some means such as reverse engineering could still threaten the value of the invention. In this

⁴⁶⁴ Richard A Jefferson et al, "Genetic Use Restriction Technologies: Technical Assessment of the Set of New Technologies which Sterilize or Reduce the Agronomic Value of Second Generation Seed, as Exemplified by U.S. Patent No. 5,723,765, and WO 94/03619", Expert paper, prepared for the Secretariat on 30 April 1999 (Annexed to UNEP/CBD/SBSTTA/4/9/Rev.1) 13 at 36.

⁴⁶⁵ Ibid at 39-40.

⁴⁶⁶ Louwaars, supra note 290 at 91-92; Oguamanam, supra note 290 at 60; Muscati, supra note 290 at 481; Shi, supra note 290 at 19.

⁴⁶⁷ Supra note 464 at 18.

circumstance, patents and trade secrets would still have a place; but they would be secondary in importance to the protective ability of the technology to prevent end-users from using the seeds contrary to the wishes of the inventor.

One other threat to the use of GURT as a means of protecting GE seed IP could occur with T-GURT seeds. With this type of GURT, an inducer/promoter is required to activate the value added trait. Technically speaking this could occur at various instances along the supply chain. The first location would be at the GE seed company that produces the seed. The second location is at the authorized seed supply company that acquires the seed from the seed creator. The final location is at the level of the farmer. At each of these stops along the supply chain it may be possible, if T-GURT design allows, to apply the inducer to seed that the farmer will use to plant the trait enhanced GE crop. Unlike the GE seed itself, the inducer is likely to be an easily identifiable chemical and the knowledge required to apply it may be easily acquired. If this chemical is a product that is in common use for other purposes and has existed for a long period of time, the product itself will very likely not be patentable. Even if the process of applying the inducer to the T-GURT seeds were patentable, the GE seed firm would be no farther ahead from an IP protection perspective than it would be if it had simply patented traditional GE seeds. In both cases, all of the costs and difficulties in protecting the company's IP would still exist. In both cases, it is the patents that would ultimately have to be protected.

How then can the GE seed inventor protect the T-GURT from value leakage? The technological protection would be weak unless the inventing seed company is responsible for applying the inducer in some unique way, or at some point in the growth cycle of the plant and before the seed left the company premises. One alternative is to have a very specific chemical that is difficult to obtain. Another possibility is to have an inducer protected by trade secret law.

It seems then that from the perspective of IP protection, V-GURT is a more secure method of IP protection than T-GURT since the latter will still require a patent on some aspect of the technology for protection but the former will not.

One may still question whether it is possible to acquire a permanent or enduring broad-based monopoly in a technologically disruptive product such as GURT. At the firm level such a monopoly is of secondary concern to the GURT innovator. The goal of GURT is not primarily to

establish a monopoly over the GURT technology as a means of sustaining a competitive advantage over rival firms. Rather, the goal is to prevent value appropriation of the value added traits within the GURT seeds at the farmer level; to “monopolize” the customer base (i.e. the farmers). This value appropriation can occur in the developed world where farmers may attempt to illegally use GE seeds but it is especially likely in the developing world where it is most difficult to effectively utilize legal IP protection.

Despite ongoing technological developments, farmers using GURT would be faced with an ongoing, absolute lack of control over GURT seeds and, whether patented or not, the GE firm would maintain an endless monopoly over its customers. This would allow the GE seed firm to continue to capture significant value from the value added traits embedded within the GURT seed.

This monopolization could occur in a number of ways. First, the value added traits are specific to the firm that develops them. Although other firms may develop similar traits, the lead-time of the original innovator due to the extended R&D time frame for GURT or GE seed development would deter new entrants. Second, GE seed firms could profit in the face of a potentially short life cycle of a GURT product by replacement with new sustaining innovative products, thereby, cannibalizing the original product yet extending the monopolization established by that original GURT offering. This would also hinder new entrants. Third, the high switching costs due to the specificity of the complementary products (farmer’s sunk costs) needed to successfully utilize specific GURT seeds would tie farmers to the existing seed or its successors. Finally, the established local and international agricultural supply networks specific to the GURT product that develop and become entrenched would also make switching a difficult proposition. This is particularly true in the case of small-scale, low-intensity farmers in the developing world who number in the millions and who are isolated from the mainstream competitive seed environment. Those hoping to introduce new technological disruption in seed technology would find it extraordinarily difficult to infiltrate this environment.

Given the new paradigm that the use of GURT predicts, one might question the effect of GURT on the Schmeiser and Bowman cases.

The Schmeiser and Bowman Cases in a GURT World

How would these two cases have been different if GURT technology had been commercialized at the time? The answer to this question is twofold. First, if the seeds had been of the V-GURT variety, neither of these cases would have existed because the infringement that occurred in both cases could not have occurred. In both cases, the farmer involved would still have been able to isolate the GE plants, and therefore the GE seeds that would develop on these plants, using the Roundup Ready herbicide. However, isolating these seeds would be of no value to the farmer. That is because the purpose of isolating the plants in both the Schmeiser and Bowman cases was to harvest viable GE seeds with value added traits without paying the added cost of purchasing the patent-protected seeds. If the seeds were V-GURT based, the isolated seeds could not be grown because they would have been sterile.

What if the seeds had been of the T-GURT variety? If the seeds were T-GURT based, the isolated seeds could be grown, but because some firm-supplied inducer or promoter would be required to activate the value-added trait(s), the second-generation crop would produce a traditional crop without the value-added results. However, if the farmer is already willing to infringe on the patent of traditional GE seeds, as both Schmeisser and Bowman affirmatively demonstrated, they would likely also have been willing to infringe on the patented process of applying an inducer to activate the second generation seeds. This could only be successful if they knew what the inducer was and how and when to apply it to the GE seeds. Since even GURT technology is patented for competitive reasons, the identification of the inducer and its method of application would be readily available. However, the ability to apply the inducer at the proper time in the seed growth cycle may not be possible in the field by the end user.

In the case of V-GURT plants, Schmeiser's claim of inadvertent contamination could not occur because the seeds from a V-GURT plant are sterile and therefore would not grow. In the case of T-GURT plants, the claims of inadvertent contamination would be of no concern to the seed company since the value-added trait would not be active so there would be no need for the company to guard their IP, which has not been violated.

From the farmer perspective, inadvertent contamination with T-GURT seeds would also be of no consequence since the value-added trait is not activated and the crop that is grown is,

therefore, a non-GE crop.

The Organic Farmer Case in a GURT World

In this case, the organic farmers are concerned that they might be sued for patent infringement for inadvertent contamination of their fields by GE seeds. V-GURT technology is specifically designed to prevent this possibility and this case would also not have found its way before a court. Just as in the Schmeiser case, should seeds from a nearby farm growing V-GURT seeds accidentally appear in a non-GE field nearby, they would not grow since they are sterile. If some stray original seeds did grow, the fact that their progeny are sterile makes this a self-limiting problem.

Contamination by T-GURT plants would be somewhat different. In the case of an inactivated T-GURT plant, the seed from this plant would grow but the value added trait would be inactive resulting in a non-GE plant. Although the plant would not produce the proteins that the value added gene had the potential to express, the gene responsible for that trait would still exist in the DNA of the GE seed. The situation would be the same as that demonstrated by the algorithm in Appendix D where the inactivated code exists in the algorithm but that code is bypassed. In the case of contamination due to a seed from an activated T-GURT plant, that seed would have the value-added trait in its DNA, and the seed would grow. However, since the next generation seed has not been activated, the resulting plant would be the same as that which would grow from an inactivated T-GURT plant.

Of course, there is also the possibility that pollen from a V- or T-GURT plant could fertilize a non-GE plant [outcrossing] as described by Visser et al. in their 2001 paper “The impact of terminator technology.”⁴⁶⁸ Visser et al. and authors such as Niels Louwaars, and Eaton and Tongeren who have been previously referenced in this thesis suggest that the resulting seeds would be either sterile or trait-inactive.⁴⁶⁹ The real problem for organic farmers would not be related to patent infringement but rather a possibility that the seeds resulting from potential contamination would invalidate the organic certification of the crop that is produced. However,

⁴⁶⁸ B Visser et al, “The impact of 'terminator' technology” (2001) 48 *Biotechnology and Development Monitor* 9.

⁴⁶⁹ *Ibid* at 12; Louwaars, *supra* note 290; *supra* note 440.

this is a questionable argument since in the case of V-GURT the resulting seeds are simply inactive and in the case of T-GURT the resulting seeds produce a non-GE plant unless intentionally activated. However, a genetic test of these seeds would indicate the presence of GE DNA.

In some countries, the GE free requirements for organic certification are strict. However, inadvertent contamination is not a major issue for certification. This contamination problem is more of a product marketing issue rather than a patent infringement issue. In 2011, the U.S. Department of Agriculture, National Organic Program (NOP) issued a memorandum in response to concerns about the impact of genetically modified organisms [GMO = GE seed] under the U.S. National Standards.

Issue: If a producer adheres to all aspects of the NOP regulations, including never utilizing genetically modified seeds, but a certifying agent tests and detects the presence of genetically modified material in the crop, is that crop's status determined to be no longer certified organic?⁴⁷⁰

Reply: Organic certification is process based...If all aspects of the organic production or handling process were followed correctly, then the presence of a detectable residue from a genetically modified organism alone does not constitute a violation of this regulation...⁴⁷¹

Issue: Are organic products free of GMO contaminants?⁴⁷²

Reply: Organic standards are process based. The NOP regulations prohibit the use of genetically modified organisms, prohibit commingling or contamination during processing and handling, and require preventative practices to avoid contact with GMOs. Organic agricultural products should have minimal if any GMO contaminants; however, organic food products do not have a zero tolerance for the presence of GMO material.⁴⁷³

In the end, the OSGATA inadvertent infringement case is unrelated to whether the crop involved is GURT-based or simply patent protected non-GURT seed. For OSGATA, this is a case that is focused on the potential threat that farmers will be sued by the GE seed firm if their

⁴⁷⁰ USDA, *Genetically Modified Organisms*, (USDA, Agricultural Marketing Service, National Organic Program, Policy Memo 11-13, 2011) online: USDA <
<https://www.ams.usda.gov/sites/default/files/media/GMO%20Policy%20Training%202012.pdf> > at 6.

⁴⁷¹ Ibid at 7.

⁴⁷² Ibid at 17.

⁴⁷³ Ibid.

fields are inadvertently contaminated by GE seed. As the previous discussion of this case demonstrated, the courts agreed that, based on Monsanto's website assurance that farmers will not be sued for inadvertent contamination, the potential threat to organic farmers does not exist. Also, the worry over the loss of organic certification if contamination does occur is minimal since organic certification is process-based.

The Argentina Case in a GURT World

The problem that Monsanto had in not being able to patent their GE soybeans in Argentina would not have been an issue for the company in the Argentina Case noted above if the seeds had been of the V-GURT variety. There would have been no need to patent the V-GURT protected GE seeds to prevent Monsanto's loss of value capture to Argentinian farmers since the seeds are self-protecting at the farmer level. As such, Monsanto would have been able to capture a great deal of value if Argentine farmers had used these seeds to the same degree as the non-V-GURT seeds. The seeds would have had to be repurchased for each growing season.

Of course, this raises the question of whether the V-GURT protected seeds would have diffused to the same degree throughout Argentina if farmers there were forced to purchase the seeds for each planting. As it is, it is not unreasonable to assume that the vast extent of this seed diffusion in Argentina occurred because farmers were able to save Monsanto seeds that had superior traits for which they were not required to pay at each planting.

Farmers in developed nations such as the U.S. or Canada are paying for new seeds for each planting season and are also subject to the strict terms and conditions of the Monsanto (or other GE seed firm) TSA contract. On the other hand, Argentinian farmers were not only saving the cost of new seed each planting season but also were free of those terms and conditions.

Would the situation have been different had the GE seeds been of the T-GURT variety? That would depend to some degree on whether or not the inducer was known, readily available, easily utilized and whether it was patented. First, the simpler question is related to whether the inducer was patented. If the inducer was patented, there would be little value, at the farmer level, for the seeds themselves to be patented since if they are grown without the inducer application, they result in a normal non-GE plant. With a patented inducer, the IP protective capacity of the

T-GURT seeds would be the same as with traditional patented GE seeds if farmers observed the patent. Monsanto would have been able to capture substantial value if farmers in Argentina considered the GE traits to be cost effective. The amount of value would depend on the strength of the IP environment in Argentina [a borderline developing country]. According to the International Property Rights Index 2014, Argentina scores quite low. “Argentina’s overall IPRI score has remained relatively stable over the past five years and has remained unchanged from 2013-2014, receiving a score of 4.4. Argentina ranks 83rd amongst countries studied and ranks 18th among Latin American countries.”⁴⁷⁴

If the inducer was not patented, let us say, for the same reason that the seeds were not patented [i.e. a strategic error on the part of the company], then the situation could have been similar to the actual case in Argentina in which the GE seeds were not patented. If the inducer, in this case, were readily available and easily applicable, the case would be identical.

If the inducer was not patented and it was not readily available or applicable, the company’s value capture would depend on the degree of availability and complexity of application.

In the end, the Argentina case would not occur if the GE seeds were of the V-GURT variety; it would be unlikely to occur to the same degree if the GE seeds were of the T-GURT variety and the inducer were patented; and it would likely have occurred in the same way with T-GURT seeds and an unpatented and easily and readily applicable inducer.

5.1 Innovation Promotion: Patents and GURTS

This section begins by setting the stage for a comparison of the current innovation promotion capacity of patents and the innovation promotion potential of GURT. The positioning of knowledge as an innovation precursor as well as a product of innovation is followed by an investigation of R&D and knowledge as key innovation promotion indicators for both GURT and non-GURT (i.e. patented only) GE seeds. Within this context, hybrid corn is revisited, as are farmers and GE seed firms. The R&D potential of GURT is followed by an assessment of

⁴⁷⁴ *International Property Rights Index 2015*, online:IPRI<<http://www.internationalpropertyrightsindex.org/>>.

commercialization as an indicator of innovation promotion as it applies to GURT and non-GURT GE seeds.

The long history of crop research in OECD countries gives this organization significant credibility in addressing issues related to agricultural research initiatives and their effects on relevant stakeholders. Other organizations with high levels of credibility due to their past efforts in agricultural data collection, policy development and regulatory input are the FAO, USDA and WIPO. Data produced by these organizations plays a key role in this portion of the thesis.

Innovation promotion has long been considered a byproduct of innovation protection. The protection of innovation allows for value capture and value capture promotes further innovation. This is a familiar scenario in most industries. Given this, the degree to which the patenting of GE seeds or the technology embedded in GURT seeds protects innovation may be suggestive of the degree to which these alternatives will promote innovation. However, demonstrating innovation promotion requires that there must be a demonstration of innovation output. As a result, one must look at the indicators of innovation output.

R&D and product commercialization are the most useful indicators of innovation for this thesis because they can be measured either quantitatively or qualitatively. While it is true that R&D expenditure is an input of innovation, it is also true that successful innovation, especially in a disruptive technology such as GE seeds, can act to spur further R&D and it is, therefore, also an output of innovation. As such, innovation promotion can be demonstrated by an increase in R&D output.

One aspect of innovation promotion that directly leads to increased R&D is knowledge diffusion. Knowledge diffusion provides those, other than the inventor of a product, with the ability to take the next inventive step based on information disseminated as a result of the invention of a product or process. The literature review notes that Muscati, Oguamanem, Srinivasan and Thirtle all emphasize the importance of patents as a source of knowledge diffusion. In addition, Shipp et al. highlight knowledge as Attribute 3 and Attribute 9 in their list of ten attributes of innovation.⁴⁷⁵ Knowledge diffusion as a subset of R&D is both an output indicator and a required input for innovation.

⁴⁷⁵ Supra note 20 at II-1-II-8.

Successful product commercialization is also a clearly identifiable output indicator of innovation. Shipp et al. list commercialization within Attribute 10 as an attribute of innovation.⁴⁷⁶ If the patenting of GE seeds or the use of GURT promotes innovation, this indicator should demonstrate this. After all, based on the attributes of innovation previously outlined, invention without successful commercialization is arguably not innovation but simply an interesting idea.

A further output indicator of innovation is the number of patents issued, but, as discussed earlier, patenting occurs for reasons other than simply IP protection such as strategically preventing rivals from commercializing a product or process. Innovation is closely aligned with commercialization in the definitions section of this thesis, making patenting, which does not provide for a right to commercialize, only a loose indicator of innovation. Patenting is more of an indicator of invention, and the difference between invention and innovation is clearly outlined earlier in this thesis.

There are other innovation indicators identified in the literature such as innovation surveys, networks, clusters and system dynamics.⁴⁷⁷ These seem useful for discussing the existence of innovation rather than its promotion, and they are therefore not addressed in this thesis.

Earlier in this thesis, there is an extensive elaboration of other research indicating that patents promote innovation in other industries. Studies by Mansfield and Lerner are presented to show that patenting has, in fact, promoted innovation in the pharmaceutical industry. From this, it is argued that there are significant similarities between the pharmaceutical industry and the GE seed industry and that, based on these similarities, it seems logical to conclude that patents also promote innovation in the GE seed industry.

Because GURT GE seeds are not commercialized, there can be no empirical evidence to indicate that this technology will promote innovation. One can certainly not look at the output of R&D or the level of commercialization that has occurred from GURT. What one can say is that the biological lockout technology imbedded in GURT protects innovation and, therefore, on this

⁴⁷⁶ Ibid.

⁴⁷⁷ Supra note 20.

basis should act to promote innovation.

For innovation promotion, the characteristics of GURT, and how they compare to those of patents, can provide some clues as to whether and how GURT technology will affect innovation in GE seeds. In addition, there is the case of hybrid corn, which represents an existing method of technological innovation protection that has existed since the early 20th century. One can look at the case of hybrid corn for clues as to the potential for GURT to promote innovation in the same way that hybrid corn acted as a model for innovation protection. First, however, it is important to understand what type of a “good” that GE seeds and the knowledge that they contain represent. This provides a basis for understanding the R&D output potential for both GURT and non-GURT GE seeds.

Knowledge as a Toll Good

The knowledge produced or output created by R&D is just as important as that required to take part in R&D (i.e. an R&D input). The knowledge incorporated in a GE seed can be thought of as a product in the same way as the seed itself. This knowledge, just like the GE seed, can be classified on the basis of excludability and rivalry.

Most goods thought of in economics are “rival” meaning that they can only be used by one individual at a time. So, for example, when one drives a vehicle, one individual drives it. No one else is able to do so at the same time. In contrast, many can use a non-rival good without limit and without incurring a marginal cost.⁴⁷⁸ An example of this would be a public highway.

Another important term classifying goods in economics is excludability.⁴⁷⁹ A good is excludable if it is possible to prevent its use by those who have not purchased it. An example of this would be a traditional *toll* highway. Without payment, a driver cannot use the toll highway.

Where does knowledge fit into the excludability/rivalry model and why is this important for the discussion of patents and GURT? First, knowledge is often thought of as a classic public good just like a public traffic signal due to its non-excludability and non-rivalry. As such, this

⁴⁷⁸ Richard Gray, “Intellectual property rights and the role of public and levy-funded research: Some lessons from international experience” (2012) in OECD, *Improving Agricultural Knowledge and Innovation Systems: OECD Conference Proceedings*, (Paris: OECD Publishing, 2012), online: OECD <<http://dx.doi.org/10.1787/9789264167445-en>> at 187.

⁴⁷⁹ Ibid.

type of knowledge is unlikely to be produced by private industry because there is no profit to be made from its creation. However, the knowledge produced in private industry is, ideally from the industry's perspective, protected by IPRs. This makes this type of knowledge a toll good. That is, it is non-rival and excludable, like a toll highway.⁴⁸⁰

Because it is non-rival, a knowledge toll good that represents the primary input in a final product only has to be produced once and then there can be an unlimited output at minimal cost. Looking at GE seeds, the IPR protected genetic knowledge only has to be produced once and then it can be incorporated endlessly into GE seeds containing this knowledge, at virtually no additional cost in knowledge creation.⁴⁸¹

GE seeds, which are currently patented only, disclose this important knowledge in order to obtain the patent and this process increases the diffusion of some types of fundamental knowledge. To some degree, this acts as a counterweight to the lack of diffusion of fundamental knowledge that results when a process needed to take "the next step" is patented and thereby prevents others from taking that next step.

As a form of IP protection, GURT is also a toll good, however, because there is no actual requirement to patent the technology to protect it, the lack of a disclosure requirement inherent in the patenting process would diminish the diffusion of direct fundamental knowledge. Currently, all GURT GE seeds are patented, meaning that the diffusion of fundamental knowledge for this technology should be no different than that for patent-only GE seeds. However, at the farmer level, there would be no capacity to produce GURT plants without the help of the seed firms. This is in contrast to the situation that exists with patent-only protected GE seeds, which can be grown by anyone legally or illegally. So, the primary difference between GURT GE seeds and patent-only protected GE seeds is that while the knowledge contained in both is a toll good (i.e. both are non-rival, both are excludable) the level of excludability in GURT seeds is far superior to that of patented GE seeds.

The fact that GE seeds and the knowledge they contain are both toll goods should provide a basis for understanding the degree to which R&D in this aspect of agricultural biotechnology

⁴⁸⁰ Ibid.

⁴⁸¹ Ibid.

takes place in the private or public sectors. The assumption is that the toll good nature of GE seeds should encourage private sector R&D at the expense of the public sector R&D.⁴⁸² This should affect the structure of global research such that R&D in GE biotechnology should be greatest in the private sector in free market economies. Is this in fact the case?

5.1.1 Research and Development (R&D) and Knowledge Diffusion

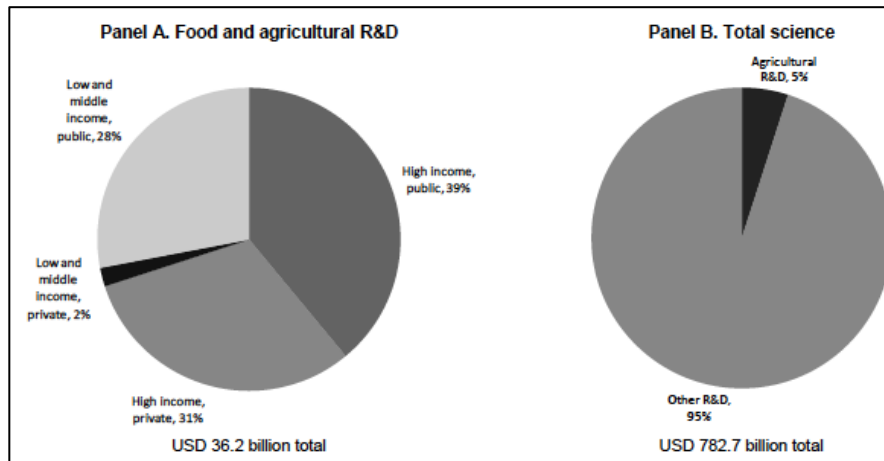
i) Public/Private innovation promotion: where is the R&D focus?

The “OECD 2012 Conference Proceedings on Improving Agricultural Knowledge and Innovation Systems” contains a section on global and U.S. trends in agricultural R&D that deals with the structure of global research in 2000. Figure 8 below, which is reproduced from that report, was constructed five years after GE seed commercialization. Panel A represents the small wedge identified in Panel B as “Total Agricultural Research”. At the time of this conference, public agricultural research in low and middle-income countries (i.e. primarily developing countries) was 28% of total agricultural R&D. The corresponding figure for high-income countries (i.e. developed countries) was 39%. This is a significant difference. However, the difference in the private sector for developing countries (2%) and developed countries (31%) is much more revealing.⁴⁸³ These levels of private sector research demonstrate that given a choice, private sector research tends to occur in developed countries. There could be many reasons for this such as the legal and political environment including the existence and quality of physical and IP rights. Other factors could include the quality of research facilities, the closeness of related research facilities or resources, and the availability of human resources.

⁴⁸² Ibid at 190.

⁴⁸³ Philip G Pardey & Julian M. Alston, “Global and US trends in agricultural R&D in a global food security setting” (2011) in OECD, *Improving Agricultural Knowledge and Innovation Systems: OECD Conference Proceedings* (Paris: OECD Publishing, 2012), online: OECD <<http://dx.doi.org/10.1787/9789264167445-en>> at 25.

Figure 8: Structure of Global Research 2005⁴⁸⁴



Note: All data denominated in 2005 international prices using purchasing power parity indexes. Former Soviet Union and Eastern European countries excluded for lack of data.

Source: Pardey and Chan-Kang (2001, beta version) for private and public food agricultural R&D series for high-income countries; Beintema and Stads (2008) for public food and agricultural R&D for developing countries, and Dehmer and Pardey (2011) for total science spending estimates for all countries.

One important piece of data relevant to this research would be a demonstrated correlation between the amount of agricultural R&D that takes place in a country and the strength of the IP environment within that country. This correlation would not be a surprising revelation given that the excludability aspect of a toll good is what underpins private sector R&D. A weak IP environment should discourage private sector R&D, and a strong IP environment should encourage R&D. Specifically, the strength of a country's patent laws is based on what is patentable; the restrictions, enforcement and duration of patent rights; and country participation in international IP treaties and organizations.

Appendix M, taken from the 2013 International Property Rights Index Report, demonstrates that, in general, the nations of the developing world have lower IPR scores than those in the developed world. These IPR scores are based on three factors: the protection of IPRs (Source: World Economic Forum's 2012-2013 Global Competitive Index);⁴⁸⁵ patent protection

⁴⁸⁴ Ibid.

⁴⁸⁵ *International Property Rights Index: 2013 Report* (2013) online: Property Rights Alliance <<http://internationalpropertyrightsindex.org>> at 16.

(Source: Ginarte-Park 2005 Index of Patent Rights);⁴⁸⁶ and copyright piracy (Source: International Intellectual Property Alliance's 2013 Special 301 Report, Ninth Annual BSA and IDC Global Software Piracy Study (2011)).⁴⁸⁷

Figure 8 reveals that the private sector conducts approximately 40% of global agricultural R&D, and significantly 95% of that takes place in developed countries where IPRs are strongest. The correlation between agricultural R&D and the strength of the IP environment appears to be a positive one.

Keith Fuglie, writing for the USDA Economic Research Service in a paper titled, "Research Investments and Market Structure in the Food Processing, Agricultural Input, and Biofuel Industries Worldwide" commented that the importance of the private sector in GE seed R&D is demonstrated by the fact that, in 2007, at least five different firms had a higher level of crop R&D investment than the USDA's Agricultural Research Service (ARS), which is the largest public sector research agency. The largest private sector investments were by Bayer (\$978M U.S.), Syngenta (\$830M U.S.), and Monsanto (\$770M U.S.). By 2013, these three firms were investing a total of over \$4 billion in agricultural R&D.⁴⁸⁸ Private firms are unlikely to invest vast sums of money in R&D without expecting a return on this investment.

Since the private sector is very concerned with value capture, one might assume that any increase in R&D related to the introduction of GURT would take place in developed countries with strong IP environments. While this may be true initially, it may not be the case in the long term. The fact that GURT takes IP protection out of the control of local governments could go a long way to increasing agricultural biotechnology R&D by private multinational firms in developing countries. This is understandable considering that one of the factors limiting the level of R&D investment in developing countries is their variable and often weak IP environments.

Looking at public versus private sector R&D and developing world versus developed

⁴⁸⁶ Ibid.

⁴⁸⁷ Ibid.

⁴⁸⁸ USDA, *Research Investments and Market Structure in the Food Processing, Agricultural Input, and Biofuel Industries Worldwide* by Keith O Fuglie et al (ERR-130) (Washington D.C.: USDA, Economic Research Service, 2011), online: USDA, Economic Research Service < <http://www.ers.usda.gov/publications/err-economic-research-report/err130.aspx>> at 18-19.

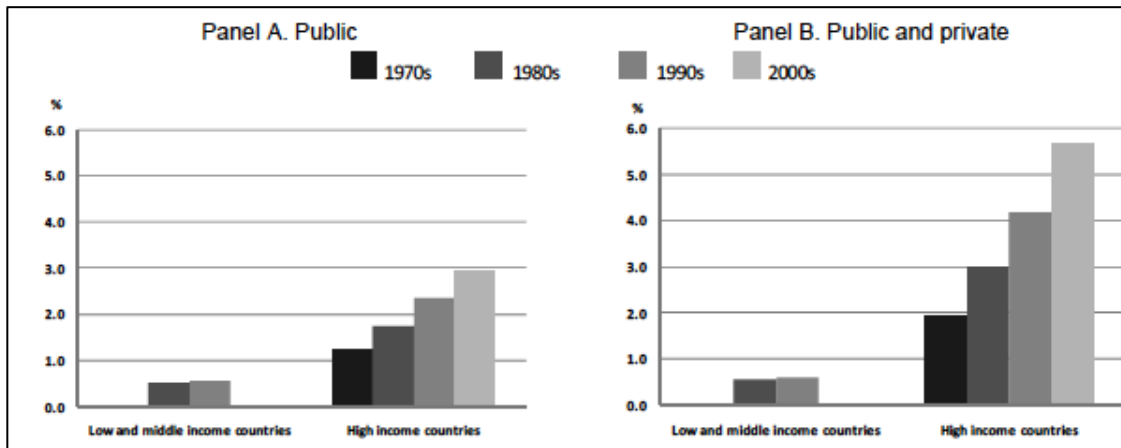
world R&D as two separate phenomena is useful in identifying the important aspects of these two classifications of R&D. However, in each case, R&D cannot be effectively understood as separate silos that do not interact. That is, R&D in the public and private sectors overlap just as R&D in the developing world and the developed world overlap. One inevitably has an effect on the other. For example, private sector R&D in a developed country may emphasize certain high-value crops yet local low-value crops may have social benefits that the government wishes to encourage. The private sector may avoid the latter products forcing the public sector to respond to this market failure by addressing the issue directly through public sector R&D.

In contrast, a high level of public sector involvement by governments in developing countries may disadvantage (crowd out) the private sector in its attempts to access human and financial capital needed to function in that environment. Governments may have to incentivize the private sector to participate in that environment leading to a loss of some of the limited funding available to the public sector.

The data provided in Chapter 1 of the OECD 2012 Conference Proceedings and displayed here as Figure 9, identifies the disparity between rich country and poor country agricultural research intensity⁴⁸⁹ in both private and public sectors. In 2000, the developing country group had an overall research intensity of 0.54% as compared to developed countries where the intensity ratio was 5.28%. The key takeaways from this graph are twofold. First, there is the absence of any significant change in research intensity since the 1970s in low and middle-income countries as compared to the large increase in high-income countries, especially in the private sector. Second, this major change in the private sector occurred between 1990 and 2000 when agricultural biotechnology, and specifically GE seed biotechnology protected by patents, was commercialized.

⁴⁸⁹ Research intensity is the ratio of expenditures on R&D to sales by firms or the ratio of expenditures on R&D to GDP by countries.

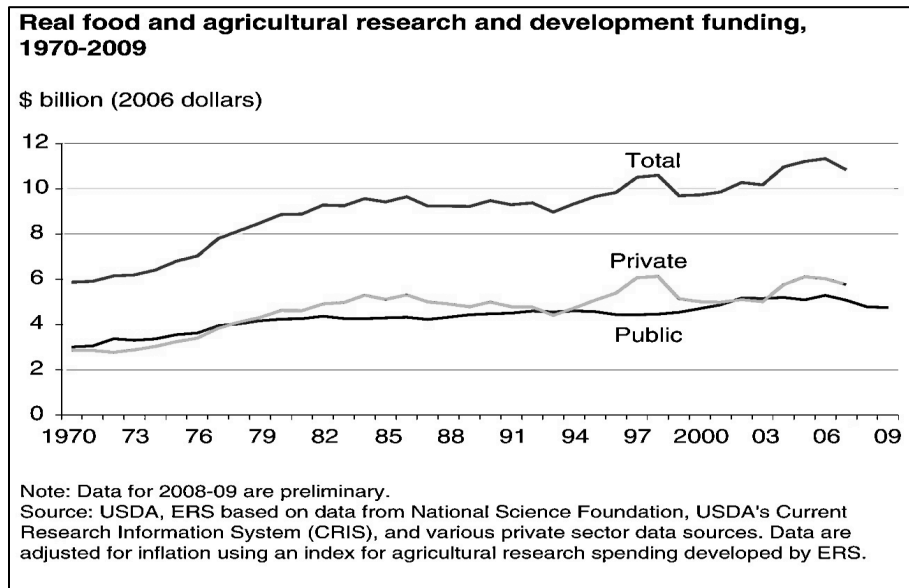
Figure 9: Agricultural Research Intensity⁴⁹⁰



Not only does the vast majority of R&D in agricultural biotechnology take place in the developed world but also a significant portion of this R&D takes place in the U.S. The USDA collects a large amount of data on public and private research in agriculture. Figure 10 gives a general overview of what is taking place in R&D in the U.S. private and public sectors. As a developed nation, the U.S. pattern of public versus private agricultural investment follows the global pattern for developed nations. That is, both private and public levels of research are significant.

⁴⁹⁰ Supra note 483 at 31.

Figure 10: U.S. Real Food and Agricultural R&D Funding 1970 – 2009⁴⁹¹



A noteworthy feature of this graph is the spike that occurs on the private sector curve between 1995 and 2000. This time frame directly corresponds to the initial commercialization of patented GE seeds and the entry of biotech firms into this aspect of agriculture. Once again there is a correlation between IP protected (patented) GE seed commercialization and a bump in agricultural R&D in the private sector. As we will soon see, there are a number of other indicators that this conclusion is valid, even though the patenting of GE seeds does not provide absolute IP protection.

One may reasonably ask if, in fact, this increase in private sector R&D was prompted by the commercialization of IP protected GE seeds, why did private sector R&D fall off shortly after the “bump up.” If GE seed development was flourishing and the R&D needed for this to continue was still important, it seems reasonable that R&D would continue to increase. One possible answer seems to be that the earlier described concentration in the industry decreased the immediate need for each firm to continue a high level of R&D because mergers and acquisitions could lead to the acquisition of R&D assets. In fact, as previously noted, mergers and acquisitions were a strong feature in this industry at this time.

⁴⁹¹ Ibid at 27.

A 2011 paper prepared for the USDA, Economic Resource Service confirms this increase in concentration by providing data that shows a large increase in the Herfindahl Index (1994: 171; 2009: 991).⁴⁹² This increase in concentration is due to a number of factors, the most relevant for this discussion is that it is likely that GE firms were seeking out technology in order to limit the lag time and cost of developing the technology on their own.⁴⁹³ The ability to purchase the needed technology lowered the necessity of carrying out those aspects of R&D that could be acquired by the takeover of firms that already possessed it. The result was the temporary decrease in R&D intensity after 2000.⁴⁹⁴

It seems reasonable to assume that the lifting of the moratorium on GURT would result in a similar surge in R&D intensity; however, because so much concentration has already occurred in the industry there may be minimal potential for further concentration. It may then be less likely that technology will be derived from acquisitions of firms and more likely that existing firms will be the source of that new technology. That is, private sector R&D would increase to meet the demands for innovation.

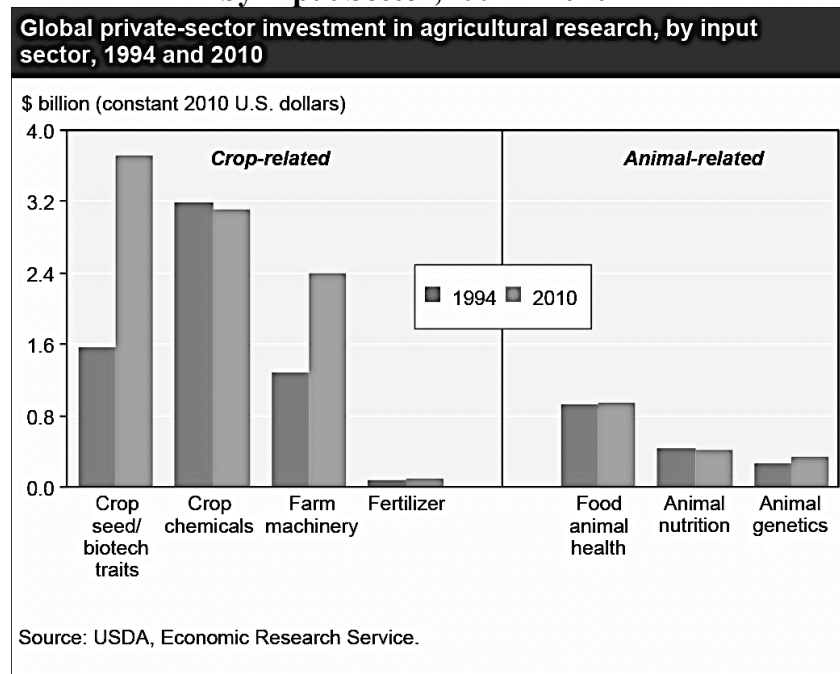
Another way to demonstrate that the surge in private sector R&D from 1995 to 2000 shown in Figure 10 is related to patented GE seeds and the improved value capture that they allowed is in Figure 11 below. What we can see from this 2010 graph from the USDA is that R&D is shifting from crop chemicals [i.e. herbicides and pesticides] to a focus on seeds and biotech traits. As in any other field, R&D in the private sector will focus on the area that will lead to the greatest profitability. A more secure protection for IP will reduce value leakage and the resulting increase in value capture translates directly into an increase in profitability. The commercialization of GE seeds after 1994 caused an explosion in private sector research in this field. The following graph highlights the key timeframe when the commercialization of patented GE seeds caused a spike in R&D especially by private firms.

⁴⁹² Supra note 488 at 15; The Herfindahl Index is a measure of the size of firms in relation to the industry. The larger the index number, the greater the market power of firms and the lower the level of competition.

⁴⁹³ Supra note 488 at 15.

⁴⁹⁴ Ibid at 16.

Figure 11: Global Private Sector Investment in Agricultural Research, by Input Sector, 1994 – 2010⁴⁹⁵



According to Figure 11, obtained from the USDA Economic Research Service, total worldwide private R&D spending on agricultural inputs increased by \$4.4 billion to \$11 billion in 2010 from the level in 1994. This represents a 3.6% [1.4% adjusted for inflation] average annual growth rate. As the graph demonstrates, most of this increase was crop-related improvement. Significantly, the area of greatest growth was for crop seed and biotechnology traits. There is no indication, and it has not been argued, that this dramatic increase in seed-biotechnology research expenditures was due to anything other than the commercialization of GE seeds. In addition, based on Mansfield’s study that was discussed earlier, the increase in this area of high tech R&D would have been unlikely without a high level of IP protection.

It is not surprising then that GE seed firms and organizations that represent them have concluded that increased IP protection will enhance R&D expenditures and, therefore,

⁴⁹⁵ USDA, *Global private-sector agricultural research increasing for crop seeds & biotechnology*, (2014) online: USDA, Economic Research Service < <http://www.ers.usda.gov/data-products/chart-gallery/detail.aspx?chartId=48125>>.

innovation on the part of GE seed firms.

GURT, as the alternative to patents, is the specific form of enhanced IP protection under consideration. GURT is described in a 2003 paper presented to the Convention on Biological Diversity Ad Hoc Technical Expert Group on the “Impact of Genetic Use Restriction Technologies on Smallholder Farmers, Indigenous People, and Local Communities as highly protective of IP.”⁴⁹⁶ Therefore, it is reasonable for the International Seed Federation (ISF) that represents the seed industry to argue, as they have, that the development and commercialization of GURT could have many benefits such as:

“...GURTs could be an interesting technical alternative to stimulate plant-breeding activities... Non-viable seed produced on V-GURT plants will prevent the possibility of volunteer plants, a major problem in areas where rotation is practiced... V-GURTs have the potential to be used in the development of entirely new uses for plants and animals, which will enable the farmer to address new markets... V-GURTs can be regarded as a possible technical solution to concerns about the possible adverse effect of Living Modified Organisms (LMOs) on the conservation and sustainable use of biological diversity... The induced sterility in seed using GURTs cannot spread. By its very nature, sterile seed cannot reproduce and thereby produce pollen necessary for propagation. Biodiversity is not threatened... GURTs target modern varieties, in particular transgenic varieties of self-pollinated crops. They are not at all aimed at being introduced in landraces and local varieties used by small- scale subsistence farmers...”⁴⁹⁷

The previously discussed legal (i.e. Schmeisser, Bowman) cases involving individual farmers, demonstrate that patent protection is not air-tight in that it does not physically prevent someone from attempting to circumvent GE seed IP protection. It is unlikely that the lack of iron-clad IP protection would lead a firm to reduce R&D expenditures in the developed world since the IP protection offered is strong enough and illegal activity is small in relation to overall legal activity.

⁴⁹⁶ UNEP/CBD, *Report of the Ad Hoc Technical Expert Group Meeting on the Potential Impact of GURTs on Smallholder Farmers, Indigenous & Local Communities and Farmers Rights* (9th meeting SBSTTA Montreal, 10-14 November 2003; 3d meeting CBD/WG8J 8-12 Montreal, December 2003) UNEP/CBD/SBSTTA/9/INF/6-; UNEP/CBD/WG8J/3/INF/2 (29 September 2003) at para 21(b).

⁴⁹⁷ International Seed Federation, *Genetic Use Restriction Technologies* (2003), online: ISF<http://www.worldseed.org/wp-content/uploads/2015/10/Genetic_Use_Restriction_Technologies_20030611_En1.pdf>.

What about the developing world where private sector investment is already very low? International agreements such as TRIPS attempt to make the developing world attractive for GE biotechnology investment by private firms. However, by limiting investment in these regions, these private firms demonstrate their lack of faith in the IP environment of developing countries to deliver increased and secure value capture.

More significantly, there are examples, such as the Argentina soybean case, where GE seed firms have been unable to attach IP rights to an otherwise successfully patented product due to unique national regulatory issues. The inability of Monsanto to protect its IP early on in Argentina led to significant “free riding” there with one result being a cut in firm R&D in that country. This conflict between Monsanto and Argentine farmers over seed saving was a well-reported topic by Marcela Valente of the Inter Press Service in 2014.⁴⁹⁸ It is likely that had Monsanto been able to introduce a GURT based soybean, the IP issue would not have arisen to the same degree and the fear of value leakage would not have been a source of R&D reduction.

The importance of private sector R&D in agriculture and its reliance on strong IPRs can be demonstrated further by some additional statistics. First, 15,000 scientists work for the world's top ten plant science companies. These same companies spend a total of \$5 billion U.S. on R&D each year.⁴⁹⁹

The “2012 OECD Conference on Improving Agricultural Knowledge and Innovation Systems” has a great deal to say about the role of the private sector in public –private partnerships. While differentiating the profit-seeking goals of the private sector from the concern of the public sector in finding solutions to broader public needs, the conference stressed that the private sector role is vital to stimulating agricultural R&D.⁵⁰⁰ The conference notes also highlight the major role of IPRs in promoting innovation. The resulting return on investment is specifically noted as key to generating incentives and preventing the “free-riding” that inevitably

⁴⁹⁸ Marcela Valente, “Monsanto Fights with Farmers in Argentina over Seed Saving” *Inter Press Service* (10 February 2014) online: Organic Consumers Association <https://www.organicconsumers.org/old_articles/monsanto/argentina021204.php>.

⁴⁹⁹ Dominic Muyltermans, “Public-private partnerships: The role of the private sector” (2011) in OECD. *Improving Agricultural Knowledge and Innovation Systems: OECD Conference Proceedings* (Paris: OECD Publishing, 2012), online: OECD <<http://dx.doi.org/10.1787/9789264167445-en>> at 280.

⁵⁰⁰ *Ibid.*

leads to a disincentive to invest.⁵⁰¹ When referring to IPRs here, the conference proceedings are referring to all IP protective mechanism available with special attention to patents. However, from a purely innovation promotion perspective, if legal innovation protection incentivizes the private sector to increase R&D investment because of its ability to reduce “free-riding” would R&D investment not increase further if the level of innovation protection could be further improved? There is no predictable answer to this question. However, it seems reasonable that for the private sector the answer is likely yes, and that GURT would accomplish this protective goal for private industry.

But it is not only the private sector that can benefit from increased R&D from improved IP protection. The conference notes that the returns generated from commercialized technologies in developed countries can then drive R&D in developing countries by supporting and subsidizing the publically funded R&D system. The conference proceedings are quite clear in arguing that without adequate private sector return on investment, the cost of publically funded R&D would inevitably increase as the private sector reduced their R&D investments.⁵⁰² With the limited funds available in the public system, especially in the developing countries, it is probable that this would decrease the level of publically funded R&D. How could GURT affect this public sector R&D issue? GURT has the capacity to incentivize private sector R&D in developing countries because the risk of loss of control of a company’s IP is significantly reduced since that IP does not completely or even necessarily depend on the local IP environment.

In the OECD Conference Proceedings, it is also reported that, private sector inventors are unable to appropriate all of the benefits of their research because at least some of the results of that research has a public-good component to it.⁵⁰³ According to the Proceedings, this has been the primary reason for private-sector underinvestment in agricultural R&D.⁵⁰⁴ This is not to say that the level of private-sector investment has not been high, but rather that there is a significant potential for increased investment.

⁵⁰¹ Ibid.

⁵⁰² Ibid.

⁵⁰³ Supra note 483 at 34.

⁵⁰⁴ Ibid.

The 2011 USDA, Economic Resource Service paper on “Research Investments and Market Structure in the Food Processing, Agricultural Input, and Biofuels Industries Worldwide” states that several factors have and will continue to influence the level and composition of R&D investment by the private sector in seed biotechnology:

- 1) Potential for future market expansion.⁵⁰⁵ This includes the greater use of improved seed, especially of the GE variety. It also includes farmer and consumer attitudes toward GE crops. In addition, market expansion will be tied to specific biotechnological applications of GE seed that allows for improved crop qualities related to nutritional content or crop survivability in harsh environments.
- 2) Industry structure, seed pricing, and advancements in seed-biotechnology.⁵⁰⁶ It has already been demonstrated that these issues have been affected by the introduction of GE seeds. GURT will also affect these issues, however, predicting how is a matter of speculation.
- 3) Interaction between other policies and seed-biotechnology R&D.⁵⁰⁷ Of particular concern here is the potential for anti-competitive behavior that has been previously discussed in relation to GE seeds. This becomes a larger issue with GURT because the patenting of non-GURT GE seeds allows for some societal control over the temporary monopoly presented to the GE seed firms in exchange for invention disclosure. GURT, without new methods of regulation, increases the severity of any anti-competitive behavior.

The potential for GURT to increase innovation promotion can be evaluated theoretically. However, to judge this technology as a potential alternative to non-GURT patented GE seeds, a practical example of an existing similar agricultural technology would be useful. As has been shown previously in relation to innovation protection, hybrid corn is an existing product that technologically protects seed IP. Once again, hybrid seeds should be able to predict to some degree the effect of GURT on innovation promotion. In fact, the OECD Conference Proceedings

⁵⁰⁵ Supra note 488 at 44.

⁵⁰⁶ Ibid.

⁵⁰⁷ Ibid.

specifically mention options such as hybrid crops and patents as promoters of innovation.⁵⁰⁸

ii) Hybrid corn and Innovation Promotion through increased R&D

Hybrid corn, with its seventy-year track record, is the best-known example of technological IP protection in agriculture prior to the development of GURT. As such, hybrid corn can provide a historical context on the effects of the technological protection of IP on innovation promotion. For example, how has hybrid corn affected agricultural R&D? First of all, virtually all corn grown today is hybrid corn so when one speaks of corn it is hybrid corn that is being discussed.

The USDA collects and compiles a great deal of data on U.S. agriculture and is a source for some very compelling information establishing the unusually high level of hybrid corn R&D. The data that is particularly intriguing was gathered before 1996 when there was no GE-based hybrid corn [there was only non-GE hybrid corn] or any other GE seed product. From this data one can, therefore, examine agricultural R&D prior to the biotechnological advances of genetic engineering. The particular document produced by the USDA that fits this timeline is, “Agricultural Research and Development: Public and Private Investments Under Alternative Markets and Institutions”⁵⁰⁹ Within this document, the chapter titled, “Incentives for Private Investment in Agricultural Research” is especially revealing.

This document contains information on the level of value capture for both hybrid and non-hybrid crops and the corresponding levels of R&D that took place. At the time this data was produced there were two main hybrid crops, corn and sorghum. However, sorghum represented less than 10% of the seed sales that were derived from corn (corn \$1,031M USD; sorghum \$90M USD).⁵¹⁰

Seed company value capture from hybrid seed ranged from 35% to 48% with 52% to

⁵⁰⁸ Supra note 483 at 34.

⁵⁰⁹ USDA, *Agricultural Research and Development: Public and Private Investments Under Alternative Markets and Institutions* by Keith O Fuglie et al (AER-735), (Washington D.C.: USDA, Economic Research Service, 1996) online: USDA, Economic Research Service <
<http://www.ers.usda.gov/publications/aer-agricultural-economic-report/aer735.aspx>>.

⁵¹⁰ Ibid at 43.

65% going to the farmers.⁵¹¹ In contrast, the level of firm value capture for non-hybrid crops was only 12% to 24%. The question is whether the ability to capture an increased level of value from hybrid crops affected the level of seed company R&D. Intuitively, one might believe that, yes, there would be a greater level of R&D expenditure because the potential for greater value capture would incentivize increased R&D. The data from the USDA confirms this belief. While more than 10% of hybrid seed crop sales were reinvested in research, seed companies invested only 4% to 5% of non-hybrid seed sales in this way.⁵¹² According to this USDA paper, the ability to capture a greater share of value from the hybrid seeds acted as an incentive for seed companies to invest in research in this area.⁵¹³ By 1989, 70% of the total R&D expenditures on varietal corn improvement occurred in the private sector.⁵¹⁴

Before the introduction of GE seeds, hybrid corn was the segment where private seed companies could appropriate the greatest share of value. As such, hybrid corn was the first crop to begin the shift from public to private R&D.⁵¹⁵ A snapshot of the situation in 1994, the year before the commercialization of GE crops clearly demonstrates the R&D situation. Table 3 below identifies major crop R&D in the public and private sectors in 1994 with a stark illustration of the importance of R&D in corn readily apparent. At that time, no commercial crops were GE, however, one crop, hybrid corn was biotechnologically protected just as GURT crops would be protected. Note that in the U.S., where hybrid corn was developed, public sector R&D (in scientist years) in corn represents only 6.48% of the total R&D for this crop. In contrast, private sector R&D is 93.52%.

⁵¹¹ Ibid.

⁵¹² Ibid.

⁵¹³ Ibid.

⁵¹⁴ Ibid at 43-44.

⁵¹⁵ Supra note 488 at 39.

Table 3: Number of scientists years (SY) devoted to plant breeding, public and private, by crop, 1994)⁵¹⁶

Crop/Crop Category	Public Sector		Private Sector		Total	
	Number of SY Employed	Share of Total For the Crop (%)	Number of SY Employed	Share of Total For the Crop (%)	Number of SY Employed	Share of Total SY(%)
Corn	35	6.48	510	93.52	545	24.72
Soybeans	55	35.01	101	64.99	156	7.07
Cotton	31	22.94	103	77.06	134	6.09
Wheat	76	58.63	54	41.37	130	5.91
Other cereal crops	77	35.48	139	64.06	217	9.84
Other grain legumes	26	50.98	25	49.02	51	2.31
Other fibre crops	2	100.00	0	0.00	2	0.09
Forage	71	58.20	51	41.80	122	5.53
Fruit vegetable	46	21.60	167	78.40	213	9.66
Other crops	287	45.27	348	54.89	634	28.75
Total	706		1499		2205	

Source: Frey (1996), p6-11

It is difficult to accurately estimate the amount of R&D that a company dedicates to a particular crop because most companies produce many crop seeds that share R&D resources and costs. However, the USDA is clear that the largest proportion of seed/biotech research currently is directed toward corn (maize).⁵¹⁷ Expert opinion elicited in 2009 from a personal communication from Anthony Cavalieri [Former Vice-President and Director for Trait and Technology Development at Pioneer Hi-Bred International] indicates that research in corn represents about 45% of all private sector seed-based research.⁵¹⁸ This is notable because corn represents only 25% of the overall seed market. Furthermore, it confirms that private firms consider corn seed to be the most profitable.⁵¹⁹ It is not just a coincidence that corn is so

⁵¹⁶ Kenneth J Frey, *National Plant Breeding Study-1: Human and Financial Resources Devoted to Plant Breeding Research and Development in the United States in 1994* (Special Report 98, 1996), (Iowa State University, Iowa Agriculture and Home Economics Experiment Station) as cited in USDA, *The Seed Industry in U.S. Agriculture: An Exploration of Data and Information on Crop Seed Markets, Regulation, Industry Structure, and Research and Development* by Jorge Fernandez-Cornejo. (ERS-AIB786) (Washington D.C.: USDA, Economic Research Service, 2004), online: USDA, Economic Research Service< <http://www.ers.usda.gov/publications/aib-agricultural-information-bulletin/aib786.aspx>> at 50.

⁵¹⁷ Supra note 488 at 39.

⁵¹⁸ Ibid.

⁵¹⁹ Ibid.

profitable. Although the amount of corn produced, the acreage planted, and the prices of the final product are not out of line with other major crops, the one attribute that corn has that the other major crops do not is a long history of hybridization making value capture of proprietary corn seeds very high.

The ability to technologically protect IP that hybrid corn demonstrates, suggests that GURT by its capacity to lock out “free-riders” technologically, can accomplish the same objective given the opportunity.

As far as R&D is concerned, these expenditures could be significantly increased in a world of GURT. However, there is no evidence to suggest that this is guaranteed. It is also possible that GURT may result in a transfer of R&D expenditures from existing varieties to GURT rather than simply adding to GURT R&D expenditures.

iii) Farmers, Seed Sales, GURT and R&D Intensity

It is a common belief that today farmers, particularly in the developing world, save seed from crops in the field to plant a new crop in the next growing season. Historically, this had been a common practice. However, the high quality and uniformity of proprietary seed have made this type of seed the first choice of farmers for many crops and in many parts of the world. Proprietary seed, which includes conventional seeds, GE seeds, as well as hybrid seeds, are those seeds purchased each year by farmers either due to preference or necessity. Table 4 below produced from USDA ERS data shows that total worldwide sales of proprietary seeds increased substantially between 1995 and 2006.

Table 4: Size of Global Seed Market (Table 2.1)⁵²⁰

Year	Proprietary Conventional Seed	<i>Proprietary Genetically Modified Seed</i>	Total Proprietary Seed	Public Commercial Seed	Farmer Saved Seed	Total Value of All Seed	ISF Value Of Total Seed
<i>Million Constant 2006 U.S. Dollars</i>							
1995	13,447	95	13,542	5,550	6,333	25,425	Not available
2001	11,847	3,645	15,492	3,539	5,923	24,954	34,173
2002	11,210	4,148	15,358	3,483	6,390	25,231	33,631
2003	11,084	4,938	16,022	3,409	6,694	26,125	32,922
2004	11,525	5,869	17,394	3,315	6,616	27,325	32,013
2005	12,082	6,815	18,897	3,408	6,402	28,707	30,979
2006	11,800	7,800	19,600	3,300	6,100	29,000	34,000

Sources: USDA, Economic Research Service using Context Network (2007) for all columns except ISF value of total seed, which is from International Seed Federation (ISF). Values adjusted for inflation by U.S. Gross Domestic Product implicit price deflator (Economic Report of the President, 2009)

Well before 1995, hybrid corn began the trend to use proprietary seed in the 1930s. This trend is reported in the 2006 UNCTAD paper, “Tracking the Trend Towards Market Concentration: The Case of the Agricultural Input Industry” where it is stated that the development of hybrid corn in the U.S. in the early 1900’s began the movement away from this seed saving model both in the U.S. and internationally.⁵²¹ Figure 2 on page 174 illustrates this hybrid corn trend and also demonstrates the success of this product. The pattern for non-GURT GE seeds has been similar.

Table 4 above shows that from 2001 to 2006, global market sales of proprietary seed was five to six times that of commercial seed sales originating from the public sector (Public Commercial Seed). The data clearly establishes that the increase in total proprietary seed sales is directly related to the sale of proprietary GE seeds. The first significant commercial sales of proprietary GE seeds occurred in 1995. Since 2006, GE seeds have represented over 40% of the value of all proprietary seed sold.⁵²²

Particularly significant is that the global market for farmer-saved seed, proprietary conventional seed, and public commercial seed was static from 2001 to 2006. This was a time

⁵²⁰ Ibid at 25.

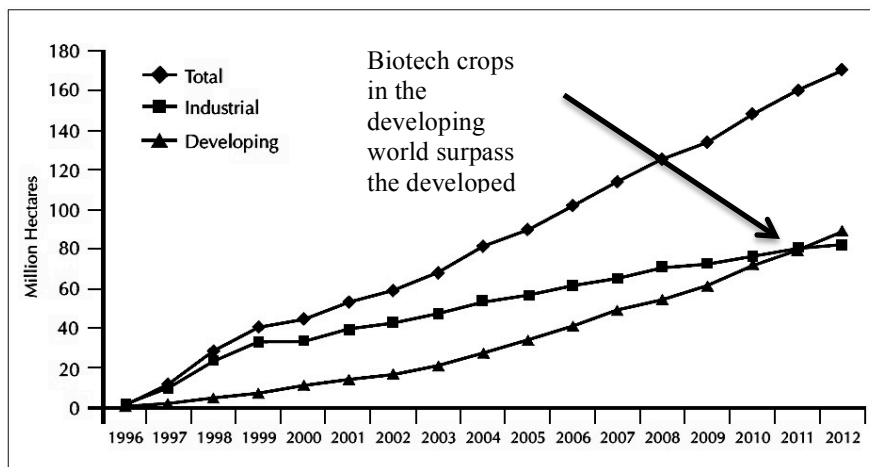
⁵²¹ Supra note 198 at 15.

⁵²² Supra note 488 at 26.

when the commercialization of GE seed, which began in 1995, was beginning to significantly affect the market. After a slow start in 1995, the data in Table 4 shows that the primary change in seed sales was a result of an increase in the use of GE seeds. One might argue that those GE seeds are being grown primarily in the developed world where farmers can afford the higher prices of these high-tech seeds. This assumption would be incorrect. Figure 12 below graphs the “Global Area of Biotech Crops”, and it shows that this is not the case. In fact, by 2012, the acreage of biotech crops (hybrid corn is now also GE) in the developing world surpassed that in the developed world for the first time.

Remember that earlier in this thesis it is noted that R&D in developing countries is low compared to developed countries at least in part because of the weak IP environment. In spite of this, Figure 12 highlights the fact that it is in these developing countries where the fastest growing use of GE seeds is occurring.

Figure 12: Global Area of Biotech Crops, 1996 - 2012
Industrial and Developing Countries (Million Hectares)⁵²³



Source: Clive James, 2012.

The increasing rate of commercialization of patented GE seeds suggests that this product has promoted innovation and further that this innovation has supported the global GE seed market. Recall in the definitions section of this thesis, that a key aspect of innovation is

⁵²³ Supra note 415 at 10.

successful commercialization. However, the protection of IP that is a source of that innovation was shown earlier to be more effective in the developed world than in the developing world due to significant weakness in the IP environment of the latter. One would therefore expect that this should result in less R&D taking place in the developing world than the developed world. That is in fact the case.

The 2011 U.S. Department of Agriculture, Economic Research Service paper, “Research Investments and Market Structure in the Food Processing, Agricultural Input, and Biofuel Industries Worldwide” by Keith Fuglie, points out that there is an the expected correlation between research investments and industry sales unless other factors change the incentives for R&D.⁵²⁴ These other factors could include changes in future demand; technological advances; stronger IP protection; or market structure changes that alter the level of value capture.⁵²⁵ The key point here, with respect to stronger IP protection, is that this can occur either by changes to the “rules” that are in place for existing IP protection or by what is know as “changing the game.” This latter concept is something that students of game theory will find familiar.

In the field of agricultural biotechnology changing the game is what occurred with corn when this product was hybridized allowing for its IP to be self-protective. It is also what GURT has the potential to accomplish if ever commercialized. What hybrid corn first accomplished and what GURT has the potential to extend is the innovators’ ability to change the game. The traditional rules of the IP game involve legal structures that provide protection on which innovation promotion through R&D is to a large extent dependent. GURT, like hybrid corn, can limit the need for the legal rules to protect the IP and the consequences of these rules.

The data provided by the USDA ERS 2011 paper confirms that R&D intensity (i.e. R&D spending as a percentage of sales) for various significant agricultural input sectors was fairly stable from 1994 to 2009.⁵²⁶ Only in the private crop-seed biotechnology sector was this stability disrupted. The R&D intensity statistics show that, over the 1994 to 2009 period, the animal health industry averaged an R&D intensity of 8.6%; the agricultural chemical industry

⁵²⁴ Supra note 488 at 14.

⁵²⁵ Ibid.

⁵²⁶ Ibid.

averaged 6.7%, and the farm machinery industry averaged 2.3%.⁵²⁷ On the other hand, the crop seed industry had an R&D intensity of 11.0% in 1994 increasing to 15.0% in 2000 followed by a decline to 10.5% in 2009.⁵²⁸ The reason for this surge in R&D intensity in the crop seed industry is noted in the USDA ERS 2011 paper and has significance to the potential effect of GURT technology on R&D in this sector.

The USDA indicates that the post-1994 increase in R&D intensity in the crop seed sector was due to industry efforts to commercialize GE seeds as they were first being introduced.⁵²⁹ The drop in R&D intensity after 2000 can be attributed to the previously noted [earlier background discussion] increase in the private sector concentration in this industry.

According to a 2011 WIPO Report on “How the Private and Public Sectors Use IP to Enhance Agricultural Productivity”, the percentage of seeds turnover (i.e. seed sales) reinvested into seeds-related R&D for the leading companies in 2009 was: 11% (Pioneer Hi-Bred), 15% (Monsanto), 14% (Syngenta), 27% (Bayer Crop-Sciences), 31% (Dow).⁵³⁰ To highlight the large amounts of money involved, the report noted that bringing a new plant trait to market as a commercialized GE seed costs approximately \$200M over a period of 10 to 15 years.⁵³¹ This amount is composed of R&D and commercialization costs.

The WIPO report highlights the fact that the industry claims that farmer legal and illegal seed saving on average reduces revenues by over 50%.⁵³² The report further suggests that there is nothing that the industry can do to affect legal seed saving except to produce a higher quality low-cost GE seed that would entice farmers who save seed to switch to commercial seed.⁵³³ As Figure 12 illustrates, the high level of developing world GE seed use suggests that the switch is

⁵²⁷ Ibid at 15.

⁵²⁸ Ibid.

⁵²⁹ Ibid.

⁵³⁰ Michael A Kock and Christine Gould, “Patents on Plants: A tool or threat for sustainable agriculture? The role of intellectual property rights on plant innovations” in WIPO, *Global Challenges Report, Food Security and Intellectual Property: How the Private and Public Sectors Use Intellectual Property to Enhance Agricultural Productivity*, Proceedings of a Seminar (14 June 2011) (WIPO/IP/LSBIOT/GE/11/1) (Geneva: WIPO, 2011), online: WIPO <http://www.wipo.int/edocs/mdocs/mdocs/en/wipo_ip_lsbiot_ge_11/wipo_ip_lsbiot_ge_11_www_183501.pdf> at 94.

⁵³¹ Ibid.

⁵³² Ibid at 95.

⁵³³ Ibid.

occurring. In spite of this, the industry is still having issues with value capture.

On the face of it, this is an apparent admission that the current standard of legal IP protection in all its forms including the utility patent still lends itself to substantial value leakage. Nowhere in this WIPO report is GURT considered as a value leakage prevention alternative. The fact that GURT is not deemed worthy of discussion does not bode well for the ultimate lifting of the moratorium on commercialization.

iv) Can Quality R&D be Predicted from GURT?

In a Convention on Biological Diversity paper titled, “Genetic Use Restriction Technologies: Technical Assessment of the Set of New Technologies which Sterilize or Reduce the Agronomic Value of Second Generation Seed, as Exemplified by U.S. Patent No. 5,723,765, and WO 94/03619” dealing with GURT, Richard Jefferson asserts that the proponents of GURT see this technology as a means of encouraging private sector investment in agricultural improvement.⁵³⁴ Although the logic of this argument is difficult to ignore, it is the quality of the investment that is questioned by this report. Specifically, the report questions the nature of any potential investment; the expected outcomes of that investment; and who the beneficiaries might be.⁵³⁵ This report goes beyond questioning whether the investment in GURT and its consequences would address the public good, to question what exactly might be the nature of the public good represented by that investment.⁵³⁶

Even though the protective capacity of GURT may encourage investment in new plant varieties or new traits for old varieties, there is no guarantee that these investments will promote socio-economic equity. Of course, the private sector investors in this technology may not rate socio-economic equity high on their list of priorities. The report notes this when it raises the point that investment by private firms is most likely to address products that are most profitable; that is, those products that meet farmers’ needs in developed countries where the bulk of profit is generated. The report laments the likelihood that private sector investment in GURT would be of

⁵³⁴ Supra note 464 at 15.

⁵³⁵ Ibid at 18.

⁵³⁶ Ibid at 19.

little value to subsistence farmers in developing countries.⁵³⁷ As such, the report suggests that it is in the private sector where the new enabling technologies will be developed and that the public sector may be denied these technologies.⁵³⁸ Furthermore, new investments are likely to continue to focus on high value crops for farmers in developed countries who are already well off.⁵³⁹ So, the report suggests that the quality of the potential R&D growth spurred by GURT would be both unequal in geographical distribution by focusing on developed countries and directed to the high-value crops specific to the developed world or large farming systems that exist in the developing world.

The 2003 UNEP/CBD “Report of the ad hoc technical expert group meeting on the potential impacts of genetic use restriction technologies on smallholder farmers, indigenous and local communities and farmers’ rights” has much to say on this subject. It suggests that one problem associated with a product such as GURT, that successfully addresses the private sector value capture issue, is that once the product is successfully commercialized, R&D changes. There is less motivation for private sector R&D to continue the search for alternatives that may be superior in their ability to solve the value leakage problem in a way that is more equitable for those farmers in the developing world. There is also less incentive to pursue R&D that searches for seeds with potentially fewer negative consequences such as those that may have fewer negative impacts on the environment.⁵⁴⁰

For example, the 2003 CBD report suggests that if GURT can successfully contain transgenes, this technology might prevent further research on other methods [both legal and biological] of containing transgenes that may be superior to GURT and with fewer potential negative consequences.⁵⁴¹ Of course, if GURT is safe and effective, one might question why there would need to be further research to improve transgene containment? Unfortunately, as with many new products or processes, occasionally their successful use uncovers unintended consequences. In addition to the idea that new R&D on superior transgene containment might be

⁵³⁷ Ibid at 43.

⁵³⁸ Ibid at 9.

⁵³⁹ Ibid at 14.

⁵⁴⁰ Supra note 496 at 9.

⁵⁴¹ Ibid at 6.

neglected because of the success of GURT, there is a potential anti-innovation consequence of this technological success.

The earlier suggestion that GURT might simply transfer R&D funds from other areas of agriculture rather than increase overall R&D is a possibility that is worrisome. According to this CBD paper, there is an indirect way in which GURT could increase overall private and public sector R&D selectively even if there is no increase in overall private sector R&D. If GURT increases private sector R&D in GURT-specific technology, which is likely if the history of hybrid corn and GE crops is an indication, then there could be an increase in public sector R&D into minor more local crops as the private sector concentrates on the more profitable major crops.⁵⁴² The public sector would be able to take the limited funds available for public R&D and use them to focus on these minor crops that are important to local economies in developing countries, but which are less profitable.⁵⁴³ As much as this is a possibility, how much of this would occur is questionable since private sector research has already taken over a significant portion of GE seed biotechnology. Any increase in public R&D into minor crops may not be significantly greater than what has already occurred.

5.1.2 Successful Commercialization: An Indication of Innovation Promotion

In the definition section of this thesis, seven innovation definitions from a variety of high quality sources are listed as provided by Shipp et al.⁵⁴⁴ These definitions stress various aspects of innovation making any single one of them inadequate as the ideal standalone definition. The common thread that runs through these definitions is that they either explicitly or implicitly include successful commercialization as an important feature of innovation. However, Shipp et al. suggest that the attributes of innovation are a more useful way to describe innovation and these authors offer ten innovation attributes. For example, Attribute 5 states that innovation involves activity for the purpose of creating economic value. Economic value is captured through

⁵⁴² Ibid at 10.

⁵⁴³ Ibid.

⁵⁴⁴ Supra note 20 at II-2.

the successful commercialization of a product. In another example, Attribute 10 explicitly states that innovation involves R&D and commercialization.⁵⁴⁵

R&D has been shown to be a significant output of the development of GE seeds. It has also been demonstrated that GURT has a high likelihood of enhancing R&D in GE seeds by providing a robust value capture mechanism that further encourages GURT use. The next step is to compare GURT and non-GURT seeds for their capacity to promote innovation through commercialization.

The success of GE seed commercialization can be measured by the growth in the use of these seeds and the current and future demand for this product. It is the end user (the farmer) demand for the product that supports its commercialization. The patenting of GE seeds is an indicator that seed companies see a profit in protecting the development and use of these seeds. Successful innovation is indicated by widespread market acceptance of the product; that is, it is indicated by successful commercialization. This success originates from the clear and growing farmer demand for GE seeds.

The initial commercialization of patent-protected GE seeds occurred twenty years ago. The commercialization question for this thesis has two parts. First, would GURT, if allowed to proceed to commercialization, be a successful product. Further, would it meet the previously listed attributes of innovation of which successful commercialization is a prime component. Second, to what degree would it match the success of traditionally patent-protected GE seeds? To answer these questions, one must first investigate the current status of commercialization of patented GE seeds.

i) Commercialization of Traditional Patent Protected Non-GURT GE Seeds

As of 2012, four principle crops represented 99% of all biotech crops grown worldwide. These crops are soybeans (47%), corn (23%), cotton (11%) and canola (5%). Other biotech crops such as sugar beet, alfalfa, papaya, etc. combined to make up the other 1%. Each of these biotech

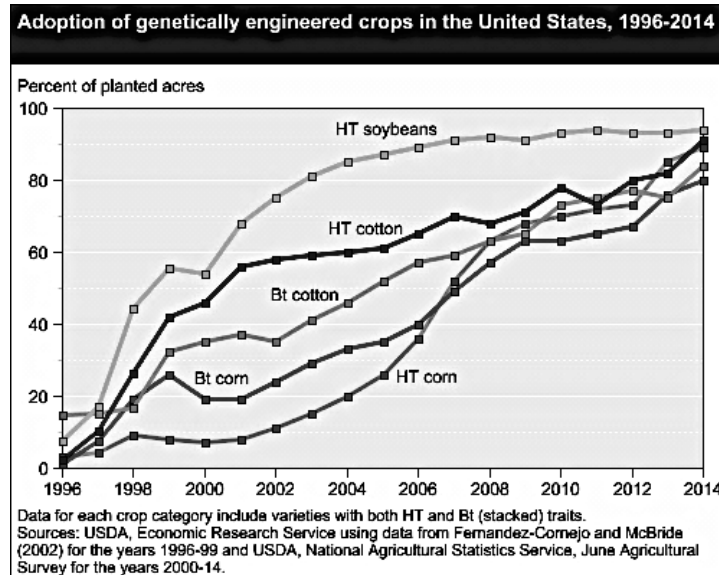
⁵⁴⁵ Ibid at II-1-II-8.

crops exhibits one or two traits. They are either herbicide tolerant, insect resistant, or a combination of the two (i.e. stacked traits).⁵⁴⁶

Of the countries growing GE crops, the U.S. grows the most acreage. In 2012, the U.S. grew 41% (by area) of all GE biotech crops.⁵⁴⁷ Of the four major GE crops, the U.S. grows three, soybeans, cotton and corn.⁵⁴⁸

Figure 13 below, from the USDA, shows the change in each GE crop grown as a percentage of the overall total of both GE and non-GE crops grown in the U.S. from their initial commercialization in 1995 to 2014. This graph indicates that the GE varieties shown have become prominent in these specific, highly important crops. Eighty percent or more of these crops (soybeans, cotton, corn) grown in the U.S. are of the patented GE variety. This is clear evidence that the commercialization success of patented GE seeds in the U.S. is extraordinarily high and that this level of success has developed quickly.

Figure 13: Adoption of GE Crops in the U.S., 1996 – 2014⁵⁴⁹



⁵⁴⁶ Supra note 415 at 219.

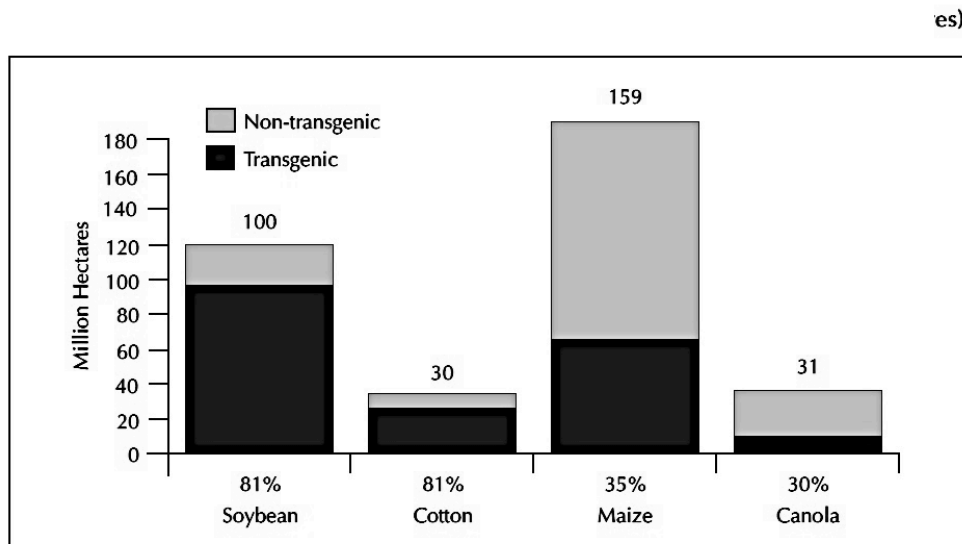
⁵⁴⁷ Ibid at 11.

⁵⁴⁸ Ibid at 17.

⁵⁴⁹ USDA, *Adoption of Genetically Engineered Crops in the U.S.*, USDA ERS (2015) online:USDA < <http://www.ers.usda.gov/data-products/adoption-of-genetically-engineered-crops-in-the-us/recent-trends-in-ge-adoption.aspx> >.

An examination of the FAO data from 2009 as shown in James (2012) states that the four principal crops noted above which have been commercialized with GE traits are also in use worldwide. Of all soybeans grown worldwide in 2012, 81% were GE. In the case of cotton, 81% were GE. For corn, the figure is 35% and for canola, the figure is 30%.⁵⁵⁰ James (2012) combined the areas planted with these four crops (GE and non-GE) and the result is that of the total of 320 million hectares planted with these four crops worldwide, 53% were GE. This is an increase from 50% in 2011.⁵⁵¹ See Fig 14 below

**Figure 14: Global Adoption Rates (%) for Principal Biotech Crops, 2012⁵⁵²
(Million Hectares)**



FAO Global hectares for 2009.
Source: Compiled by Clive James, 2012.

One may argue that the emphasis placed on these four crops by the GE seed companies is due to their importance to agriculture in the developed world. This is in fact not the case. Two-thirds of the total 320 million hectares planted in these four crops are in the developing world.⁵⁵³

⁵⁵⁰ Supra note 415 at 222.

⁵⁵¹ Ibid at 221.

⁵⁵² Ibid at 222.

⁵⁵³ Ibid at 221.

In 2012, the market value of all GE crops grown worldwide was \$14.84USD (the updated figure for 2013 was \$15.6 billion USD) of which \$11.4 billion USD (77%) was in developed countries and \$3.4 billion USD was in developing countries.⁵⁵⁴ However, the overall acreage of GE crops in developing countries surpassed that in developed countries in 2012. (See Figure 12) This trend, where the acreage of GE crops in the developing world has surpassed that of the developing world continued in 2013.⁵⁵⁵

It is estimated that global value of GE seeds and associated technology fees that have accumulated from initial commercialization in 1996 to 2012 is \$102.2 billion USD.⁵⁵⁶ Direct data on the economic value of the various aspects of the GE seed industry and the crops that result from GE seeds is not readily available. However, Carlson (2009) was able to estimate this value for the U.S. The USDA carefully details many aspects of U.S. agriculture and Carlson (2009) used this data to estimate the value of GE products (crops included) in the U.S. The result is that Carlson estimated this value to be equivalent to 2% of GDP.⁵⁵⁷ James then extrapolated this data globally to estimate the value of global biotech harvested products and found this figure to be \$170 billion USD.⁵⁵⁸

Acreage and value of GE crops, seeds and complimentary products represent an important feature of GE seed commercialization. However, it is also important to look at the number of countries commercializing or on the verge of commercializing GE seeds to predict the future growth in this segment of the agricultural industry.

⁵⁵⁴ Ibid at 221-222; Clive James, “Global status of commercialized biotech/GM crops: 2013 – ISAAA Brief No 46” (2014) online: ISAAA <<http://www.isaaa.org>> at iii [James 46]; That is, 23% of the market value of GE crops was in developing countries. One reason that the dollar value of developing world GE crops does not match the acreage involved is that a portion of the crops is used domestically and would be priced locally.

⁵⁵⁵ James 46, supra note 554 at “Title Page.”

⁵⁵⁶ Supra note 415 at 223.

⁵⁵⁷ R Carlson, “The Market Value of GM Products” (2009) 27 *Nature Biotechnology* 984 <http://www.nature.com/nbt/journal/v27/n11/pdf/nbt1109-984a.pdf> & http://www.agbioworld.org/newsletter_wm/index.php?caseid=archive&newsid=2926 as cited in Clive James, “Global status of commercialized biotech/GM crops: 2012 – ISAAA Brief No 44” (2013) online: ISAAA <<http://www.isaaa.org>> at 224.

⁵⁵⁸ Supra note 415 at 224.

As of 2012, 89% of the global area of GE crops planted occurred in six countries (U.S. 41%; Brazil 21%; Argentina 14%; Canada 7%; India 6%).⁵⁵⁹ James (2012) notes that from the perspective of global regulatory approvals of GE seeds:

“While 28 countries planted commercialized biotech crops in 2012, an additional 31 countries totalling 59 have granted regulatory approvals for biotech crops for import, food and feed use and for release into the environment since 1996. A total of 2,497 regulatory approvals involving 25 GM crops and 319 GM events⁵⁶⁰ have been issued by competent authorities in 59 countries, of which 1,129 are for food use (direct use or processing), 813 are for feed use (direct use or processing) and 555 are for planting or release into the environment. Of the 59 countries with regulatory approvals, USA has the most number of events approved (196), followed by Japan (182), Canada (131), Mexico (122), Australia (92), South Korea (86), New Zealand (81), European Union (67 including approvals that have expired or under renewal process), Philippines (64), Taiwan (52) and South Africa (49).”⁵⁶¹

A detailed GE approval database can be found at: <http://www.isaaa.org/gmapprovaldatabase/>.

For traditionally patented GE seeds one can look at the degree of successful commercialization that has already taken place as an indication of the level of innovation promotion that has occurred. The fact that the seeds are patented has indeed encouraged the GE seed firms to innovate. But it is the demand for the seeds by the customers [farmers] that has been a key source of innovation promotion. If farmers do not find added value in GE seeds as compared to non-GE seeds, then the patenting of the GE seeds would not be relevant; they would simply not sell. However, as pointed out earlier by Kesan (2000), those opposing GE seeds argue that to survive farmers have no choice but to use these products as they become available and that farmers are further encouraged to use these new products since the seed companies heavily market their GE seeds.⁵⁶² So, it is not the patent itself that is the source of innovation promotion but rather the invention that, for whatever reason, is in demand. Of course, if the GE seed firms

⁵⁵⁹ Ibid at 12.

⁵⁶⁰ An “event” refers to the unique DNA recombination occurrence that takes place in one plant cell, which is then used to generate entire transgenic plants.

⁵⁶¹ Supra note 415 at 224.

⁵⁶² Kesan, supra note 2 at 497.

could not capture the value inherent in the invention by protecting it, there would be little incentive for them to invest in further innovation.

The concept of a good invention that is in demand is the first requirement of successful commercialization and, therefore, innovation promotion. The second requirement is that the inventor must somehow be able to capture the value from that invention through commercialization. If demand and value capture are non-existent, then successful commercialization will not occur, and there will be no innovation promotion. In the case of GE seeds, demand has been demonstrated, and commercialization has occurred. This commercialization has been successful because the patent protection of non-GURT GE seeds has been sufficient to be profitable and the consequence of this profitability has been further innovation and enduring commercialization.

GURT as the technological alternative to patented GE seeds can be evaluated for innovation promotion through its potential for successful commercialization rather than its actual commercialization. For this one must judge its unique characteristics and how they may affect its potential future commercialization. Also, one can evaluate this commercialization potential by noting the differences between traditional patented GE seeds and GURT seeds and how these differences can affect this commercialization.

ii) Commercialization of GURT

As noted previously, there is no current commercialization of GURT. Therefore, there is no way to predict with any certainty that the commercialization indicator would support the innovation promotion potential of GURT over patents. One can present expert opinion on the subject or one can describe the degree to which hybrid corn, another technologically protected seed, has been successfully commercialized. In the end, the best one can hope for in this matter is a well-supported although speculative conclusion.

Initially, just as with any product, a period of R&D and testing would be required to determine how well GURT could accomplish that which it is intended to do. So, let us assume that the R&D and testing have taken place for both V-GURT and T-GURT. As a GE seed firm readies for the introduction of a GURT seed, part of the pre-commercialization process would include the patenting of this product for at minimum, competitive reasons. As previously noted,

the patenting of this technology is superfluous at the farmer level since saving GURT seeds is of no value to farmers since they would be unable to access the value added traits without the cooperation of the developing company.

At this point a quick review of T-GURT's unique characteristics is necessary before continuing to the question of will GURT commercialization succeed.

While it appears to be true that farmers require GE seed firm cooperation to access GURT value added traits, this may not necessarily be totally accurate in the case of T-GURT. As previously described, T-GURT requires an inducer/promoter to access the value-added trait(s). As such, it is possible for an illegal market for these products to develop under the right circumstances. This problem can be mitigated to some degree by the need to apply the inducer at some specific point in the plant growth cycle or to apply it using a specific series of steps. The problem here is that the inducer/promoter may be a common existing chemical. If this is the case, it cannot be patented although the method of use may be subject to trade secret or patent protection. So, T-GURT could theoretically have better IP protection than non-GURT GE seeds, but because the inducer /promoter can be a weak link in this protection, the T-GURT IP protection would not necessarily be as effective as the V-GURT IP protection.

There appear to be at least two ways around this problem. First, if the inducer/promoter were a patentable chemical, the GE seed firm would have at least some added protection for its IP. However, reverse engineering could still make this problematic from the perspective of the GE seed firm. Second, the process of activating or deactivating the value added traits could be one that must be carried out by the seed firm before the seed is sold. The technique and chemicals required for this could be kept secret by the GE seed firm. Alternatively, the process for inducer/promoter use may be patentable.

In the case of V-GURT, the IP is airtight as far as farmer-level IP protection is concerned because the farmer can in no way alter the viability of the seeds. So, the IP security that GURT offers is tightest for what has become regarded as the least ethically palatable type of GURT, V-GURT or the "terminator" seed. This is the specific version of GURT that is heavily criticized by social media and authors such as Oguamanam⁵⁶³ and Endres and Goldsmith.⁵⁶⁴ On the other

⁵⁶³ Oguamanam, *supra* note 290 at 71.

hand, the IP protection is weakest for the most innovative version of GURT, T-GURT, which has the potential to allow for a wide range of value-added traits to be turned on or off as required. These traits can include drought resistance; the timing of maturation; the nutritional content; etc.

The increased IP protection and specific unique value-added traits from GURT could support its successful commercialization since both the producers and the users of the product have benefits available. If the benefits for all exceed the costs, successful commercialization is possible.

The big question for successful commercialization of GURT is whether farmers will purchase GURT seeds over traditional GE seeds. We have already seen that the question is not whether farmers will continue to drift more and more to patented GE seeds over non-GE seeds. That is occurring in both the developed and developing world. For GURT to be commercially successful requires more than a superior method of value capture by the seed industry. While the industry might be satisfied with no productivity improvement from GURT as long as the value capture and, therefore, the profitability of the product is increased, the same cannot be said for the consumer of the product, that is the farmer. For the farmer to be willing to purchase GURT seeds, the use of these seeds would have to show an increase in the benefit/cost ratio over what the farmer is currently using. If the productivity level of GURT is no more than occurs with traditional GE seeds, there may be no reason for the farmer to increase their input costs with the same outcome as non-GURT GE seeds provide.

Oguamanam argues that V-GURT does not add any user-focused value added traits to the seed.⁵⁶⁵ However, the prevention of transgene spread from the use of V-GURT is a farmer benefit. The other value-added traits in V-GURT seeds that are important to farmers originate from the GE traits in the seed and not from the IP protection technology that it contains. These traits do not require V-GURT technology to be a benefit to farmers. They simply require GE technology.

On the other hand, GE seed firms would benefit from lower transaction costs due to the technological protection afforded by GURT. This lower cost to GE seed firms would include the

⁵⁶⁴ Supra note 200 at 38.

⁵⁶⁵ Oguamanam, supra note 290 at 71.

elimination of the farmer-monitoring requirement that is currently needed to prevent the unauthorized use of patented non-GURT GE seeds. Lower costs would also come from a significant reduction in the need to protect the patents through the courts. One can say that the GE seed firms would be highly supportive of V-GURT commercialization. The same cannot be said for farmers.

In contrast to GURT, the transaction costs associated with patents are an ongoing cost as long as the patent must be protected. Because of the need for large scale adoption of a technology in order for prices to drop to the point where they are attractive to users, R&D and commercialization in V-GURT would most likely take place initially in major crops that have wide spread application such as soybeans, wheat and cotton.

Again here, the comparison of GURT to hybrid corn is revealing. Hybrid corn is very much like T-GURT from the perspective that saved hybrid corn seed does not produce a full quality plant in the ensuing generations. Hybrid corn has been widely adopted and has been the subject of extensive R&D. As has been shown earlier, the price at the user level [i.e. farmer] is no longer out of synch with other non-hybrid crops. As previously noted, hybrid corn has been commercialized to the point where it is the world standard for corn crops. The reason is simple. Farmers benefit from increased yield and the high quality of hybrid corn and are willing to pay a premium for this added value. While input costs may be higher at times, the output of high yield, high quality seeds compensates for this. In addition, the seed firms reap higher returns on this product and the consumer receives a high quality end product.

T-GURT seeds, more so than V-GURT seeds, *do* add user value added traits to the seed. The capacity for farmers to control the activation of GE seed traits such as drought resistance offers a specific benefit that can promote commercialization. Although this is possible with traditional patent only GE seeds, the added technological protection of T-GURT could incentivize its development and successful commercialization because both the farmers and seed firms can see value in the product. This commercialization then becomes an incentive for further R&D and therefore further innovation.

R&D and successful commercialization are two key indicators of innovation promotion. Since it is ultimately the private sector in developed countries that is responsible for

commercialization of GE seeds and the bulk of the specific R&D directly related to that commercialization, a practical example of a seed firm in action is useful to further the goal of answering the thesis question. Again, in this case, Monsanto is chosen.

5.2 Monsanto and Innovation Protection and Promotion

The degree to which an agricultural biotechnology firm invests in R&D; in what aspect(s) of agricultural biotechnology it specifically invests; and the level of commercialization success it achieves are factors in a firm's choice between the legal and technological IP protection and promotion alternatives under consideration.

IP protection for biotech seeds is an essential condition for innovation because the development and commercialization of new products involve extensive research expenditures, uncertain outcomes, and long and costly regulatory procedures before a successful outcome can be achieved.⁵⁶⁶ “Monsanto, for example, estimates that R&D investments for new GE corn products requires \$5–\$10 million USD for the proof-of-concept phase and then \$10-\$15 million USD for early product development.”⁵⁶⁷ To this one can add a further \$7 -\$15 million USD for regulatory approval. This latter figure is based on data compiled by Kalaitzandonakes, Alston, and Bradford (2007).⁵⁶⁸

In their annual report filed with the U.S. SEC in 2013, Monsanto specifically notes the obvious under Item 1A (Risk Factors), where it states that their efforts to protect their IP can increase the company's costs significantly. The company states that because these efforts will not always succeed, an inability to establish the needed protection invariably will affect their sales and profitability negatively.⁵⁶⁹ The report goes on to state that IPRs are “crucial” to the

⁵⁶⁶ Keith E Maskus, “Intellectual property rights in agriculture and the interests of Asian-Pacific economies” (2006) 29:6 *World Economy* 715 as cited in Katherine Linton & Mihir Torsekar, *Innovation in Biotechnology Seeds: Public and Private Initiatives in India and China* (2011) 3:1 *Journal of International Commerce and Economics* at 197.

⁵⁶⁷ Katherine Linton & Mihir Torsekar. “Innovation in Biotechnology Seeds: Public and Private Initiatives in India and China” (2011) 3:1 *Journal of International Commerce and Economics* at 197.

⁵⁶⁸ Kalaitzandonakes, Nicholas, Julian M Alston & Kent J. Bradford. “Compliance costs for regulatory approval of new biotech crops” (2007) 25:5 *Nature Biotechnology* 509 as cited in Katherine Linton & Mihir Torsekar, *Innovation in Biotechnology Seeds: Public and Private Initiatives in India and China* (2011) 3:1 *Journal of International Commerce and Economics* 189 at 197.

⁵⁶⁹ *Supra* note 408 at 9.

company's Seeds and Genomics segment. The company also mentions that seed saving by farmers involving the company's biotechnology traits has been a particular problem *outside of the U.S.*⁵⁷⁰ It should, therefore, not be surprising that Monsanto investigated the potential of GURT to accomplish technologically what patents could not effectively manage legally.⁵⁷¹ Not surprisingly, Monsanto found that this new, disruptive technology was in conflict with some existing national and international agricultural regulations that were developed over many years to deal with a pre-GURT environment.

As with all agricultural biotechnology companies, Monsanto sales and profitability are affected by extensive regulation of the company's seed biotechnology and agricultural productivity products. The company notes in their annual report that this can lead to, among other things, restrictions or moratoria on testing, planting or use of biotechnology traits.⁵⁷² This is what transpired when GURT interacted with the pre-GURT international regulatory environment leading to an international moratorium on the testing and commercialization of GURT.

As Monsanto states in their annual report, the company is aware that not only the degree of public acceptance of their biotechnology products but also the perception that the products are not publicly accepted can negatively affect sales and profits.⁵⁷³ Even a low level of biotechnology traits in conventional crops can put the company and its products in a bad light. The action of some European governments to try to ban GE food products in 2005 is just one example of the problems faced by Monsanto and other GE seed companies. Even though the company successfully overcame this attempted restriction at the WTO, as described earlier in the thesis, the reputational damage that resulted made this victory more symbolic than effective.

Further, in their 2013 annual report, Monsanto makes a point that the cost of successful development and commercialization of the company's products is affecting future plans. The company states that greater than anticipated development cost is one of the reasons that the company may abandon new products or concepts. Other grounds for product abandonment

⁵⁷⁰ Ibid at 10.

⁵⁷¹ Ibid a 11.

⁵⁷² Ibid at 9.

⁵⁷³ Ibid.

include technical problems, competition, variations in the strength of national IP environments, and regulatory obstacles. Issues with regulation and the IP environment are of particular concern to Monsanto.⁵⁷⁴

With all the difficulties claimed by the company, they continue to find certain aspects of their biotechnology business quite profitable. In Monsanto's Seeds and Genomics Segment, corn seed and traits represent more than half of the net sales and gross profit.⁵⁷⁵ The company reports that their global volumes are higher primarily due to an increased demand for their corn technologies. Remember corn is both a hybrid crop and a crop that contains patented GE traits. As such it protects its IP both technologically and legally.

Corn seed represents a bright spot for the company. Monsanto announced in their Annual Report (2013) that the increase in net sales of corn seed and traits is due to a combination of increased planted acres and stronger customer demand among other reasons.⁵⁷⁶ Monsanto has a successful global market for their hybrid corn seed in both developed and developing countries even though farmers must purchase this product every planting season. Seed saving is simply not a viable option for hybrid products, but this does not seem to have deterred both rich and poor farmers worldwide from increasing the demand for this product.

As a result of the success of hybrid corn, Monsanto stresses that this is an area of substantial investment for the company. In the 2013 Annual Report, the company states that over the previous three years R&D expenses were as follows: 2013 (USD \$1.533B); 2012(USD \$1.517B); 2011(USD \$1.386B).⁵⁷⁷ Not surprisingly, more than 90% of the company's R&D is spent on seeds and traits with an emphasis on corn.⁵⁷⁸

Corn has also been responsible for Monsanto's increased capital expenditures in 2013 to USD \$741M from USD \$646M in 2012 and \$540M in 2011. The company states that the primary driver of this increase is higher spending related to "corn seed plant expansion in North

⁵⁷⁴ Monsanto Annual Report 2013, (2013) online: Monsanto<
<http://www.monsanto.com/investors/documents/annual%20report/2013/monsanto-2013-annual-report.pdf>> at 10.

⁵⁷⁵ Ibid at 16.

⁵⁷⁶ Ibid at 21.

⁵⁷⁷ Supra note 408 at 18.

⁵⁷⁸ Supra note 574 at 17, 25, 28, 86.

America, Latin America and Europe.”⁵⁷⁹ Monsanto projects 2014 capital expenditures at \$1B-\$1.2B USD due to global seed manufacturing expansion and investment in technology research facilities.⁵⁸⁰

The hybrid nature of corn combined with the GE technology that has been incorporated into this hybrid crop has produced a situation which closely resembles the GURT concept by providing unique, specifically designed traits with a high degree of self-protective capacity. Monsanto’s success with hybrid corn is clearly demonstrated by two statistics. Corn sales represent 63.8% of total sales [\$6.596B USD of a total \$10.340B USD] in the “Seeds and Genomics Segment” for the company and 64.6% of gross profit [\$3.929B USD of a total of \$6.083 USD]. (See Table 5 below).

Table 5: Monsanto Seeds and Genomics Segment Financials⁵⁸¹

(Dollars in millions)	Year Ending August 31 (\$)			Change (%)	
	2013	2012	2011	2013 vs. 2012	2012 vs. 2011
Net Sales					
Corn seed and traits	6,596	5,814	4,805	13	21
Soybean seed and traits	1,653	1,771	1,542	(7)	15
Cotton seed and traits	695	779	847	(11)	(8)
Vegetable seeds	821	851	895	(4)	(5)
All other crops seeds and traits	575	574	493	-	16
Total Net Sales	\$10,340	\$9,789	\$8,582	6%	14%
Gross Profit					
Corn seed and traits	3,929	3,589	2,864	9	25
Soybean seed and traits	948	1,160	1,045	(18)	11
Cotton seed and traits	519	585	642	(11)	(9)
Vegetable seeds	337	419	534	(20)	(22)
All other crops seeds and traits	350	306	221	14	38
Total Gross Profit	\$6,083	\$6,059	\$5,306	(6)%	14%

There are intercompany moves by Monsanto that further demonstrate that research in corn is a high priority for Monsanto. In 2007, the company announced a long- term R&D and

⁵⁷⁹ Supra note 408 at 17.

⁵⁸⁰ Ibid at 27.

⁵⁸¹ Ibid at 21.

commercialization venture with BASF. The first result of this was the 2013 approval for a biotech drought-resistant corn product. This collaboration is expected to extend to the development of “yield and stress tolerant traits for corn as well as soybeans, cotton, canola and wheat.”⁵⁸²

It is not surprising that the hybrid nature of corn is a significant reason why this product is so important to Monsanto. The U.S. grows approximately 40% of the world’s corn and 98% of that is of the hybrid/GE variety. While the GE nature of corn can provide value-added traits, it is the hybrid nature of the product that allows for maximum value capture. Monsanto can strongly control its IP when it comes to hybrid corn. However, the company must be strategically creative in its value capture of other GE seed products, which have patent-only protection.

Monsanto went through a costly, value leakage issue with its inability to patent soybeans promptly in Argentina leading to endemic “free-riding”. The company is now much more diligent in addressing its international markets but the point is that it must put time and effort into doing so. For example, Monsanto is attempting to establish grower and grain handler agreements in Argentina so that the company can capture value from its technology in that country.⁵⁸³ Monsanto’s Roundup Ready GE soybean value leakage situation in Argentina has improved recently through negotiation with the Argentine government and farmers. The company has agreed not to collect payments on first generation Roundup Ready soybeans but has established a business plan so that farmers can make payments on new legally saved seed based on a model that has been successful in Brazil.⁵⁸⁴

From the company’s perspective, it is clear that Monsanto would financially benefit from GURT, yet the company has thus far abided by the international moratorium on GURT commercialization. This intention is plainly stated on the company’s website.⁵⁸⁵ It is likely, however, that should that moratorium ever be lifted, Monsanto would be at the forefront of the GURT commercialization bandwagon. At that point, the viability options for both patented and GURT GE seeds that are investigated in the next section of this thesis would come into play.

⁵⁸² Ibid at 31.

⁵⁸³ Ibid at 32.

⁵⁸⁴ Ibid at 31-33.

⁵⁸⁵ Supra note 372.

Chapter 6

Research and Analysis: Part 2

Viability of Patents v. GURT

6.0 A Touchy Situation

Support or opposition to the adoption of GURT has led to intense debate over whether GURT or the patent is a more *viable* alternative for the protection and promotion of innovation in agricultural seeds. In contrast to the discussions over the effectiveness of innovation protection and promotion of these two alternatives, the viability issues are often highly polarized leaving little room for a nuanced discussion. The intensity of the debate is evident in the 2002 FAO technical study “CGRFA-9/02/17Rev. – Potential impacts of genetic use restriction technologies (GURTS) on agricultural biodiversity and agricultural production systems”⁵⁸⁶ that was the subject of consideration by the FAO Commission on Genetic Resources for Food and Agriculture at its Ninth Regular Session. Overall, this study shone a negative light on GURT.

As a major supporter of genetic engineering in agriculture, the U.S. response to this anti-GURT document is appended to the “Conference of the Parties to the Convention on Biological Diversity” report.⁵⁸⁷ This response by Carolee Heilman, Acting Permanent Representative U.S. Mission to the “U.N. Agencies for Food and Agriculture”, begins by noting that reliable scientific data is very limited as to the potential effect of GURT on agriculture. The response also states that this lack of data limits any conclusions about any potential societal or economic effects of GURT.⁵⁸⁸ Also, the U.S. representative highlights the safety and success of GE crops and cautions against an unfair assessment of GURT before solid evidence is available. Heilman

⁵⁸⁶ UNFAO/CGRFA, Potential impacts of genetic use restriction technologies (GURTs) on agricultural biodiversity and agricultural production systems: Technical Study (CGRFA-9/02/17 Annex Rev.1) E, 9th Regular Session, Rome (14 – 18 October 2002) (Annexed to UNEP/CBD/COP/7/INF/31).

⁵⁸⁷ Letter from Carolee Heilman, Acting Permanent Representative, U.S. Mission to the U.N. Agencies for Food and Agriculture to Louise Fresco, Assistant Director General, Agriculture Department, UNFAO (10 January 2003) in UNFAO/CGRFA, *Potential impacts of genetic use restriction technologies (GURTs) on agricultural biodiversity and agricultural production systems: Technical Study* (CGRFA-9/02/17 Annex Rev.1) E, 9th Regular Session, Rome (14 – 18 October 2002) (Annexed to UNEP/CBD/COP/7/INF/31).

⁵⁸⁸ Ibid.

explicitly accuses the report of excessive speculation about hypothetical risks while glossing over potential benefits. Building on this, the response also accuses the report of being unbalanced and of not being scientifically well grounded.⁵⁸⁹ It is apparent from the U.S. response that the U.S. side considers the conclusions of the report, especially the forecasts of specific socio-economic effects of GURT to be speculative and premature.⁵⁹⁰ This is the conclusion by the U.S. side even though numerous authors have supported the concerns raised in the report. Shi, Muscati and Oguamanam stress the concerns over seed monopoly by firms.⁵⁹¹ Cullet, Kesan, and Louwaars et al. emphasize the plight of developing world farmers who will be unable to save sterile V-GURT seeds for planting in subsequent years and become more dependent on seed suppliers.⁵⁹² And yet the U.S. position is at least partially accurate in that the forecasts referred to in the report are speculative although not necessarily premature if one is attempting evaluate all contingencies prior to making major changes in crop biotechnological composition.

The U.S. response then goes on to highlight specific concerns with the report that in general include: “premature conclusions, imbalanced discussions, speculations unsupported by data, and technical inaccuracies.”⁵⁹³

Some of the specific issues within the FAO report detailed in the U.S. response are:

1) Paragraph 4 of the FAO Report suggests that V-GURT, in particular, would not add value, to which the U.S. response is that farmers would decide if the added cost of V-GURT is justified based on the level of demand for new traits offered by the technology. In the case of T-GURTS, the U.S. response notes that even greater value could be present because the expression of certain traits could target specific environment conditions.⁵⁹⁴

2) Paragraph 19, 28, and 51 (iii) of the FAO Technical Study suggest that GURT would reduce biodiversity by replacing traditional crops with GURT crops in traditional [“low intensity, informal, farming systems”]. Furthermore, the report states that GURT would

⁵⁸⁹ Ibid.

⁵⁹⁰ Ibid.

⁵⁹¹ Oguamanam, *supra* note 290 at 68; Muscati, *supra* note 290 at 484; Shi, *supra* note 290 at 19.

⁵⁹² *Supra* note 194 at 55-59; Kesan, *supra* note 290 at 497; Louwaars, *supra* note 290 at 91.

⁵⁹³ Ibid at 2.

⁵⁹⁴ Ibid.

increase the divide between formal farm systems⁵⁹⁵ and informal farm systems.⁵⁹⁶ In response, the U.S. letter notes that no GURT currently exists beyond the laboratory and, therefore, there is no data on this matter.⁵⁹⁷ There is, however, fairly sketchy practical support for the U.S. position from the hybrid corn experience. Hybrid corn data presented in this thesis supports the position that the commercialization of technologically protected hybrid corn seed may have been at least partially responsible for raising the overall level of everyone's yield and income as yield/acre rose. As a result, the question of an increasing "gap" between formal and informal farm systems may be a meaningless statistic if it is based on the informal system simply advancing at a slower rate than the formal system.⁵⁹⁸

The U.S. response also states that, because of the high initial cost of GURT technology, informal farm systems are unlikely to be affected since they will not use GURT. As a result, these farmers will not have an affordability issue. The U.S. also makes the point that many factors such as any crop substitution [not only GURT] can displace traditional varieties.⁵⁹⁹ [This was the case during the Green Revolution of the 1960's, when a few very specific varieties of wheat were substituted for traditional varieties for reasons of yield and vigor.]

3) Paragraph 36 of the Report suggests GURT will result in an increase in the privatization of agricultural R&D. The U.S. response indicates [and the research in this thesis confirms] that the trend toward the privatization of agricultural R&D occurred long before the idea of GURT arose, and suggests that this has much to do with political decisions on the allocation of public sector funding for research.⁶⁰⁰ Schenkelaars et al.

⁵⁹⁵ Formal farm systems taken as a whole include seed production, control, and distribution activities carried out by the public and commercial sector.

⁵⁹⁶ An informal farm system is a flexible, localized system in which farmers produce, distribute and access seed from their harvest, or through exchange interactions among friends, neighbours, or local grain markets.

⁵⁹⁷ Supra note 587.

⁵⁹⁸ Supra note 435 at 4, Appendix Figure 3.

⁵⁹⁹ Supra note 587.

⁶⁰⁰ Ibid.

maintain that this privatization of agricultural R&D occurred after the 1980s.⁶⁰¹ Essentially, in the report the U.S. is suggesting that there may be a funding correlation that is identifiable but that there is no data to demonstrate that GURT will cause an increase in privatization of agricultural R&D.

The U.S. response also highlights what it considers to be technical inaccuracies in the FAO Report. One particularly relevant inaccuracy noted occurs in Paragraph 44 of the Report, which recommends that governments may want to discriminate as to whether GURT should be granted IPRs based on whether GURT acts to improve agricultural production rather than acting primarily as a value capture mechanism. The U.S. response notes that Article 27.1 of the TRIPS Agreement prevents WTO nations from discrimination in patent availability based on the specific field of technology that is under consideration for a patent.⁶⁰²

Overall the FAO Report and the U.S. response demonstrate some politicization of the GURT issue that appears to be an extension of that which exists for the overall GE seed issue. The interaction between the FAO and the U.S. representative also reveals the intensity of the opposing positions in the GURT debate at the highest level.

What follows is an examination of the key viability issues in this discussion. These issues go beyond the government to government or government to international organization interaction to include the GE seed industry, individual farmers and consumers. The viability issues of particular importance are global food security; environmental safety, security and biodiversity; economic well being of the industry; farmers and formal seed systems; policy and regulation; and consumer acceptance. These are the issues that are most susceptible to being affected by the biotechnological difference between GURT seeds and non-GURT GE seeds. They are also issues stressed by authors in the literature review.

⁶⁰¹ Supra note 166 at 89, 92, 93.

⁶⁰² Supra note 587.

6.1 Global Food Security

i) Assessing Food Security in Contemporary Agriculture

According to the 2009 FAO expert meeting on “How to feed the world in 2050”, several factors on the supply and demand sides are expected to result in tighter global grain markets over the next forty years.⁶⁰³ It is the grain⁶⁰⁴ situation that is of paramount concern in any discussion of global food security since grain represents the most important direct and indirect global food source.⁶⁰⁵

As such, grain crop yield growth is an ongoing concern for long-term global food security. Unfortunately, there is convincing evidence of a worldwide decrease in crop yield growth as reported by Pardey and Alston in their OECD paper titled, “Global and US trends in agricultural R&D in a global food security setting”.⁶⁰⁶ For example, they report that in more than half the countries, rice, wheat, corn and soybean yields from 1990-2007 increased at a slower rate than during the period from 1961-1990. In addition, excluding the unusual case of China, the 1990- 2007 period saw a decrease in land and labour productivity for the world’s leading twenty grain producers compared with 1961- 90 according to their 2005 value of agricultural output data.⁶⁰⁷ Excluding the twenty top producers, this productivity growth was, on average, slower in the rest of the world. For these other countries, land productivity growth was down to 0.88%/year for 1990 to 2007 from a growth rate of 1.74% per year during 1961- 90. The corresponding values for labour productivity were 1% and 0.07%.⁶⁰⁸

A major concern brought forward by this data is whether this decline in growth rate indicates a technological plateau for crop yield and if so, how this may affect future food security. As a consequence of this trend, it appears that future agricultural growth may be reliant on finding new methods of increasing yields on current cropland or by increasing the ability of

⁶⁰³ RA Fischer, Derek Byerlee & GO Edmeades, *Can Technology Deliver on the Yield Challenge to 2050?* Paper produced for the UNFAO Expert Meeting on How to Feed the World in 2050 (24-26 June 2009) (Rome: UNFAO, Economic and Social Development Department, 2009) online:FAO< <http://www.fao.org/3/a-ak977e.pdf>> at 3.

⁶⁰⁴ To avoid confusion it should be noted that cereal and grain are used interchangeably in this thesis although, in fact, cereal is grain without the bran coating.

⁶⁰⁵ Supra note 603.

⁶⁰⁶ Supra note 483 at 23.

⁶⁰⁷ Ibid at 24.

⁶⁰⁸ Ibid at 23.

crops to grow on poorer quality land or in less than ideal climates. However, food security enhancement requires more than a scientific capability that allows food to grow in less than ideal circumstances or that produces more food on existing land. What is required is an incentive to innovate on the part of private sector firms that are increasingly responsible for cutting edge agricultural R&D.

In a 2012 LLM paper, I argue that IPRs [primarily in the form of utility patents] enhance food security and that this linkage is based on private sector innovation that is promoted by those very IPRs. That paper outlines the ongoing controversy over whether IPRs associated with GE seeds enhance or hinder food security. That paper concludes that GE crops enhance food security and that IPRs associated with those GE crops are fundamental to the vitally important private sector innovation that advances the development of food security-enhancing traits.⁶⁰⁹

There is no widely accepted argument that counters the view that the ability of private industry to capture value from the commercialization of GE seeds is, to a great extent, dependent on an effective method of protecting IPRs. GURT has shown the potential to alter the dynamics of innovation protection and innovation promotion. Can GURT have just as great an effect on food security?

GURT not only protects seed IP but also can allow GE seeds to act dynamically.⁶¹⁰ That is, the seeds can adapt or be adapted to climatic and land quality situations by switching genes on and off to match plant growth potential to the environment. Ultimately, for this thesis, the question is not does GURT promote food security but rather what is the difference in food security when GE seeds are protected by patents alone or by the primarily technological IP protection of GURT. Specifically, is there a difference in the outcomes of the FAO dimensions of food security [availability, access, utilization and stability] when comparing the legal and the technological methods of GE seed protection?

While there are four FAO recognized dimensions of food security, not all of them are equally relevant to the thesis question. After all, in the case of both alternatives we are dealing

⁶⁰⁹ Supra note 71 at 92.

⁶¹⁰ T-GURT allows for the activation or deactivation of the value-added traits through the application of an inducer.

with GE seeds and these seeds have specific characteristics that affect food security without even considering IP protection.

The specific attributes of the food security dimensions that are most affected by the method of IP protection associated with GE seeds can be narrowed down to: production [yield of important crops as this relates to the availability dimension]; affordability [price volatility, price index and relative expenditures on food for the access dimension]; nutritional content for the utilization dimension; and stability [the stability of the other three dimensions over the long term]. A key question is whether GURT is superior or inferior to patents for enhancing these aspects of food security.

To assess global food security from an availability perspective, one should focus on the yield projections of major crops such as wheat, rice, and corn because as pointed out in the paper produced for the UNFAO Expert Meeting on “How to Feed the World in 2050,” these are the cereals that dominate the human diet.⁶¹¹ As such, yield growth in these crops can be considered to be critical to meeting future global demand for food for human and farm animal consumption.⁶¹²

Cereal crops supply half of all global food calories and these crops are grown on 58% of the available global cropland.⁶¹³ Since 1960, rice and wheat together “have accounted for half of the increased per capita energy intake in developing countries.”⁶¹⁴ A third cereal, corn is extensively used in commercial animal feed where it is the source of over 60% of the energy in those feeds. Together, corn, wheat and rice are predicted to be the major source of increase in cereal consumption by 2050. In fact, they are expected to represent 80% of that increase.⁶¹⁵

The importance of these three cereals (wheat, rice and corn) as a current and future source of food, and therefore, food security highlights the need for sustainable, stable crop

⁶¹¹ Supra note 603 at 1.

⁶¹² Supra note 71 at 71.

⁶¹³ Supra note 603 at 3.

⁶¹⁴ Ibid.

⁶¹⁵ Mark W Rosegrant et al, “Exploring Alternative Futures for Agricultural Knowledge, Science and Technology (AKST)” ACIAR Project Report (ADP/2004/045)(FR2009-34) (Canberra, Australia: ACIAR, 2009) as cited in RA Fischer, Derek Byerlee & GO Edmeades, *Can Technology Deliver on the Yield Challenge to 2050?* Paper produced for the UNFAO Expert Meeting on How to Feed the World in 2050 (24-26 June 2009) (Rome: UNFAO, Economic and Social Development Department, 2009) online: FAO < <http://www.fao.org/3/a-ak977e.pdf> > at 3.

productivity growth.⁶¹⁶ The UNFAO Expert Report explains that sustainability is critical to maintain food supply stability. An unsustainable system of production could result in environmental damage and an inability to maintain this stability.⁶¹⁷

Ongoing changes, such as stagnant or decreasing levels of arable land or negative climate issues that diminish the growth rate in global yields have obvious negative implications for global food security. The problem of arable land is addressed in a report titled, “Transgenic Plants and World Agriculture”, which was prepared with the support of the Royal Society of London, the USA National Academy of Sciences, the Brazilian Academy of Sciences, the Chinese Academy of Sciences, the Indian National Academy of Sciences, the Mexican Academy of Sciences and the Third World Academy of Sciences.⁶¹⁸ The Report states that the increase in production required in widely consumed staple crops (i.e. corn, rice, wheat) and some lesser more regional staple crops (i.e. cassava, yams, sorghum, potatoes and sweet potatoes) requires that yield per acre must increase because current farmland is already intensively cultivated.⁶¹⁹

As a result of these issues, it is reasonable to assume that a greater reliance on trade will be required to meet food demands for an increasing number of countries. As long as trade barriers are not an issue, high production costs will encourage crop growth to shift to areas of the world where production costs are low.⁶²⁰ However, as the Expert Report concludes, trade will not likely be able to meet food demand in all circumstances such as for countries such as China and India. They must produce most of their own staple foods because their massive demand cannot be satisfied by the relatively small size of world agricultural trade in food.⁶²¹

In Africa, lack of adequate infrastructure, limited access to the sea, and financial considerations dictate that most food must be locally produced.⁶²² The potential for GE crops to grow in poor agricultural conditions or to produce high yields is a powerful argument in favour

⁶¹⁶ Supra note 71 at 72.

⁶¹⁷ Supra note 603 at 4.

⁶¹⁸ Royal Society of London et al. *Transgenic Plants and World Agriculture* (Washington, D.C.: National Academy of Sciences, 2000).

⁶¹⁹ Ibid at 5.

⁶²⁰ Supra note 603 at 4.

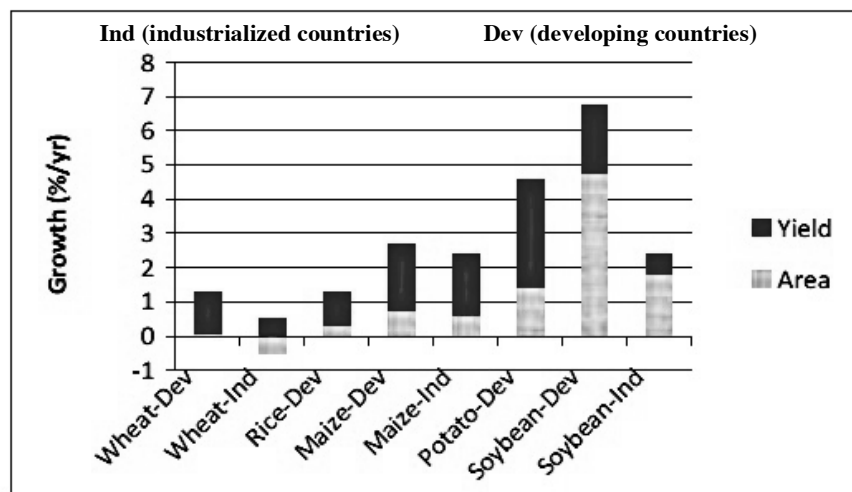
⁶²¹ Ibid.

⁶²² Ibid.

of their use. GE crops can also counterbalance the failings of the global trade infrastructure to meet the demand for food.⁶²³

It is intuitive that increased production of specific crops can occur either by increasing the yield per acre or by increasing the amount of arable land on which the crop is grown and maintaining the existing yield per acre. A third alternative is to do both. As can be seen in Figure 15 below, yield has been a significant factor responsible for increasing production in many of the key crops that are critical for global food security in recent years in both developing and industrialized (developed) countries. This graph illustrates that in the crops most important for food security [corn, wheat, and rice], increased production has been due to yield growth.⁶²⁴ Incidentally, this graph also highlights the recent and dramatic growing intrusion of soybeans into the realm of important crops. This has created the unusual anomaly in Figure 15 where soybean area growth is shown to be greater than yield growth. The explanation here is that there has been a shift from other crops to soybeans, thereby increasing the area of soybeans farmed.

**Figure 15: Contribution of Area Yield to Production Growth
1997-2007⁶²⁵**



Source: FAOSTAT

⁶²³ Supra note 71 at 73.

⁶²⁴ Ibid at 73-74.

⁶²⁵ Supra note 603 at 9.

Since the beginning of the Green Revolution⁶²⁶, one of the major factors that led to an increase in developing world crop yields was fertilizer use. This type of chemical crop growth enhancement accounted for between one-third to one-half of yield increase.⁶²⁷ Currently, 68% of total fertilizer use takes place in developing countries. The remainder of the increased yield growth comes from a combination of improved farming methods and seed varieties.⁶²⁸

The global picture for cereal in Figure 16 below reveals important differences in cereal production by region and by crop. Of particular significance is the dramatic decrease in yield growth in developing countries that followed a strong increase at the time of the Green Revolution.⁶²⁹ “The ten-year moving average growth rates for wheat and rice in developing countries has declined from the mid-1980s to about 1% annually by 2001”.⁶³⁰ Although yields are still increasing, they are doing so at a decreasing rate. Should this trend continue, it is possible that yields will begin to decline resulting in serious consequences for food security.

⁶²⁶ “The Green Revolution is the term used to describe the spread of new agricultural technologies that dramatically increased food production in the developing world beginning in the middle of the 20th century. The crops that were developed, as part of this effort were superior to other locally planted crops in yield increase, yield stability, wide-scale adaptability, short growing season duration, resistance to biotic stresses (diseases and insects), tolerance to abiotic stresses (drought and flooding), and grain quality.” The Green Revolution significantly increased food production in Asia and Latin America when these areas were at risk widespread malnutrition. (Felicia Wu & William Butz, *The Future of Genetically Modified Crops: Lessons from the Green Revolution*. (Rand Corporation, 2004) 11-12).

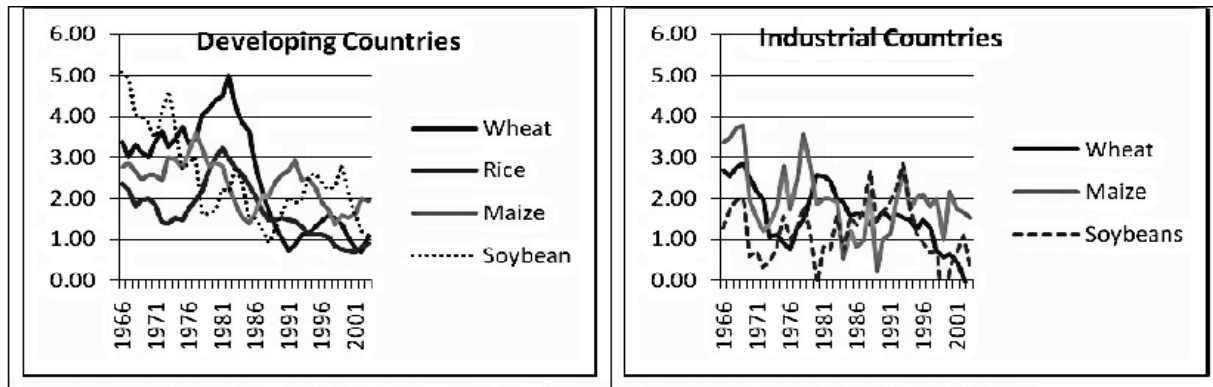
⁶²⁷ P Heisey & GW Norton, *Fertilizer and other Chemicals* (2007) p2747-2783 in eds R Evenson & P Pingali. *Handbook of Agricultural Economics, Vol 3*. (Elsevier BV, Amsterdam) as cited in RA Fischer, Derek Byerlee & GO Edmeades, *Can Technology Deliver on the Yield Challenge to 2050?* Paper produced for the UNFAO Expert Meeting on How to Feed the World in 2050 (24-26 June 2009) (Rome: UNFAO, Economic and Social Development Department, 2009) online: FAO < <http://www.fao.org/3/a-ak977e.pdf>> 9.

⁶²⁸ Supra note 603 at 9.

⁶²⁹ Ibid at 11.

⁶³⁰ Ibid.

Figure 16: Ten-Year Moving Average Yield Growth Rates⁶³¹



Note: Growth rates estimated by log linear trend regression. Year refers to the mid year of the decade.
Source: Computed from FAOSTAT

[Wheat, rice, maize (corn): in developing countries (left panel); in industrial countries (right panel)]

Currently, per capita global demand for direct consumption (i.e. as food) for cereals is expected to rise only in sub-Saharan Africa.⁶³² At first glance this lack of increasing demand would seem to be a positive development. However, this decrease in demand for direct consumption cereals in developing regions can often be attributed to upwardly mobile consumers extending their diets to include high value livestock that require feed grains such as corn.⁶³³ This means that rather than being used for direct consumption, these cereals are increasingly being used to feed cattle. Furthermore, corn and wheat are used for biofuels removing an increasing portion of their production from the food system. The International Food Policy Research Institute (IFPRI) predicts that grain demand for biofuel production will grow until 2020-25.⁶³⁴

It is further estimated that biofuel production by industrial countries will use 150 kg/capita of corn by 2020.⁶³⁵ This is the equivalent of the current per capita consumption of cereals as food in developing countries.⁶³⁶

If one projects a global population of 9.2 billion by 2050 combined with projected

⁶³¹ Ibid.

⁶³² Ibid at 12.

⁶³³ Ibid.

⁶³⁴ Supra note 615 at 12.

⁶³⁵ Ibid.

⁶³⁶ Ibid.

demands for biofuel, it is estimated that an increase from 2000 levels of 1.048 billion tons (56%) in cereal production would be required to meet total demand by 2050. Of this increase, 41% is for livestock feed. Based on FAO, OECD, and World Bank data, corn, wheat and rice will respectively represent 45%, 26% and 8% of the estimated increase in cereal demand.⁶³⁷

All of this crop yield data has significant implications for future global food security. According to the FAO 2009 expert meeting on how to feed the world in 2050, food, feed and biofuel needs cannot be met if global yields continue to increase at the rate established over the past five decades.⁶³⁸ If the current trend continues, the food security situation, especially in the developing world, will likely deteriorate because with decreasing arable land, traditional alternatives available for maintaining or increasing crop yields are limited. The use of patented herbicide and insect resistant GE seeds, while once representing a non-traditional alternative, is fast becoming a more traditional alternative that has greatly increased crop yields. That is why GE seeds, which are currently legally protected through patents, may be seen as a necessity to meet future food requirements. This is also the conclusion of the GE seed companies. However, many authors feel the opposite. Cullet, Haugen, and Tansey, while acknowledging that some aspects of food security may be improved by patented GE seeds, see patent based IPRs associated with GE seeds primarily as a way to strengthen the private seed industry.⁶³⁹

ii) Food Security Attributes and IP Protection Alternatives

The situation described above represents the current situation and projected trend in some of the most important cereal crops. The question for GURT seeds is whether their commercialization would affect the future global food security situation beyond that which would occur from the use of non-GURT GE seeds.

First, would GURT improve the production/yield of current non-GURT patented only GE seeds? The science that allows for GE seeds to be optimized for drought or other environmental conditions is established and if found to be effective will undoubtedly be made commercially available for non-GURT GE seeds. These non-GURT environmentally optimized seeds could be

⁶³⁷ Ibid.

⁶³⁸ Supra note 603 at 13.

⁶³⁹ Supra note 194 at 12; supra note 196 at 12; supra note 76 at 13.

useful for regions where conditions are known before planting. However, once planted they cannot be adapted to environmental changes since the value-added trait would be active by default. Therefore, for example, non-GURT GE seeds can be developed for an area subject to drought such that they can grow optimally with a decreased need for water. If that region should have an unusual growing season where more rainfall than normal occurs, this crop may produce a lower yield if it is optimized for drought conditions.

Ideally, a seed that can dynamically adapt or be adapted to changing environmental conditions would have the advantage of being able to grow optimally under various conditions. This is where a GURT seed could flourish. The theory behind GURT suggests that T-GURT could potentially improve the availability food security attribute (yield) beyond what is possible with non-GURT seeds because of the ability to turn genes on and off depending on environmental conditions. The result is improved long-term food security.

Non-GURT GE seeds are also problematic for seed firms because of their legal IP protection. The fact that these non-GURT seeds could be saved illegally by farmers in weak IP environments would further limit the seed's availability in these locations since seed firms would be hesitant to sell their seed in circumstances that did not adequately address value leakage.

T-GURT seeds would be more likely to be available in these unfavourable IP environments since the activation of the value-added attribute would require company input and second generation seeds would not have activated value-added traits. Unlike in the case of non-GURT GE seeds, developing world farmers could grow second-generation T-GURT seeds without the value-added traits activated and, in this way, not infringe on the seed firm's patent. In this way, farmers could choose to grow a value-added trait-free crop based on these second-generation seeds without running afoul of the seed firm's trait patents.

The technological control that T-GURT seeds provide could be successful in increasing crop yield in both developed and developing countries. In developed and developing countries, the primary benefit is the ability to grow dynamically in various climatic and soil conditions. In developing countries, one can add two benefits to this. First, the IP protective capacity of T-GURT should encourage seed firms to sell the product there. Second, seed saving of T-GURT seeds would not be a serious IPR issue since the value added traits in the save seed are not

activated.

V-GURT is the other GURT that must be addressed to determine its impact on productivity/yield. V-GURT offers no developed or developing world benefit for productivity/yield that is superior to non-GURT GE seeds. However, V-GURT can have a detrimental effect on food security in the developing world. A very real food security problem could result from the use of V-GURT seeds if we accept that there are farmers in the developing world illegally using second-generation non-GURT GE seeds because of the limited possibility of detection. The illegal use of second-generation non-GURT GE seeds adds to food security in some areas of the developing world and their replacement with V-GURT seeds would decrease food security there because the second-generation seeds are sterile. Not only is this a food security problem but also the previously noted TRIP protections that allow nations to bypass IPRs in some cases would be irrelevant with the use of V-GURT technology that is independent of existing legal IPR regimes.

While T-GURT seems to offer significant potential for increased food security through increased productivity/yield, there is the question of affordability not only from the perspective of the farmer but also for the food processor and the consumer.

Maintaining or reducing prices of food staples should rival productivity improvements as a key agricultural concern. From 1961-2006 real global food staple prices declined “at an average annual rate of 1.8% for wheat, 2.6% for rice and 2.2% for corn”.⁶⁴⁰ The more efficient and intense use of inputs has been the source of this reduction and it has been a key source of poverty reduction during this period.⁶⁴¹

Governmental tax and price policies can be influential in affecting crop yields and prices and promoting agricultural efficiency. Many developing countries had relied on agricultural taxes to help subsidize cheap food. Although the result was cheap food, a long-term consequence was to limit growth in this sector. Agricultural liberalization policies introduced in the 1990s largely corrected this problem and the average tax on agriculture has decreased.⁶⁴² Another

⁶⁴⁰ Keith O Fuglie, “Is a slowdown in agricultural productivity growth contributing to the rise in commodity prices?” (2008) 39 *Agricultural Economics* 431 at 437.

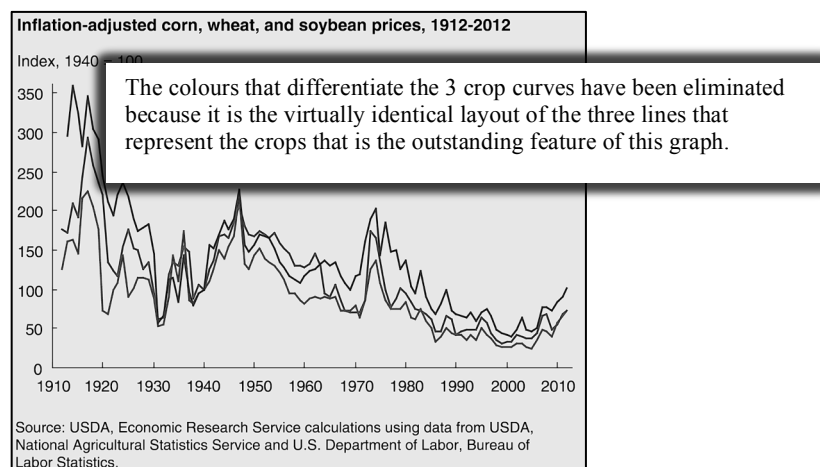
⁶⁴¹ *Ibid.*

⁶⁴² K Anderson, ed, *Distortions to Agricultural Incentives: A Global Perspective, 1955-2007*, (London: Palgrave

factor affecting the price of food crops is elasticity. In the short term the supply of food crops is usually inelastic⁶⁴³ with respect to prices.⁶⁴⁴

GE crops and their effect on supply have presented some unanticipated pricing trends. One perspective on crop prices is shown in Figure 17, which includes two of the most important GE crops, corn and soybeans. As previously noted, these two crops have reached a stage where genetic engineering is the rule rather than the exception.

Figure 17: Inflation-adjusted Corn, Wheat and Soybean Prices, 1912–2012⁶⁴⁵



Macmillan and Washington DC: World Bank, 2009) as cited in RA Fischer, Derek Byerlee & GO Edmeades, *Can Technology Deliver on the Yield Challenge to 2050?* Paper produced for the UNFAO Expert Meeting on How to Feed the World in 2050 (24-26 June 2009) (Rome: UNFAO, Economic and Social Development Department, 2009) online:FAO< <http://www.fao.org/3/a-ak977e.pdf>> at 37.

⁶⁴³ Elasticity is an economic term that describes the degree to which changes in the price of a product affect the quantity of the product produced. When one says that yields of basic food crops are supply inelastic, it means that the yield is not greatly affected by price in the short term. This is because once crops are planted to meet anticipated demand price changes will not affect the crop yield in the short term. On the demand side there is also inelasticity. People require food and, as a result, they are more willing to pay the market price, whatever it is, to obtain that food. This especially the case for basics such as grains. However, this is a short-term effect because, in the long term, people find substitutes for foods that are costly.

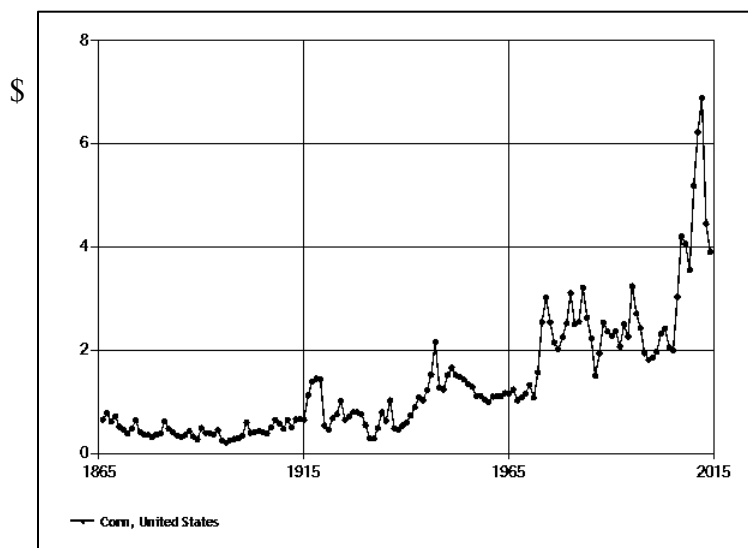
⁶⁴⁴ Supra note 615 at 37; Hans Binswanger, “The policy response of agriculture” in *Proceedings of the World Bank Annual Conference on Development Economics 1989*, (Washington D. C.: World Bank, 1989) 231 as cited in RA Fischer, Derek Byerlee & GO Edmeades, *Can Technology Deliver on the Yield Challenge to 2050?* Paper produced for the UNFAO Expert Meeting on How to Feed the World in 2050 (24-26 June 2009) (Rome: UNFAO, Economic and Social Development Department, 2009) online:FAO< <http://www.fao.org/3/a-ak977e.pdf>> at 37.

⁶⁴⁵ USDA, *Inflation-adjusted Corn, Wheat and Soybean Prices, 1912-2012*, (2014) online:

USDA<<http://www.ers.usda.gov/data-products/chart-gallery/detail.aspx?chartId=40093&ref=collection&embed=True#.VDLj7y9icy4>>.

The significance of this graph comes from three of its features. First, it represents data accumulated over a prolonged period of time. The extended time period results in data that includes periods of many differing macroeconomic and weather conditions as well as the development of many new, often disruptive, technologies. Second, this graph is concerned with three different crops of major importance not only in the U.S. but also internationally. Third, the prices reported within this graph are significant in understanding price trends because the prices are inflation adjusted, thereby eliminating an often-present confounding factor (in this case, that factor is inflation) that distorts the true meaning and usefulness of price trends. One can see the effect that controlling for inflation has on the meaning of the data by looking at Figure 18 showing unadjusted prices of corn received by U.S. farmers from 1865 to 2015(projected).

Figure 18: Prices Received by U.S. Farmers (U.S. Dollars)⁶⁴⁶



The first inflation-adjusted graph in Figure 17 shows a decreasing trend in prices for corn whereas the second graph (Figure 18) with unadjusted prices shows the opposite trend. One can see from these two graphs that the more meaningful inflation-adjusted price of corn provides a completely different conclusion as to corn price trends over time.

⁶⁴⁶ USDA. *Prices Received by U.S. Farmers*, (2015) online: USDA <<http://www.ers.usda.gov/data-products/feed-grains-database/feed-grains-custom-query.aspx#ChartPanel>>.

Some revealing conclusions can be drawn from Figure 17. First, the prices of the three crops have for the most part paralleled each other for the time period of the graph. Even with the dramatic technological introduction of corn hybridization in the 1930's and the resulting gradual elimination of farmer-saved corn seed for replanting, the trend for corn matched the other two crops.⁶⁴⁷ Even under these circumstances the inflation-adjusted price of corn is not strikingly high even though the technological IP protection is very high.

Furthermore, Figure 17 illustrates that the introduction of GE corn and soybeans after 1995 still did not lead to any dramatic changes in inflation-adjusted crop prices. In fact, these high-tech crops followed the same trend as low tech wheat suggesting that the price was not heavily influenced by the technology. From a food security perspective and specifically looking at the access determinant of food security, the price trends of hybrid corn have not been out of line with non-GE wheat and non-GE soybeans. And even since the introduction of GE hybrid corn and GE soybeans in the mid to late 1990s, there are no dramatic increases in prices. In fact, the prices for all three crops are within their historic lows (inflation adjusted). The price of corn, which has been technologically protected for a long period of time, does not vary from the trend of non-hybrid crops on the graph prior to the introduction of GE crops in the mid-1990s. The trend demonstrated by the technologically protected corn suggests that technologically protected GURT, if commercialized, may behave similarly and not automatically result in high, monopolistic prices.

What would be the likely effect of GURT on food access in terms of the price of food? Initially, it is possible that GURT seeds and food products could have a higher price than their non-GURT counterparts. Like any new technology, at least at the outset, it could be priced high to help recover R&D costs. Haugen suggests that price hikes in in the most sought after GE seeds would translate into price hikes in specific food varieties.⁶⁴⁸ Stiglitz correctly predicted the initial increase in the price of patented GE seeds due to a lack of competition.⁶⁴⁹ There is no reason to believe that GURT seeds would not follow the same pattern. However, as with non-

⁶⁴⁷ Recall that in hybrid corn we have an example of IP that is technologically protected and that protection is not time-limited as would be the case with a patent protected GE seed.

⁶⁴⁸ Supra note 196 at 15.

⁶⁴⁹ Supra note 214.

GURT GE crops and hybrid corn, as GURT-based products become more readily available, and a competitive market develops, prices should fall. Is it possible to guarantee this outcome? No, but the historical account of the price path of non-GURT GE seeds suggests that GURT could behave similarly. However, it must be stressed that this conclusion should be considered to be speculative.

There does not appear to be much advantage from a nutritional perspective for GURT since traditional GE technology can accomplish many of the same goals. The growing environment is not necessarily a significant issue if one is concerned with the nutritional content of a crop. Any nutritional trait that can be introduced with GURT can also be introduced with traditional patented GE seeds. The question is how likely is it that a GE seed firm will produce the new trait if IP protection is questionable. As already established, GURT would have a greater protective ability and provide a greater incentive for a GE seed firm to take the investment risk on a new nutritional trait. Just as is the case with increased productivity/yield, the increased protective capacity of GURT seeds should encourage their use in developing countries. The difference between nutritionally enhanced non-GURT GE seeds and GURT seeds is that the GURT seeds will be of no value for those farmers who wish to use the technology illegally because the value added nutritional trait will be inaccessible with T-GURT or V-GURT. In contrast, with the non-GURT GE seeds, illegal use and benefit by farmers is possible.

Purely from the perspective of yield, one can see that with the illegal use of T-GURT seeds the plant will grow but the value added nutritional trait would be inactive. However, if a farmer is concerned specifically with a nutritional content, then the yield if it does not contain that nutritional value-added content, may not be relevant. This leaves GURT at no significant advantage in the realm of food security when it comes to nutritional content.

Stability is the final food security dimension, and here traditional GE seeds can deal with many food stability matters. However, GURT has the added potential benefit of addressing stability issues dynamically. For example, the ability of GURT to adjust growth phases of GE seeds to match environmental conditions could increase the stability of the food supply by decreasing the likelihood of crop failure if, for example, the germination of the seed can be prevented in poor environmental conditions. The importance of the stability aspect of global food

security cannot be underestimated. The 2000 “Transgenic Plants and World Agriculture” report from the U.S. based National Academy of Sciences finds this aspect of food security so compelling that it recommends enhanced production stability as a key goal of transgenic crop research.⁶⁵⁰

T-GURTS in which traits can be activated or deactivated depending on external environmental conditions would be particularly useful for this type of improvement in production stability. For example, if there were a trait that can be activated that will cause a plant to grow when there is insufficient water rather than remain dormant, production stability would be enhanced. This is because stability emphasizes access to food at all times which means that access is not subject to economic or climatic shocks or cyclical events. According to the 2006 UNFAO Policy Brief on Food Security, stability emphasizes the importance of reducing the risk of adverse effects on availability, access and utilization.⁶⁵¹

While the case can be made that T-GURT promotes overall food stability, the same cannot be said for V-GURT. There is no indication that V-GURT seeds can accomplish this goal to a greater degree than non-GURT GE seeds. In fact, the sterility of second-generation V-GURT seeds can decrease food security if many developing world farmers depend on the use of illegally obtained patented GE seed.

Food security is also influenced by other viability criteria such as biodiversity, biosecurity and the economic well being of the industry, farmers and formal seed systems. As these viability criteria are addressed, the interrelationships among them become obvious and underlines the importance of assessing each one with an eye to the influence that they may have on each other.

6.2 Environmental Safety, Biosecurity and Biodiversity

Biodiversity is a broad term that is defined elegantly on the World Wildlife Fund website as, “... the variety within and between all species of plants, animals and micro-organisms and the

⁶⁵⁰ Supra note 618 at 9.

⁶⁵¹ UNFAO(a), supra note 77.

ecosystems within which they live and interact.”⁶⁵² The aspect of biodiversity that is specific to this thesis is agricultural biodiversity which includes, according to the United Nations Environmental Program (UNEP) through the Convention on Biological Diversity (CBD), “all components of biological diversity of relevance to food and agriculture, and all components of biological diversity that constitute the agricultural ecosystems, also named agro-ecosystems: the variety and variability of animals, plants and micro-organisms, at the genetic, species and ecosystem levels, which are necessary to sustain key functions of the agro-ecosystem, its structure and processes.”⁶⁵³ Although narrowed to focus on agriculture, even this subdivision of biodiversity is too broad for the requirements of this thesis. This is not because the various elements of agricultural biodiversity can somehow be detached from the genetic manipulation of seeds but rather that to remain within the bounds of the specific thesis question, it is the potential effects on biodiversity of the *artificial* manipulation of crop genes that is the primary focus here. Also, it is only the differences that arise in the comparison of GURT with non-GURT GE seeds that are relevant to this thesis topic. Because of the importance of this issue for future food security, both industry and international regulatory bodies have waded into the GURT biodiversity discussion.

As an organization representing the global seed industry, the International Seed Federation (ISF) view on biodiversity and GURT is focused on the effects of this technology on industry and farmers. In contrast, the CBD has a broader scope of interest by also reflecting the biodiversity/biosecurity concerns of other stakeholders such as consumers and governments. As noted in the 2002 FAO Technical Study “CGRFA-9/02/17Rev. – Potential impacts of genetic use restriction technologies (GURTS) on agricultural biodiversity and agricultural production systems”, the CBD raises concerns that the spread of GURT into non-target plants could negatively affect biodiversity.⁶⁵⁴ In a position paper specifically addressing this CBD/GURT biodiversity concern, the ISF states that the sterility that V-GURT seeds impart to second generation seeds cannot spread beyond the first generation plants because a sterile seed (second

⁶⁵² *What is Biodiversity* (2015) online: WWF
<http://www.wwf.org.au/our_work/saving_the_natural_world/what_is_biodiversity/>.

⁶⁵³ Supra note 289 at para 23.

⁶⁵⁴ Supra note 586 at 18-25.

generation seed) cannot grow and therefore cannot produce pollen. The ISF position paper explicitly states that because of this GURT attribute, V-GURT seeds do not threaten biodiversity.⁶⁵⁵

However, as much as this specific assertion may be true, various authors with no ties to the GE seed industry have mixed opinions on the potential effect of GURT on biodiversity. For example, Muscati identifies a potential biodiversity problem in developing countries because the use of GURT would emphasize major rather than local crops.⁶⁵⁶ In contrast, Collins and Kreuger suggest that seed company competition will increase biodiversity.⁶⁵⁷ Even if one is inclined to agree with the broad industry biodiversity position, there is still the question of the pollen from the initial non-sterile seeds that are initially purchased and planted by the farmer. To this point, the ISF paper notes that GURT is designed to target modern varieties of self-pollinated transgenic crops. The ISF paper emphasizes that GURT is not for use in landraces⁶⁵⁸ or varieties used by subsistence farmers.⁶⁵⁹ The ISF position is that there would be low levels of cross-pollination between V-GURTS and local varieties or cross-pollinated crops.⁶⁶⁰ This latter belief is troubling in two ways. First, should this belief be inaccurate and cross-pollination was to occur at a more than minimal level, it is possible that non-targeted plants may unintentionally produce sterile seeds. While this is not an issue when it comes to the use of these seeds as food, it is a concern if those seeds are required for replanting by developing world farmers with no interest in GE seeds. As much as this could be a problem in the developing world, it would be less so in the developed world where the problem would be self-limiting since the sterile seeds produced could not produce another crop.

Unfortunately, developing world farmers who save seed and are subject to this problem may find themselves planting a less than optimal amount of viable seeds. To make matters worse, this result would not be evident until after planting had occurred. While this is not a significant long-term biodiversity/biosecurity issue, it does demonstrate how a viability issue

⁶⁵⁵ Supra note 497.

⁶⁵⁶ Muscati, supra note 290 at 483.

⁶⁵⁷ Supra note 314 at 14.

⁶⁵⁸ A landrace is a regional or locally developed traditional plant/crop variety developed over a long period of time.

⁶⁵⁹ Supra note 497.

⁶⁶⁰ Ibid.

such as biodiversity can overlap into another viability issue. In this case, that other viability issue is the economic viability of the farmer in the developing world who depends on saved seed for future crops.

The self-limiting and short-term nature of this GURT problem suggests that it may not be a widespread biodiversity/biosecurity issue. As such, this is not a significant problem for crop biodiversity. In contrast, non-GURT GE seeds have a greater potential to affect biodiversity because all seeds and pollen are viable. So, in a comparison between GURT and non-GURT seeds, the industry perspective is that GURT would be less of a problem for biodiversity/biodiversity than traditional GE plants because there is a diminished likelihood of transgene transmission, and that transmission, if it did occur, would be low-level and self-limiting.⁶⁶¹

Of course, the industry also holds that traditional GE seeds do not pose a biodiversity/biosecurity problem beyond that which occurs with naturally breeding.⁶⁶² This makes perfect sense when one considers that a non-GURT GE plant reproduces in the same way as a non-GE plant. Current evidence supports this contention, but there may be those who question evidence presented by someone or some organization (such as the ISF), which may benefit from the production of this evidence. This does not make the evidence unreliable, but it may provide a basis for suspicion.

Several international science academies, while extolling the virtues of GE seeds in general and GURT specifically, do note that biosecurity can be an important issue as the scope of GURT traits expands. A previously discussed report titled, “Transgenic Plants and World Agriculture,” prepared under the auspices of various national science academies, stresses the importance of the transgene spread prevention attribute of GURT as an enhancement to the high overall value that they ascribe to GE crops. This report recommends that transgenic crop research should focus on this biosecurity aspect of biodiversity for the benefits of GE seeds to be maximized.⁶⁶³ Specifically, the research should focus on plants that will not inadvertently spread traits that are unwanted by those who did not specifically request them. This is specifically a

⁶⁶¹ Ibid.

⁶⁶² Ibid.

⁶⁶³ *Supra* note 618 at 12.

beneficial attribute of V-GURT. This report also emphasizes that certain traits that allow plants to produce pharmaceuticals or industrial chemicals are especially in need of security and that again V-GURT, in particular, is very useful in supporting this goal.⁶⁶⁴

As much as the “Transgenic Plants and World Agriculture” report lauds GURT as an environmental control mechanism for GE crops, it does acknowledge that there is an ongoing debate on this issue.⁶⁶⁵ The ability to prevent inadvertent spread is an absolute requirement if GE plants are to be used for pharmaceutical or industrial chemical production. Non-GURT GE crops simply are unsuitable for this type of non-food crop production because the technological control mechanisms required for security are simply not possible.

This type of biosecurity concern would be an issue for large farms mainly in developed countries where the use of GE crops for the production of pharmaceuticals or industrial chemicals is much more likely to occur than in small farms in developing countries where food production is the most valuable use of these type of crops.

In the UNFAO/CGRFA-9/02/17 “Report of the ad hoc technical expert group meeting on the potential impacts of genetic use restriction technologies on smallholder farmers, indigenous and local communities and farmers’ rights,” the technical study considered that the positive biodiversity property of V-GURT limiting the release of genetic material might encourage GE seeds of the GURT variety. However, if the smallholder farmers found that the use of a single GURT variety was beneficial in this way, this use would decrease the farm crop biodiversity that comes with farmers using multiple local varieties on their land.⁶⁶⁶ This is biodiversity loss by choice rather than through natural occurrence.

This type of biodiversity loss is not something that is new. This has occurred over the past century simply from traditional breeding and the widespread adoption of the resulting high-quality varieties. The breeding and adoption of specific superior wheat varieties at the expense of older less attractive varieties in Canada is a perfect example of what some might consider as “biodiversity loss.”⁶⁶⁷ While biodiversity may have decreased as a result of this adoption, one

⁶⁶⁴ Ibid at 8.

⁶⁶⁵ Ibid at 16.

⁶⁶⁶ Supra note 586 at 6-7.

⁶⁶⁷ *Canadian Wheat Class Modernization* (2016), online: Canadian Grain Commission

might be reluctant to suggest that farmers would be better off producing lower yield, less nutritious crops in the name of biodiversity.

An often overlooked point made by the UNFAO CGRFA-9/02/17 Technical Study is that the commercialization of GURT could increase R&D in plant breeding that would lead to many new GE varieties, thereby, increasing biodiversity.⁶⁶⁸ This is the point made by Collins and Kreuger that was noted earlier. However, as with many GURT predictions, this is only speculation since it may be that this increase in R&D would be specific to GURT and might lead to less R&D in traditional GE plants that are not technologically protected. As a result, R&D expenditures would be shifting rather than increasing, leaving a negligible overall change in R&D.

The CGRFA-9/02/17 Technical Study also highlights an obvious biosecurity benefit of GURT and that is that it would reduce volunteer plants⁶⁶⁹ in neighbouring farm fields in the case of V-GURTS.⁶⁷⁰ As it is, non-GURT GE seeds can blow onto neighbouring fields and grow. Although this problem does not result in extensive field “contamination”, it can cause problems if, for instance, a farmer is differentiating his crop as non-GE for the purpose of specific buyer demands. This has not been a problem from the perspective of inadvertent patent infringement leading to legal action against farmers by seed companies. Recall that in the *OSGATA v Monsanto* case, the court found that Monsanto’s clear website commitment not to take action against farmers for fields with inadvertent crop contamination by patented seeds was sufficiently binding on the company that the court saw no reason to allow the case to continue.

The ISF concurs with the CGRFA-9/02/17 Technical Study Report that V-GURT improves biosafety by reducing the spread of transgenes, but the ISF goes a step further and suggests that this fact alone should promote the use of GURT for all GE seeds.⁶⁷¹

The Technical Study Report goes on to note that in a low-input farming system as occurs in many areas of the developing world, GURT could have a significant effect on biodiversity. In

<https://www.grainscanada.gc.ca/consultations/2015/classes-en.htm>.

⁶⁶⁸ Supra note 586 at 7.

⁶⁶⁹ A volunteer plant is one that is not intentionally grown by a farmer. It may grow as a result of a seed that floats in the wind; that may be found in compost; or may arrive at its final location in some other inadvertent manner.

⁶⁷⁰ Supra note 586 at 7.

⁶⁷¹ Supra note 497.

this type of system, farmers are regularly breeding to improve the quality of local seed. Globally, this represents a great many more sources of unique genetically diverse germplasm than can be supplied by the relatively few commercial breeders.⁶⁷² The adoption of GURT with new desirable traits would displace local genetic material as the new high-tech seed is substituted for the traditional seed. This once again supports the contention that biodiversity loss could result from farmers acting individually in what they consider to be their best interests.

So, on a macro scale, the adoption of GURT would likely lower overall farm crop biodiversity if only through farmer choice. The question is whether this situation would be any different with existing patent protected GE crops. In the latter case, again the breeders would be producing commercial varieties with specific genetic traits, which they would supply to farmers. If adopted by individual farmers in autonomous production systems, the traditional seeds with their locally developed genetic traits would not be used.

However, there is a significant difference between the GURT seeds and traditional GE seeds. That difference is that with the GURT seeds the farmer cannot access the value added traits for breeding purposes without the cooperation of the seed firm that developed it. That is because in both the case of T-GURT and V-GURT, those traits are technologically protected. In the case of patented only GE seeds, the traits are accessible. Therefore, in the case of legal environments where the patenting of seed traits is restricted or prohibited, farmers would be able to access legally those patented-only traits and use them in breeding regimes.

In the end GURT, more so than traditional GE seeds, would tend to isolate gene pools of seed companies and local farmers because there would be a reduction in incentives for local breeding due to an inability to access GURT traits.⁶⁷³

The CGRFA-9/02/17 Technical Study also examines biosecurity and environmental implications for GURT. This report highlights biosecurity as the prevention of biological contamination. The term contamination is used here not necessarily from the perspective of harm but rather that it can lead to the loss of a unique and useful biological entity. As reported in this Technical Report, one important concern of the agricultural community involves

⁶⁷² Supra note 586 at 4.

⁶⁷³ Ibid.

“contamination” of non-GE crop fields with GE crops or with GE traits.⁶⁷⁴ Both of these situations can occur with traditional patent-only protected GE seeds. Although agricultural isolation techniques can limit this to some degree, those farmers who depend on GE free crops to retain export markets or organic certifications find that GE crops pose a risk to their ability to guarantee a GE-free product.

One must consider, however, that extensive research for this thesis has not revealed any current evidence to indicate that interbreeding between GE crops and non-GE crops or wild relatives is harmful to human health. It may be harmful to some farmers’ economic health if a purchaser demands a strictly non-GE product and the farmer is unable to demonstrate that his crop meets this requirement. It may also be detrimental to the altered plant if the new gene puts the plant at a biological disadvantage. On the other hand, the gene could also be advantageous to the plant. This latter situation could also be a problem if the plant advantage is an overwhelming one that allows the new plant to displace a previous variety.

One should keep in mind that this displacement is a possibility, and yet this is not an unusual occurrence. In fact, this is the basis of evolution. However, in the case of evolution, the trigger is not specific but rather, as Charles Darwin pointed out, a result of natural selection.⁶⁷⁵ In the case of GE seeds, the genetic alteration is man-made. This does not necessarily make the loss of a variety a good or a bad thing, but if it should occur, one cannot say that nature has selected a variety to disappear. Instead, the loss is a result of a man-made intervention with unintended consequences.

Returning to the real threat that second generation V-GURT seeds could contaminate non-GE fields, one can envisage both positive and negative outcomes. A positive outcome of this scenario is that the second-generation V-GURT seeds will not have produced plants if they inadvertently found their way onto farmers’ fields. The negative outcome is the same as the positive outcome but viewed from a different perspective. Since the second-generation V-GURT

⁶⁷⁴ Ibid.

⁶⁷⁵ Darwin's Theory of Evolution states that natural selection is a slow gradual process. He wrote that, "...Natural selection acts only by taking advantage of slight successive variations; she can never take a great and sudden leap, but must advance by short and sure, though slow steps." (Charles Darwin, *On the Origin of Species by Means of Natural Selection, or the Preservation of Favoured Races in the Struggle for Life* (New York: D. Appleton and Company, 1859) at 162.)

seeds that contaminate the field will not grow, there could be gaps in the fields lowering the overall yield.

The CGRFA-9/02/17 Technical Study notes that there have been instances in North America where non-GURT GE germplasm has contaminated non-GE corn and canola varieties.⁶⁷⁶ What is the consequence of this occurrence? Other than the fact that the GE crops would technically have been grown illegally (they are patent protected) one result is that farmers who perceive these crops as somehow unsafe will be upset by their presence.

One other practical effect of non-GURT GE seed contamination of a non-GE crop is that farmers with “contaminated” fields might have a real difficulty in selling the crop to those who object to any GE contaminant. The previously noted comments by Chaturvedi and Rao over the potential loss of export markets in Europe for developing countries who choose to adopt GE technology is one example of this concern.⁶⁷⁷ The OSGATA v Monsanto case demonstrates this concern in the organic food industry. It is these types of examples that enhance the biosecurity case for V-GURT over patented only GE seeds.

The situation for T-GURT is somewhat different. Because these plants are under the control of an intentionally applied inducer, any contamination of non-GE plants would not result in the expression of the high-value trait in the subsequent plant. The plant growth outcome would be equivalent to the non-GE plant. The “non-induced” plant would contain the “dormant” gene. The CGRFA-9/02/17 Technical Study specifically noted that if outcrossing⁶⁷⁸ was to occur, the inducers would not be applied, and the T-GURT traits would remain dormant.⁶⁷⁹ This would be acceptable if the application of the inducer occurred after planting which is not how the use of this technology is envisioned. However, what if the inducer is applied to the seeds themselves before planting occurs. While the biosecurity of the T-GURT model provides some safety against contamination much is dependent on the timing of inducer application and whether one is aware that the outcrossing has occurred.

⁶⁷⁶ Ibid.

⁶⁷⁷ Supra note 247 at 9.

⁶⁷⁸ Outcrossing involves gene transfer between plants of the same species but of a different variety i.e. not closely related.

⁶⁷⁹ Supra note 586 at 4.

This latter situation could present a problem similar to that of the non-GURT patent-only GE seeds. If the T-GURT value-added traits are demonstrable only after inducer application followed by plant growth, how is one to know that outcrossing has occurred if no inducer has been applied? The only way to identify these traits would be for the plants to undergo costly genetic testing prior to applying an inducer to their seeds. And in the case where inducer application occurs at the time of seed purchase, and the trait is one that is not obvious after plant growth, how will one know that outcrossing is occurring? Again, testing is required.

There is another concern with T-GURT as well. There is a possibility that a trait “may be inducible by a related or by naturally occurring trigger events”⁶⁸⁰ in addition to the commercially applied inducer. For this reason, for T-GURT to be biosecure, very specific inducers would be required to minimize the possibility of accidental GE trait inducement.

6.3 Economic Well-Being

i) The GE Seed Industry, Firm Profitability, and The “Patent Cliff”

As the agricultural biotechnology industry has consolidated, the major firms involved in this industry continue to demonstrate high levels of profitability. Table 6 below shows data for three major agricultural biotechnology companies. In the profitability measures indicated, these leading GE seed biotechnology companies surpass the industry and market medians for the critical categories of net profit margin and, more importantly, return on equity. This high level of profitability is occurring in circumstances where patented GE seeds and the complementary products associated with them represent a significant portion of these firms’ revenue streams. This high level of profitability has occurred through a combination of a product [GE seeds] that has transformed agriculture and a well-established system of legal protection for those seeds based on patents.

⁶⁸⁰ Ibid at 6.

Table 6: 2014 Profitability of Three Major GE Seed Companies⁶⁸¹

As a Percentage (%)	Monsanto Company	BASF SE	Syngenta	Industry Median	Market Median
Gross Profit Margin	54.05	24.87	45.87	24.71	39.35
Pre-tax Profit Margin	23.35	11.32	12.48	0.07	6.76
Net Profit Margin	16.78	6.94	10.70	3.09	5.68
Return on Equity	26.17	22.90	17.62	0.46	5.93
Return on Assets	-	9.23	8.07	0.08	1.85
Return on Invested Capital		29.05	16.15	0.25	4.96

In high technology industries such as agricultural biotechnology, success is closely tied to the industry's ability to protect its IP and the cost involved in establishing and monitoring that protection. The Mansfield study, Lerner study and others mentioned earlier clearly demonstrate the importance of patents in those industries.⁶⁸² Because of the importance of patents to this protection, the GE seed industry must be concerned about its ability to manage its patents to maximize profitability. As such, firms should have a keen awareness of patent expiration dates and the mechanisms available to deal with this problem. This issue highlights the difference between legal and technological IP protection. The former provides a high level of time-limited protection in strong IP environments, and the latter offers the potential for a time-*unlimited* protection in any IP environment. How well GE seed firms can deal with non-GURT GE seed patent expiration will have an influence on whether GURT presents an alternative that can maintain or surpass the existing high level of GE seed firm economic well-being based on patents.

Monsanto is once again a good industry representative since it is the industry leader and there is a substantial amount of material available for analysis.

A 2014 Marketline Case Study states, as has been established earlier in this thesis, that there are significant similarities in the GE seed industry and the pharmaceutical industry. Because the Monsanto business model closely follows the pharmaceutical industry business model where unique products are patented, marketed and continuously protected, an unceasing

⁶⁸¹ *Mergent Inc. Financial Data in Monsanto Company*, (2015) online: Hoovers<
<http://subscriber.hoovers.com.ezproxy.library.yorku.ca/H/company360/competitiveLandscape.html?companyId=10093200000000&newsCompanyDuns=168428287>>.

⁶⁸² Supra note 3 at 9; supra note 152 at 224; supra note 134 at 283.

investment in R&D is required to maintain the economic engine of the company.⁶⁸³ Where these two industry models diverge is that while the GE seed industry model is designed primarily to prevent users [farmers] from saving seed in order to drive sales, the user [the consumer] in the pharmaceutical industry is no threat to pharmaceutical industry sales. It is solely industry rivals that are of concern to the pharmaceutical industry.

As in the pharmaceutical industry, a key to profitability of the GE seed industry is the strategic and tactical management of the “patent cliff.”⁶⁸⁴ That is, there is a point where the firm must deal with the eventual loss of a patent because of patent expiration. How a company, whether a GE seed firm or a pharmaceutical firm, faces the patent cliff goes a long way in determining how economically successful it will be in the long term. To address the patent cliff issue (which for example, Monsanto will face in 2015 with its Round Up Ready GE soybean variety), Monsanto is ready to release a new “superior” variety in the hopes that this will make the old product obsolete. The same situation exists for Monsanto’s corn and cotton products. In the company’s 2013 annual report filed with the SEC, Monsanto emphasizes this issue:

In soybeans, while Monsanto’s patent coverage on the first generation Roundup Ready trait for soybeans has expired in some markets and will expire in the United States in 2014...most of our customers and licensees are choosing our second generation Roundup Ready 2 Yield trait containing soybean seed with patents that extend into the next decade. In Brazil, we expect farmers to adopt our next generation Intacta RR2 PRO soybean traits, which will also have patent coverage extending into the next decade. In corn, patent coverage on our first generation YieldGard trait has already expired in some markets and will expire in 2014 in the United States; however, most farmers have already upgraded to next generation Genuity corn traits with patent coverage extending into the next decade. In cotton, most growers globally are already using our second-generation traits with patent coverage extending into the next decade.⁶⁸⁵

The problem for Monsanto and other GE seed firms is quite stark and is very much like the situation that exists in the pharmaceutical industry. Farmers will be able to save and grow the older patent-expired GE seeds unless they have a signed contract with Monsanto. To continue to

⁶⁸³ *Monsanto: Huge profits despite continuing controversy over its products* (2014) online: Marketline<
<http://advantage.marketline.com.ezproxy.library.yorku.ca/Product?pid=ML00013-063>> at 20.

⁶⁸⁴ *Ibid* at 11.

⁶⁸⁵ *Supra* note 408 at 8-9.

drive sales, Monsanto must convince those unrestricted farmers that the new variety is worth the expense. It would be pointless for Monsanto to continue to market the old variety since farmers will be able to produce a reasonable copy of it themselves. Somehow, the company must encourage the use of the new, patented product in order to drive sales and recoup the company's R&D investment plus a profit. One industry solution for this problem was demonstrated by the manner in which pharmaceutical giant AstraZeneca dealt with the expiration of the Nexium patent.

AstraZeneca produces a popular, highly advertised product named Nexium.⁶⁸⁶ This product went off patent in May 2014 allowing for generic reproduction of this drug.⁶⁸⁷ To counter the loss of a very profitable product, AstraZeneca had Nexium II ready to roll out as the Nexium I patent ended. However, the company had a plan to continue to profit from Nexium I even as inexpensive generic copies of this drug were being produced. AstraZeneca continued to market original Nexium to compete with the generics but at a competitive price. In this way, although the company appeared to be cannibalizing its own new product (Nexium II), it was continuing to profit from their original drug (with its high profile and highly regarded name) at the expense of the generic copy.⁶⁸⁸ This scenario was successful because the cost of production of a drug is relatively insignificant when compared to the cost of R&D and the R&D costs were long recovered along with significant profits while Nexium I was under patent.

Unfortunately for a company such as Monsanto, when a GE seed variety goes off patent, there is no source of profitability in the old product since it is self-replicating. The copy that the farmer can produce is genetically identical to the version sold by the GE seed company.

From an industry profitability standpoint, GURT would outperform patents in two ways. First, because GURT protection is indefinite and virtually ironclad (especially in the case of V-GURT), this product would maximize GE seed firm value capture as long as the company deemed it worthwhile to sell the product. Second, the patent cliff issue would no longer exist

⁶⁸⁶ Nexium is a proton pump inhibitor that reduces stomach acid. It is particularly useful for treating acid reflux.

⁶⁸⁷ *Nexium: Generic and Over-The-Counter Update* (2014) online: Medco<
<http://www.medco.com/art/sam/2014/Nexium-Generics.pdf>> [Nexium1]; *Nexium News: the "Purple Pill" Goes Over-The-Counter* (2015) online: Healthcare Solutionshttps://www.healthcaresolutions.com/pdf/alerts/Nexium%20Alert_April%202014.pdf.

⁶⁸⁸ Ibid; Nexium1, supra note 687.

because of the technological protection built into GURT. V-GURT produces sterile seeds, and patent expiration does not alter that outcome. T-GURT produces non-sterile seeds, however, if the inducer/promoter needed to activate the value added trait remains a well protected trade secret, there is little chance that a farmer or rival firm could activate the trait. If the inducer/promoter were patented, the complexity or the specific time frame of its application could make its use too challenging and costly an undertaking for the individual farmer.

GURT could also encourage Monsanto and the other GE seed companies to alter, what to this point has been, a successful business model that is centred on the legal ownership of IP. This includes the firm's licensing system and a whole range of rights enforcement methods such as the monitoring of farmers' fields and the testing of farmers' crops for patent violations. GURT would limit or eliminate the importance of patenting and therefore the need for rights enforcement activities at the all important farmer level. As a result, the cost savings that would accrue from GURT could be substantial. One noted kink in the GURT profitability picture comes from the prevailing GE seed/consumer acceptance issue which is discussed in greater detail later this thesis, but is briefly noted here as it relates to GE seed firm economic well-being.

The GE food debate has been polarized since the introduction of GE crops in the mid-1990s. The development of GURT has only served to increase that polarization. Even a cursory Internet search results in literally hundreds if not thousands of hits related to the controversial nature of agricultural biotechnology. This debate can negatively affect the brand of individual firms in this industry and the profitability that the brand supports. In the past, Monsanto has had negative brand issues related to other products containing PCB's, bovine growth hormone and Agent Orange.⁶⁸⁹ The politicization of opinion brought about by GURT since its development in the late 1990s has magnified the ongoing controversy around GE seed biotechnology in general. Attempts by Monsanto to defend the technology have met with both success and failure. GE seed use is undoubtedly increasing, as is the company's profitability. On the other hand, the controversial nature of GURT has encouraged Monsanto not to oppose the current international moratorium on GURT technology.

⁶⁸⁹ Supra note 683 at 16.

In its 2013 Annual Report, Monsanto expresses concern that bad publicity can potentially adversely affect Monsanto's ability to develop and market new products. An example of this bad publicity was the May 25, 2013 worldwide march against Monsanto in which 2 million people participated.⁶⁹⁰ This occurred again in 2014, 2015 and 2016. These marches are politically effective and are one reason that the company withdrew a number of applications for GE crop approval in Europe.⁶⁹¹

GURT, which adds a further layer of GE complexity to food and further restricts farmer control over their crops has added to the negative publicity confronting Monsanto; publicity that can impact the bottom line.

Not only do the GE seed companies have to be concerned with consumer acceptance of their product but they also have to be concerned about farmer acceptance and how this might be altered if GURT is commercialized.

Although consumer and farmer acceptance of the GURT product is of great concern to a company such as Monsanto, even a temporary GURT monopoly can create a powerful market power dynamic that favours the company. For argument's sake, let us say that there is only a single firm involved in the GE soybean seed industry selling to the whole market. As a monopoly that firm would maximize its profits by setting its price on the demand curve where the marginal revenue is equal to the marginal cost.⁶⁹² As Figure 19 below demonstrates, the result is that the company is selling less seed than is the case at competitive equilibrium (i.e. at the point where supply = demand) and at a higher price. In addition, the social cost would increase (deadweight loss increases), the producer surplus would increase (company profits rise), and the consumer surplus would decrease (consumer costs increase).⁶⁹³

⁶⁹⁰ Ibid at 17.

⁶⁹¹ Ibid.

⁶⁹² Supra note 478 at 188.

⁶⁹³ The supply curve gives the minimum price at which the company will supply the seed. In the above diagram the curve MC (marginal cost) is equivalent to the supply curve for a the *specific* firm. The curve labeled MR (marginal revenue) represents the revenue received, by the *specific* firm (a monopoly), for the production of one more unit of product. [For a perfectly competitive firm the MR curve is horizontal at point Pc because the firm is a price taker i.e. it cannot set price because of the highly competitive market] The curve labeled MB (marginal benefit) is equivalent to the total *market* demand curve for the seed.

In a perfectly competitive market, the price (Pc) and quantity (Qc) of the seed is determined from point D, where supply (MC) equals *market* demand (MB). This point (D) is known as the point of competitive equilibrium.

Figure 19: A GE Seed Monopoly

MR = marginal revenue
 MB = marginal benefit
 MC = marginal cost

Perfect Competition

$P(c)$ = Competitive Price
 FBD = Consumer Surplus
 BDG = Producer Surplus

Monopoly

$P(m)$ = Monopoly Price
 AEF = Consumer Surplus
 AECG = Producer Surplus
 ABHE = Monopoly Gain
 ECD = Deadweight Loss to Society

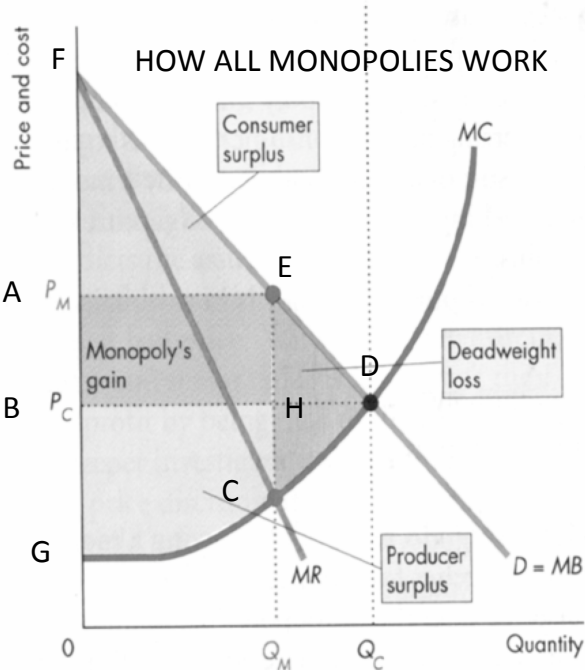


Diagram adapted from: Michael Parkin & Robin Bade, *Microeconomics: Canada in the Global Environment* 5th ed (Pearson Education Canada: Toronto, 2003)

At this point, producer surplus is the area BDG and represents profit for the producer. In the GE seed industry the producer is the GE seed company. Consumer surplus is area FBD and represents the consumer surplus (benefit to the consumer). In this industry the consumer is the grower of the crops (i.e. farmer).

A monopoly, wishing to maximize profits, will produce at the point (C) where MR equals MC because this is the production quantity (Q_m) at which maximum profit occurs (where the revenue obtained from producing one more unit of product equals the cost of producing that unit. If the firm produces one additional unit, that unit is produced at a loss. Any vertical line drawn to the right of point C will intersect the MR curve at a lower price than where it intersects the MC curve. That is, the marginal cost of production will be greater than the marginal revenue received from that production.).

The price charged by the monopoly will be the *market* price (P_m) where the monopoly quantity (Q_m) intersects the *market* demand (MB) i.e. at E. At point E, consumer surplus is area AEF, which is less than the competitive consumer surplus of area FBD. Also, at this point, producer surplus is area AECG, which is greater than the competitive producer surplus of area BDG. The monopoly profit is area ABHE and the deadweight loss (which represents a loss to society as a whole e.g. Consumer's cost of searching for alternatives at a lower price) is area ECD. In a monopoly situation, the consumer surplus is lower and the producer surplus is greater than in a perfectly competitive situation.

This is the situation that develops for any type of monopoly; higher than perfectly competitive prices and lower than optimally efficient quantities. One last question that should be addressed is, why would the monopoly not simply produce a greater quantity and charge the same higher price? The answer is that the demand curve ($D = MB$) is determined by *market* demand, which is subject to the quantity produced, not the price of the product. A higher quantity produced (lets say at Q_c) will only result in a lower price and a lower overall profit.

For example, Monsanto, which has a patent-based monopoly on its Roundup Ready™ technology, will set a price that is low enough to entice farmers to purchase the product and high enough to have a sufficient margin to be profitable. This must be at a point where the price is greater than the firm's marginal cost. This creates a less than optimal consumer (farmer) because some farmers cannot afford this price even though they might benefit from it and be willing to pay more for GE seeds than non-GE seeds.⁶⁹⁴

GURT offers an endless monopoly for an indefinite period of time. If the pricing of GURT seeds is not carefully positioned at the outset, farmers could avoid the product thus reducing demand. The resulting price decrease would affect the firm's ability to recover its R&D costs. This is more likely to occur if farmers are able to find close substitutes to GURT GE seeds.

Beyond individual firms such as Monsanto, the seed industry as a whole has a perspective on GURT. That perspective is put forth by the International Seed Federation (ISF), which represents the interests of the seed industry at intergovernmental organizations including OECD, UPOV, International Seed Testing Association (ISTA), FAO, CBD and WIPO.

The ISF has an extensive membership list made up of national seed trade and/or plant breeders associations and companies active in plant breeding and/or seed trade. This list includes all of the major GE seed companies. As such, the ISF is a good source for the industry position on GE seed topics including hybrids, GURT and intellectual property.⁶⁹⁵

In June 2003, the ISF released a position paper on GURT. In that paper, the ISF noted that GURT would be an effective method of technologically protecting a company's investment in R&D in a weak IP environment.⁶⁹⁶ The ISF further stated that it sees tremendous potential for industry profitability as the benefits of GURT can enhance GE seed technology. The ISF suggests that V-GURT can be the basis for developing new uses for plants and thus provide farmers with new markets. The Federation also identifies two areas of particular interest for increased profitability. These areas are pharmaceuticals (e.g. enzymes and polymers) and biodegradable plastics. The benefit of V-GURT over traditional GE seeds is that success in these areas if interest depends on restricted and well-managed environments. The inherent properties

⁶⁹⁴ Supra note 478 at 188-189.

⁶⁹⁵ International Seed Federation, *What We Do*, online: ISF <http://www.worldseed.org/isf/what_we_do.html>.

⁶⁹⁶ Supra note 497.

of V-GURT that limit its accidental spread, makes it ideal for these special uses.⁶⁹⁷ The ISF view of GURT is most certainly influenced by the effects that GE seed introduction has had in changing the agricultural biotechnology industry structure.

As has already been noted, vertical and horizontal integration have altered the seed industry and this change accelerated with the arrival of GE seeds. This seed industry change is noted by Kesan and Schenkelaars et al.⁶⁹⁸ There are two features of GURT that can dramatically affect industry structure and profitability beyond what has already occurred in the industry. First, the technological protection afforded by GURT can create a situation in which the barriers to entry for new firms are magnified beyond that which is present with patent only protected GE seeds. If GURT takes hold, the horizontal concentration in the industry is likely to increase as it becomes more difficult for both new entrants and small firms to compete as the R&D costs escalate for this costly, research-intensive technology.⁶⁹⁹ Additionally, vertical integration may also increase because T-GURT specifically requires inducer chemicals and other complementary assets to give them the technological capacity to protect of IP. It is likely that firms will wish to have control over complementary assets such as the inducers, especially if these inducers are protected as trade secrets rather than with patents. It is also possible that these inducers will initially be produced by outside specialty firms that could be targets for vertical integration. Chemical companies, whose expertise in this area would make them likely targets of vertical integration, are the type of firms that could be in demand as vertical integration targets.

To further enhance profitability, both vertical integration and horizontal concentration might be focused on the formal seed sector where high intensity large-scale farming is supported, and the major GE crops are dominant. This would allow for economies of scale. From the farmer's perspective, the possible increase in GE seed firm monopoly power could reduce farmers' value capture while increasing that of the seed companies. Overall, the vertical and horizontal integration that may be encouraged by GURT is very much like that which occurred

⁶⁹⁷ Ibid.

⁶⁹⁸ Kesan, supra note 2 at 468; supra note 166 at 65.

⁶⁹⁹ Supra note 586 at 7.

as the non-GURT GE seed industry matured. This was also noted earlier in the thesis as described by Kesan⁷⁰⁰ and Schenkelaars et al.⁷⁰¹

The disadvantage of this further integration and concentration in the industry is that if farmers become more dependent on GURT seed, complementary product supply could become a problem. For example, the lack of flexibility and the tendency toward inefficiency that is often inherent in vertical integrated firms could disrupt the seed or complementary product supply at a crucial time for farmers.

GURT profitability could also be hampered by the potential cost of regulatory compliance, which has been steadily increasing in all areas of agricultural biotechnology even without the commercialization of GURT. These costs are expected to decline if GE technology continues to demonstrate its safety and becomes less costly at the R&D stage.⁷⁰²

As we shall see later in this thesis, the development of safety regulations is not always scientifically based. Public opinion can have a profound effect on how politicians determine the need for regulation. Also, regulators' views on what is safe can be affected by such concepts as the Precautionary Principle, which demands an extremely high level of scientific assurance of future safety when such an assurance is impossible for any product or process.

ii) Farmers and Formal Seed Systems

The previous assessment of the economic well being of the GE seed industry takes place in a framework that stresses the interrelationship between industry and farmer economic well-being. Farmers' concerns with farm output begin with an evaluation of the requirements for inputs that are provided primarily by industry. Those inputs and their costs and benefits are well established for the non-GURT GE seed industry. However, GURT raises new input issues and along with them new cost/benefit outcomes.

There are some key impacts of GURT technology on the GE seed industry that have been established up to this point in this thesis. First, the self-protective nature of GURT provides value capture benefits for the industry. This is because GURT significantly reduces industry concern

⁷⁰⁰ Kesan, supra note 2 at 468, 469.

⁷⁰¹ Supra note 166 at 65.

⁷⁰² Supra note 603 at 31.

over the quality of national IP regimes. As a result, the cost of patenting and more importantly defending patented material becomes a secondary issue for GURT. Second, GURT significantly lowers the risks of the unwanted spread of transgenes and the associated potential damage that this may impose on non-GE crops. This reduces potential seed firm and farmer liability issues.⁷⁰³

Third, the potential for the development of new crop varieties that depend on the ability to control the activation or deactivation of high-value genes can increase the market for specialized GURT GE seeds.⁷⁰⁴

A fourth issue is one upon which the possible success of GURT commercialization is directly dependent since it will ultimately determine whether the industry will benefit from this technology. That fourth issue is the degree to which farmers will adopt this new technology if the moratorium on its commercialization is lifted.

As UNEP/CBD/SBSTTA/4/9/Rev 1 (17 May 1999) Annex: “Genetic Use Restriction Technologies” notes, the first generation of GE seeds to be commercialized reduced the level of inputs needed to manage seed growth by containing traits that cause herbicide and pest resistance. As input dependence decreases, this UNEP report envisions the potential for a significant lowering of input costs for farmers.⁷⁰⁵ This is particularly significant in developing countries where high input cost often limits farmers’ capacity to acquire new technologies. If GURT can be cost effective in the developing world, adoption of this technology is more likely. The report suggests that if this were the case, farmers would be able to take advantage of the best, high yield products available. An unintended consequence of this in the developing world may be that farmers stop using new traditional seed that may improve local varieties.⁷⁰⁶

This UNEP/CBD Report predicts that, at least initially, it is unlikely that GURT will benefit subsistence agriculture since value capture would initially be greatest in major crops on large farms in the developed world.⁷⁰⁷ Of course, the question then arises whether this

⁷⁰³ Supra note 464 at 13-16.

⁷⁰⁴ Ibid.

⁷⁰⁵ Ibid at 44.

⁷⁰⁶ Ibid.

⁷⁰⁷ Ibid.

developed world value capture and other viability criteria (e.g. The environment, the IP system, consumers, etc.) would be sufficiently positive to support GURT use.

In the developing world, adoption of V-GURT would mean that farmers there would have to give up saving seed completely since the saved seed would not grow. This is in contrast to the patent only GE seeds for which some developing countries allow legal seed saving alternatives based on international agreements such as TRIPS. The UNEP/CBD Report predicts that once these farmers were to give up seed saving the cost and ability to go back to this model may be too high for all but the most affluent farmers to overcome.⁷⁰⁸ This seed saving issue in the developing world is a major viability issue for V-GURT; one that is less technically, although not necessarily less legally, troublesome for T-GURT and non-GURT GE seeds.

Farmers in the developed and developing world are likely to make their decision on GURT just as others have historically made business decisions. It will be based on a cost/benefit analysis. Farmers will evaluate the benefits that GURT offers against the costs of using this technology when compared to non-GURT GE seeds. At first glance, one might suggest that there is no need to consider non-GE seeds in this equation at all because if farmers have already determined that GE seeds do not meet their requirements, then there is little reason for them to consider GURT seeds as a substitute for non-GE seeds. This conclusion would be ill-advised because GURT offers the potential to eliminate one of the key reasons that farmers may wish to avoid GE seed technology, and that is the possibility of escaping transgenes contaminating adjacent fields and creating liability issues with potential adverse financial consequences. As has already been noted, the prevention of the escape of transgenes is one of the key attributes of GURT.

It was noted earlier that farmers worldwide are opting more and more to incorporate GE seed biotechnology into their fields since this technology was first introduced in the mid-1990s. At the farm level, in 2013, an estimated 18 million farmers worldwide grew just over 50% of the world's GE crops. Significantly, 90% of these farmers were resource-poor farmers in developing

⁷⁰⁸ Ibid.

countries.⁷⁰⁹ The fact that these GE seeds were patented did not deter these farmers from determining that the benefits of their use outweighed the costs. Currently, GE crop use in developing countries is growing at a rate of 11% annually, which is higher than that in developed countries (3%).⁷¹⁰

The steady growth in the use of GE seeds globally indicates that farmers who have decided to grow GE crops believe that they do benefit from GE seed use. These benefits include increased yields, reduced need for pesticides (Bt varieties), less costly weed control with herbicide tolerant plants, and the reduced need for tillage.⁷¹¹

An example of how GE seeds have affected crop yield to the benefit of farmers is illustrated in the UNFAO paper presented by Fischer et al. at the UNFAO Expert Meeting on “How to Feed the World in 2050” titled, “Can Technology Deliver on the Yield Challenge to 2050?” In 1996, GE hybrid corn was first introduced to farmers’ fields in Iowa. Figure 20 below illustrates that since 1996, the rate of increase in corn yields in Iowa, where 90% of corn was GE, has been greater than that of France plus Italy combined, where GE corn is not used at all.⁷¹²

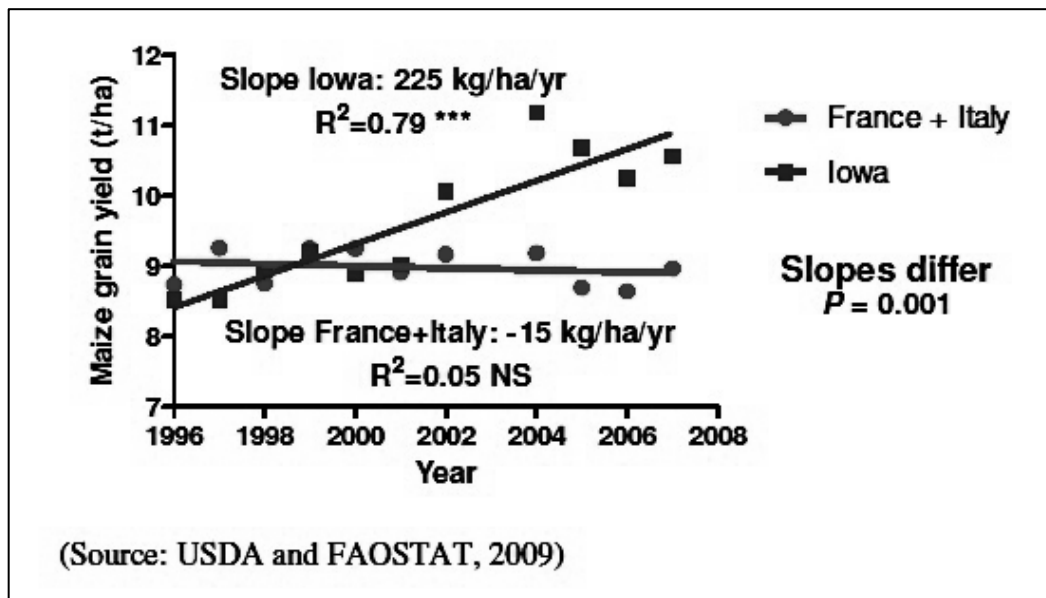
⁷⁰⁹ Supra note 415 at vii.

⁷¹⁰ Ibid at 10.

⁷¹¹ Tillage involves the physical, chemical and/or biological preparation of the soil for optimal crop growth. This includes weeding. While tillage can reduce soil erosion if carried out under the proper conditions, extensive weeding can have the opposite effect; Michael Schechtman, “The United States approach for fostering new biological technologies and ensuring their safety” (2012) in OECD, *Improving Agricultural Knowledge and Innovation Systems: OECD Conference Proceedings*, (Paris: OECD Publishing, 2012), online: OECD <<http://dx.doi.org/10.1787/9789264167445-en>> 257 at 261-262; supra note 488 at 61.

⁷¹² Supra note 603 at 30.

Figure 20: Maize (Corn) Yields 1996 – 2007 for Iowa, U.S.A. & for France + Italy⁷¹³



(The year 2003 is excluded because of severe drought in Europe)

On the graph, one can observe that the slope of the France plus Italy curve is, in fact, negative (-15kg/ha/yr) indicating a decreasing yield of non-GE corn since 1996. In contrast, the slope of the Iowa GE corn is dramatically positive.

Benefits, such as increased yield potential, inevitably come at a cost of higher seed prices than would be the case with non-GE seeds. This is no different than the situation in other high technology innovation-driven industries. Like other high technology business models, the GE seed business is based on users (farmers) paying for the R&D that supports the innovation carried out by seed and biotechnology companies. Certainly, the fact that GE seeds contain value-added attributes and that these seeds are patented invariably leads to higher priced seed.⁷¹⁴

Initially, farmers are paying a high price for the increased yield offered by GE seeds, however, Monsanto is no longer the only producer of these products as illustrated in Table 2. Other companies with competitive products are challenging Monsanto’s dominant position in GE

⁷¹³ Ibid.

⁷¹⁴ G Moschini, “Competition Issues in the Seed Industry and the Role of Intellectual Property” (2010) 25:2 Choices Magazine, online: (2010) Choices Magazine <<http://www.choicesmagazine.org/magazine/print.php?article=120>>.

seeds. By their existence, these competing products have begun to eliminate the “no close substitutes” requirement of a monopoly and the high prices that inevitably follow.

In the future, the ability of GE seed firms to command an enduring premium price for their basic products may be limited by the same factors that affect any business, competitive forces and competing products.⁷¹⁵

The adoption of GE seeds by farmers has broadly resulted in yield improvements that initially justify the higher cost of the seeds for many farmers. This is clear because farmers are increasingly using GE seeds when other non-GE options exist as Figures 12 and 13 illustrate. However, increased yields can have a negative effect on the crop prices received by farmers. This is especially financially harmful to farmers using high cost, technologically enhanced seeds that produce a high yield. The negative effect on crop prices received by farmers could occur as follows. Most soybeans in the world are priced based on the Chicago Board of Trade’s price for soybeans. This futures market for commodities is one of the oldest and largest in the world.⁷¹⁶ The futures prices can be seen with a simple Internet connection to view Chicago Board of Trade commodity soybean futures market. This price currently does not distinguish between conventional non-GE soybeans and GE soybeans. If there is an excess supply of soybeans, then the price is lower for both the non-GE and the GE crops. A non-GE crop has a somewhat lower yield than a GE crop because of the earlier noted value added attributes found in the GE crop. Also, the non-GE crop has lower input costs than the GE crop as a result of higher seed prices etc. As the total yields increase the overall price that the farmer will receive for his crop is dropping (supply and demand theory). At some point, it may be that the increased yields of the high-cost GE seed will become self-defeating for the farmer who grows it. If one was to add GURT soybeans to this mixture, one would then have one price for three different types of soybeans, conventional, GE non-GURT, and GE GURT all of which have different input costs associated with them. On the other side of the equation, although the cost per bushel of the GE or

⁷¹⁵ Supra note 71 at 86-87.

⁷¹⁶ Chicago Board of Trade, (2016) online: Encyclopedia Britannica<
<https://www.britannica.com/topic/Chicago-Board-of-Trade>>.

GURT seeds may be higher than that of non-GE seeds, the number of bushels per acre is higher as noted earlier.

There are of course many farmers who are not using GE seeds in both the developing and developed world. As previously noted, this is especially the case in Europe where the Precautionary Principle has created an anti-GE food environment. As a result, some EU farmers who wish to grow GE crops will not do so. In addition, these farmers are also subject to pressure exerted by other EU farmers who grow specialty crops such as organics. The latter group of farmers fear that they may lose their organic status and the higher prices that the organic crop differentiation affords them if field contamination occurs with GE crops. This was the concern specifically noted in the U.S. by OSGATA as this organization sought to assuage the concerns of American organic farmers by having the court for the Southern District of New York direct Monsanto to “expressly waive any claim for patent infringement [Monsanto] may ever have against [appellants] and memorialize that waiver by providing a written covenant not to sue.”⁷¹⁷

Farmers in the developing world may also find themselves in a difficult position and may avoid growing GE crops if their chief concern is the acceptance of crop exports to Europe. These nations may find themselves in an untenable situation between two trading blocks with opposing views on GE products (the US and EU). If they choose to support GE crops and export to the U.S., they risk the loss of trade with the EU where these crops are less welcome.

The farm issues associated with traditional GE seeds and crops are fairly wide-ranging. Many of the costs and benefits associated with GE seeds should exist for GURT seeds as well since they are also GE seeds. However, the specific attributes of GURT will come with specific benefits and costs if commercialization is allowed.

As such, the degree to which farmers will embrace GURT technology remains an unknown. Even those farmers who have already embraced traditional GE seed technology might find the cost, regulatory environment and consumer attitudes such that they may consider this technology to be too controversial to adopt. It is questionable whether those farmers who have not already adopted GE seed technology will see the benefits of GURT if they do not already see the benefits of traditional GE technology.

⁷¹⁷ Supra note 403.

If farmers choose to adopt GURT technology, what specific costs and benefits will they weigh in order to make this decision? The most obvious GURT-specific benefit is the previously noted high level of prevention of transgene escape. The escape of transgenes has been a concern since the first introduction of GE seeds and their artificially modified DNA.

The ISF position paper on this situation makes the point that the coexistence among different crops grown in close proximity is not something that is a new issue now that GE crops are being grown. This coexistence has been the norm since well before the existence of GE crops.⁷¹⁸ The ISF position paper stresses that this coexistence is not a problem as long as technical, and procedural guidelines are carefully followed. How well these guidelines would be adhered to by some poorly educated farmers in developing countries should be a concern.

The ISF notes that, in some countries, GE crops are treated the same as non-GE crops as soon as they are shown to be safe using common standards. Should the need arise, the industry claims that there are well-established techniques for separating different product lines in the field that have been successfully employed in the past.⁷¹⁹

It is common to see the word “contamination” to refer to the accidental presence of GE crops in non-GE fields. Unfortunately, this term has negative connotations about the final crop product that are not scientifically justified. As previously noted, according to food regulatory bodies in the U.S. and Canada labelling of GE food products is not required since they are not substantially different from their conventional counterparts.⁷²⁰

This seems to be a particularly contentious issue when it comes to organic products. This was noted previously as a concern for European farmers. Organic farming regulations prohibit the use of GE crops beyond threshold levels established at different points in different countries. However, it should be noted, as the ISF position paper points out, that in May 2002, IFOAM (International Federation of Organic Agriculture Movements) World Board stated,

⁷¹⁸ Supra note 695.

⁷¹⁹ International Seed Federation. Coexistence of Genetically Modified, Conventional and Organic Crop Production (2004), online: ISF <http://www.worldseed.org/wp-content/uploads/2015/10/Coexistence_of_Genetically_Modified_Conventional_and_Organic_Crop_Production_20040526_En.pdf>.

⁷²⁰ Supra note 190 at 103.

[...] the potential of GMO contamination does not alter the traditional approach of certifying organic as a “production method” rather than an end-product guarantee. Organic products are not defined or certified as being “free” of unwanted pollution. [...] Therefore IFOAM does not support the introduction of *de minimis* thresholds for genetic contamination. Because of this, mandatory testing for genetic contamination should not be introduced for the verification of organic production.”⁷²¹

In spite of this, IFOAM is still firmly opposed to genetic engineering in agriculture.⁷²²

Because of this position by IFOAM, whether justified or not, GURT could go some way toward protecting organic fields from “contamination.” However, based on the fact that GURT is also a GE product, the current absolute anti-GE position of IFOAM suggests that there is little likelihood of GURT being acceptable to this organization. The ISF suggests in their position paper that it is up to organic farmers to take the necessary precautions to avoid unwanted GE contamination just as it is their responsibility to avoid any other type of contamination in their fields.⁷²³ This, however, may be easier said than done since it is generally agreed that it is unrealistic to expect to find crops today that are completely free of GE “contamination.” But it is not just organic farmers wishing to avoid the spread of transgenes who may find some benefit in GURT. The prevention of transgene escape into neighbouring fields helps farmers who prefer to avoid growing GE crops for reasons such as concerns over trade.

While the prevention of the escape of transgenes is a positive biosafety feature, there is a negative consequence that would affect farmers who rely on open-pollinated [i.e. natural pollination] varieties. Growing V-GURT crops could reduce the level of production on neighbouring farms where non-GURT crops are grown, and where seed saving is important.⁷²⁴ This could occur as a result of contamination of non-GURT crops with V-GURT traits that result in the production of sterile seeds that could not be replanted the following growing season. This would only be an issue for those farmers who depend on saved seed. The actual crop harvested by these farmers, whether “contaminated” with GURT plants or not would be perfectly usable as

⁷²¹ *Position on Genetic Engineering and Genetically Modified Organisms* (2002), online: IFOAM Organics International < <http://www.ifoam.bio/en/position-genetic-engineering-and-genetically-modified-organisms>>.

⁷²² Ibid.

⁷²³ Supra note 719.

⁷²⁴ Supra note 496 at 7.

food in either case (substantial equivalence).⁷²⁵ A problem that may arise in this situation is that if a non-GE crop is a requirement for the sale or export, there could be a decrease in purchasers for their product. This is likely to be less of an issue in North and South American markets where GE seeds are widely accepted. However, it could dramatically affect exports to the EU where this technology is less welcome. The following example illustrates how this would not be based simply on the regulatory environment but also on the resistance of EU consumers to GE products.

Farmers have been caught up in the problems that trade in GE crops and foods have created between those who support these products and those who oppose them. As was noted earlier, between 1998 and 2004, the European Commission banned the importation of GE products from the U.S.⁷²⁶ Five European countries imposed eight different bans on GE products, and several other countries blocked GE crops, food products, and seeds from entering through their votes in Europe's Council of Ministers. The corporations producing GE products, in conjunction with the countries they represent (primarily, the U.S., Canada, and Argentina), concluded that this action contravened a number of trade agreements. Two of the major multinational companies, Monsanto and Syngenta, asked for immediate admission of their GE products to Europe based on the fact that the safety of these products had been "ratified by numerous credible regulatory and scientific authorities."⁷²⁷

Finally, in 2003, the major GE crop producing nations led by the U.S. took their case to the WTO in search of a favourable ruling to override the European restrictions on GE products. Under persistent pressure from the U.S. and other supporting nations, the European Commission pre-emptively ended the ban in May 2005. However, many European governments continued to fight the Commission's ruling by selectively banning GE products.⁷²⁸

On February 7, 2006, the WTO ruled that the EU was in breach of international trade rules by restricting the import of GE products.⁷²⁹

⁷²⁵ Ibid at 6-7.

⁷²⁶ Wright, *supra* note 119.

⁷²⁷ Rosenthal, *supra* note 118.

⁷²⁸ Wright, *supra* note 119.

⁷²⁹ Pollack, *supra* note 119.

One key aspect of the victory was the hope, by the biotechnology companies, that the ruling would discourage other non-EU countries from attempting to block the import of GE products. This is significant because many non-EU countries had refused to adopt biotechnology, not because they were opposed to the technology itself, but rather because they would lose exports to a Europe resistant to food potentially contaminated with GE crops.⁷³⁰

In addition to the prevention of transgene escape GURT offers another potential benefit to farmers. This is a T-GURT as opposed to V-GYRT benefit. T-GURT seeds may be able to provide farmers with a variety of valuable traits that could be turned on or off to meet environmental conditions or specific farmer or customer requirements. These traits could enhance environmental safety, yield, disease prevention, nutritional content, etc.⁷³¹ These are traits that can be made available in traditional GE seeds, but T-GURT seeds would give farmers more precise control over the expression of the traits so that they can be used only when needed.

For example, a GURT seed that normally does not grow well in dry environments can be developed to allow the activation of a gene that allows it to grow well under these conditions. Only those farmers who reside in dry environments would require the activation of this trait.⁷³²

The two key farmer benefits of GURT, the prevention of the escape of transgenes and the ability to manipulate various value-added traits, are significant and make a good case for the use of this technology by farmers. Still, the costs of introducing any new technology are significant and may be difficult to overcome.

The first of these costs is the potential price of GURT seed. As with most technological innovation in agriculture and in other sectors, the price of GURT seed would be expected to be higher than non-GE seed. As another iteration of GE seed, GURT seed would likely follow the pricing pattern of non-GURT GE seed. Not surprisingly, prices for GE seed varieties are currently higher than standard seeds. In 2001, the U.S. Department of Agriculture (USDA) began reporting discrete prices for GE and non-GE seed varieties. Figure 21 graphically displays the price data for corn and soybeans and illustrates the difference between GE seen and non-GE seed.

⁷³⁰ Ibid.

⁷³¹ Supra note 496 at 8.

⁷³² Ibid.

Figure 21: U.S. Seed Prices for Corn and Soybeans, 1990-2008
 (Source: USDA)⁷³³

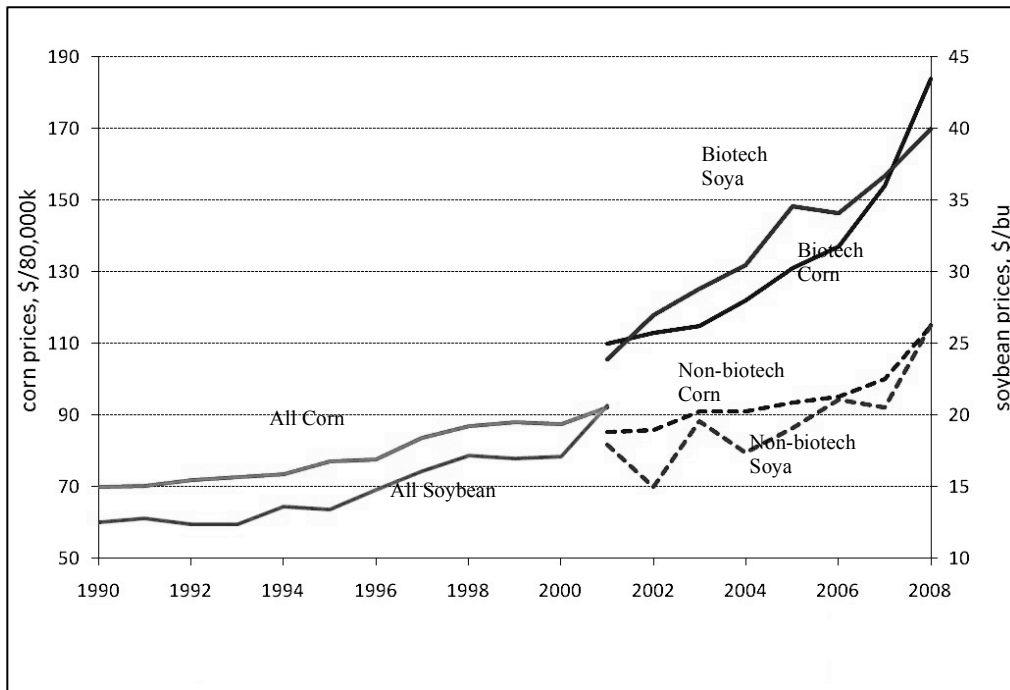


Figure 21 illustrates that although seed prices for GE and non-GE seeds have increased since the introduction of GE crops in 1996, the increase for GE seeds is greater. A comparison between the pre-GE crop year of 1995 and 2008 highlights this difference. The price increase for GE corn is 139%. The increase for non-GE corn is 49% while the corresponding prices increases for GE soybeans and non-GE soybeans are 199% and 96% respectively. In spite of this increase, data from the ISAA 2013 Brief 44 notes that the use of GE crops is steadily increasing, especially in developing countries.⁷³⁴ Overall, the increased price of patent protected GE seeds does not appear to be deterring their use, suggesting that farmers from developed and developing regions have determined that the cost/benefit ratio is in their favour.

Would the GURT cost pattern follow the same path as that for non-GURT GE seeds? The increased firm control over seed IP that is inevitable with GURT is likely to result in the same high price pattern as has been seen with non-GURT GE seeds. However, the duration of this high

⁷³³ Supra note 714.

⁷³⁴ Supra note 415 at 10.

seed cost may be extended because, without some regulatory intervention, GURT provides firms with an endless monopoly over their innovation. This looming GURT endless monopoly concerns numerous authors such as Louwaars, Oguamanem, Muscati, and Shi who raise these concerns as a source of opposition to GURT.⁷³⁵

The second cost of GURT to farmers is one that is specific to some farmers and may not be an issue for many if not most farmers and that cost comes from the inability to save seed from growing season to growing season. The 2002 United Nations Conference on Trade and Development issued a report titled “Key Issues in Biotechnology in 2002 [UNCTAD/ITE/TEB/10] in which it was noted that GURT opponents are convinced that GURT would increase poverty among the poorest developing world farmers who are dependent on saved seed.⁷³⁶ This Report then notes that the counter argument is that since these farmers would be very unlikely to be able to afford the original GURT seeds, the question of saved seed does not arise.⁷³⁷ But then it goes on to state that this, rather than the saved seed issue, might be the real problem because these farmers cannot afford the high-tech seeds with superior traits.⁷³⁸ This seed saving problem is one that already exists for farmers using non-GURT patented GE seeds. However, this is a legal problem only because the GE seeds are patented and the GE seed firms who own the seed IP demand license fees. Some farmers can use/save these patented seeds where national concerns comply with TRIP exceptions to allow this to take place.

At first glance the high cost of annual GE seed purchase to meet license requirements appears, quite rightly, to be a negative feature of these seeds. However, this is not a phenomenon that is specific to non-GURT GE seeds or potentially, GURT seeds. The need to repurchase seeds annually has been the norm for hybrid corn for decades because of the technological IP protection that hybridization promotes. This has encouraged crop improvements that have been

⁷³⁵ Louwaars, *supra* note 290 at 91-92; Oguamanem, *supra* note 290 at 60, 63,67-69; Muscati, *supra* note 290 at 481-485; Shi, *supra* note 290 at 19.

⁷³⁶ UNCTAD, *Key Issues in Biotechnology*, (UNCTAD/ITE/TEB/10) (2002) online: UNCTAD <<http://unctad.org/en/Docs/poitetebd10.en.pdf>> at 7.

⁷³⁷ *Ibid.*

⁷³⁸ *Ibid.*

incorporated into new crops.⁷³⁹ Historically, this is shown in the greater genetic gain seen in hybrid corn than in non-hybrid rice and wheat.⁷⁴⁰

It is well known that farmers in the developed world purchase seed for their new crops as they embrace new varieties and innovation to maximize the quality and yield of their crops. This is because, in many instances, there is a demand for a very high quality product to meet national health and regulatory requirements. This high demand for superior quality cannot be met by saved seed because of the risk of contamination and a lack of seed uniformity through natural genetic mutation.⁷⁴¹

From a cost and convenience perspective, it would seem likely that farmers in the developing world would be more likely to save seed. This is, in fact, the case, as the American Seed Trade Association (ASTA) reports that “formal seed commerce” (i.e. commercial purchase of seed as opposed to the use of saved seed) represents only 10%-20% of the total seed market for emerging markets.⁷⁴² It is unlikely that this figure would be higher for GURT GE seeds given the likelihood of a high initial cost for these seeds and the limited benefits of this technology to some developing world farmers. It is more likely that the increase in the use of traditional GE seeds would continue in the developing world with the use of GURT by more affluent farmers and in situations where circumstances create an obvious large-scale benefit that might be subsidized by local government or international agencies.

Another reason that seed saving could be an even greater issue in the developing world is that it is not uncommon for small-scale farmers to occasionally use food grain for seed. This is particularly the case when farmers do not have sufficient resources to purchase seed. If V-GURT seeds were included in food grain, either because commercial farms using V-GURT seeds are near those growing non-V-GURT crops, or there are V-GURT seeds in food aid, the results of planting these seeds would be yield loss that could approach 100%.⁷⁴³ T-GURT seeds and non-

⁷³⁹ Ibid.

⁷⁴⁰ Supra note 603 at 31.

⁷⁴¹ Supra note 618 at 16.

⁷⁴² American Seed Trade Association: *Intellectual Property Rights FAQ* (2014) online: ASTA <<http://www.amseed.org/issues/intellectual-property/ip-rights-faq/>>.

⁷⁴³ Supra note 496 at 9.

GURT GE seeds would not create this same problem because they would grow just as any non-GE seed.

Another issue affecting farmers, particularly in the developing world is that some of them still depend on natural cross-pollination to enhance genetic diversity. Although this has become less of an issue with the new innovations in breeding, V-GURT and the sterile seeds that it creates would threaten this reliance.⁷⁴⁴ This is not a problem with traditional GE seeds because their ability to cross-breed with non-genetic varieties means that they can enhance genetic diversity.⁷⁴⁵ While this is a possibility, it is not desirable from the perspective of the GE seed companies that prefer to keep their value added traits under their control. It is also not desirable for farmers who may wish to keep their crops GE-free.

So, here we can see both an advantage and a disadvantage of non-GURT GE crops for farmers. On one hand they are advantageous because they can increase genetic diversity through their ability to fertilize or be fertilized by non-GE plants. On the other hand, they are a disadvantage for the very same reason if farmers want or need GE free crops. In contrast, GURT is advantageous because it can severely restrict the unwanted spread of transgenes but disadvantageous because this limits genetic diversity while risking the ability of farmers to save seed where this is an economic necessity.

There is another problem that is linked to traditional GE seeds that could be exacerbated by the introduction of GURT, and that is its effect indigenous and local knowledge and practices in developing countries.

This issue is noted in the 2003 “Report of the ad hoc technical expert group meeting on the potential impacts of genetic use restriction technologies on smallholder farmers, indigenous and local communities and farmers’ rights”, where the report predicts a loss of traditional knowledge and practices as well as cultural traditions if GURT technology is widely adopted.⁷⁴⁶

This has been an argument throughout history when new disruptive technologies have been developed. There are those who look upon the “good old days” with what some might consider “rose coloured glasses.” The argument that this new technology will do irreparable

⁷⁴⁴ Ibid at 11.

⁷⁴⁵ Ibid at 7.

⁷⁴⁶ Ibid at 8.

harm to a traditional way of life and work may be accurate. However, the belief that this is necessarily a bad thing is questionable. If those who are themselves living this traditional life choose to embrace this new technology, who are we in the developed world, to suggest that they should not do so. Simply because it offends some sensibilities that this traditional life may be lost, would we deny others the benefit of the same technologies that arguably have enriched our societies?

Although the report of the Ad Hoc Technical Expert Group suggests that GURT may be able to technologically appropriate indigenous knowledge and genetic resources, the elements that could be thus appropriated are the same as is found with patented GE seeds. As such, this issue is not relevant in determining if GURT is a viable alternative to traditional, patented GE seeds.⁷⁴⁷

The Expert Group developed a characterization of “smallholder farmers” which states that, “Smallholder farmers are those farmers involved in systems that meet most of, but are not limited to, the following characteristics: (i) low external input; (ii) limited resource-base; (iii) limited market access and orientation; (iv) high capacity for local innovation of technologies related to genetic resources; and (v) vulnerable to a range of external pressures as a result of the above criteria”⁷⁴⁸

The Expert Group Report states that GURT might lead to a dependency over which the smallholder farmer and local communities have no influence or control.⁷⁴⁹ This type of dependency has already occurred with the introduction of hybrid crops beginning with hybrid corn in the 1930s and has been magnified with the introduction of GE crops in the 1990s. Neither of these two technologies has created dependency on the specific seeds as much as they have created a dependency on high yields and higher quality crops. This is more of a financial dependency on success rather than a dependency on the specific seed.

Data presented by James 2013 shows the greatest increase in the use of GE seeds has been in the developing world by smallholder farmers because they see the benefits that accrue

⁷⁴⁷ Ibid at 13.

⁷⁴⁸ Ibid at 6, Annex I, footnote 2.

⁷⁴⁹ Ibid at 8.

from their use to outweigh the costs.⁷⁵⁰ If T-GURT seeds are commercialized, there will certainly be an increased dependency on complementary products such as inducer chemicals, but this is only an issue for those farmers who choose to grow them. This is not an issue in the case of V-GURTS as inducers are only a requirement for T-GURT seeds.

The essential question here is whether there will be any more of an impact on farmers' rights from the commercialization of GURT than has already occurred as a result of the commercialization of traditional GE seeds.

In response to this question, one can note how the Expert Group Report looks at the impact of GURT on farmers' rights in the context of FAO Resolution 5/89 of the International Undertaking on Plant Genetic Resources for Food and Agriculture and FAO Resolution 3/2001 on the International Treaty on Plant Genetic Resources for Food and Agriculture. This latter treaty recognizes the historical efforts of farmers in promoting and establishing sustainable plant genetic resources. In addition, the treaty promotes fair sharing of the resource benefits.⁷⁵¹

Farmers' Rights are protected and promoted in Article 9 of the International Treaty on Plant Genetic Resources for Food and Agriculture through the following measures, "the protection of traditional knowledge relevant to plant genetic resources for food and agriculture."⁷⁵²

If farmers can freely choose the type of seed they wish to plant then a combination of market need and value attributes will determine if and to what degree GURT is adopted. However, there may be factors other than the market that may influence farmers' decisions. One of the most significant factors could be government interference in the market. This could occur through programs that, through various types of incentives, may influence choices to further government economic or social goals. For example, if the concentration in the GE seed industry continues, there is a potential for market failure as monopolization of the industry limits farmer choices.⁷⁵³

⁷⁵⁰ Supra note 415 at vii-viii, 62-63.

⁷⁵¹ Supra note 496 at 10.

⁷⁵² Ibid.

⁷⁵³ Supra note 464 at 43.

The ISF position paper on GURT claims that the existence of GURT will not dramatically alter farmers' options when it comes to selecting varieties to grow in their fields.⁷⁵⁴ They will continue to be free to choose traditional varieties that are not GE, or they may choose non-GURT GE seeds. What GURT will do is give farmers an added choice, that of GURT varieties. The ISF position on farmer options can be summarized as the belief that it is very unlikely that a farmer would select a GURT variety unless that farmer could see a benefit to that choice. However, Kesan and Muscati assert that the seed companies will have an incentive to incorporate the best traits into their GURT products forcing farmers to use these new products in order to survive.⁷⁵⁵

Perhaps then the issue is not the blocking of new technology and innovation such as GURT or hybrid seeds or in fact GE seeds but rather making this technology equitably available to the greatest number of farmers in the developing world.

An academically oriented systems-based approach can be used to garner another farm perspective on the economic viability of GURT vs. that of patented GE seeds. Two types of systems are relevant in understanding the effects of GURT in agriculture, the farming system as a whole and a subgroup of the farming system - the seed system. The farming system is defined by the FAO as, "... a population of individual farm systems that have broadly similar resource bases, enterprise patterns, household livelihoods and constraints, and for which similar development strategies and interventions would be appropriate."⁷⁵⁶

The 2002 Commission on Genetic Resources for Food and Agriculture study titled, "Potential impacts of genetic use restriction technologies (GURTS) on agricultural biodiversity and agricultural production systems" determined that the farming intensity would determine the effects of GURT on farming systems.⁷⁵⁷ Intensity in agriculture refers to the ratio of inputs such as capital, labour, fertilizer, insecticides, etc. relative to the land area cultivated.⁷⁵⁸ In the case of

⁷⁵⁴ Supra note 497.

⁷⁵⁵ Kesan, supra note 2 at 497; Muscati, supra note 290 at 494.

⁷⁵⁶ UNFAO, *Farming Systems and Poverty- Analysis of Farming Systems* (2014), online: UNFAO <http://www.fao.org/farmingsystems/description_en.htm>.

⁷⁵⁷ Supra note 586 at 5.

⁷⁵⁸ *Intensive Agriculture*, (2014) online:< Britannica Academic Edition <http://www.britannica.com/EBchecked/topic/289876/intensive-agriculture>>.

high- intensity farming this ratio of inputs to land is high and for low-intensity farming the reverse is the case.

To understand the impact of GURT on the farming system, one must address the primary attribute of the farming system that is affected by GURT, which is the seed or more specifically the seed system. A seed system is a mechanism of producing, distributing and using the highest quality seeds possible in a timely and affordable manner.⁷⁵⁹ It is the specific aspects of the seed system that differentiates GURT from non-GURT GE seed. There are two types of seed systems available in most countries, the formal seed system, and the farmer (a.k.a informal or local) seed system.⁷⁶⁰ Although they have distinct characteristics, they often both exist within most farming systems.⁷⁶¹

The formal seed system involves very specialized seed production by public or commercial breeders. It is also characterized by the involvement of government institutions in developing countries and by the private sector in developed countries.⁷⁶² This system develops varieties that large numbers of farmers can use on large acreages. It also involves large investments in the development of plant genetic resources. In the formal seed system, a limited number of seed outlets provide certified seed marketing and distribution. In this system there is also a distinct difference between seed and grain even though, as noted earlier, both can be planted and will produce crops.⁷⁶³ Specifically, in the formal seed system seed is planted; grain is eaten.

Formal seed systems are most amenable to high intensive farming systems where there is a high rate of seed replacement.⁷⁶⁴ Both GURT and traditional patent only GE seeds fit this model. On the other hand, low-intensity farming systems have low seed replacement with a

⁷⁵⁹ UNFAO, *What are Seed Systems* (2014), online: UNFAO < <http://www.fao.org/agriculture/crops/thematic-sitemap/theme/compendium/tools-guidelines/what-are-seed-systems/en/>>.

⁷⁶⁰ Supra note 586 at 5.

⁷⁶¹ Ibid.

⁷⁶² Ibid at 8.

⁷⁶³ Louise Sperling and H David Cooper, "Understanding seed systems and seed Security: A Background Paper" in Louise Sperling, Thomas Osborn & H David Cooper eds, *Towards Effective and Sustainable Seed Relief Activities*, Proceedings of a stakeholders' workshop, Rome (26-28 May 2003) (Rome: UNFAO, 2004) 7 at 9.

⁷⁶⁴ Supra note 586 at 5.

greater reliance on farmer seed systems.⁷⁶⁵ Neither GURT nor traditional GE seeds are a good fit with a low-intensity farming system because either seed cannot be saved (GURT) or it can be saved but this occurs illegally (non-GURT GE seeds).

The farmer (informal, local) seed system is a flexible, localized system in which farmers produce, distribute and access seed from their harvest, or through exchange among friends, neighbours, or local grain markets. This system uses a wide range of seed varieties of variable quality.⁷⁶⁶

Where GURT seeds have the potential to affect negatively low-intensity farmer seed systems is if V-GURT grain enters the less well controlled secondary grain market (aka the commodity market) where grains are combined in silos and meant for sale as food, feed, or as use in late season risky plantings. Since farmer seed systems often use grain as seed, there is a risk that these farmers could see significant yield drops if V-GURT seed is planted. Unlike the earlier discussion in which the potential for field contamination with V-GURT was mentioned as a yield-reducing possibility, a new yield-reducing twist comes in the form of V-GURT contaminated grain used as seed. T-GURT, which does not result in second-generation seed sterility, would not present this problem. T-GURT, however, is dependent on an inducer chemical for value-added trait activation and this inducer would be under industry control.

There are other formal seed system benefits to GURT that are less dramatic than the benefits with the use of non-GURT GE seeds. The formal seed system, and the seed industry that supports it may see GURT as a way to take advantage of commercial possibilities in crops that were previously not commercially viable.⁷⁶⁷ The ability of GURT to provide a level of IP protection that was previously unavailable for the patent only GE seeds can encourage the formal seed system to expand by investing in low-demand varieties. Those supporting the formal seed system may find that this results in a broader range of products being made available to farmers.

Although the seed industry and farmers have a tremendous influence over how the seed market operates and how the business of agriculture proceeds, this influence reflects policies and

⁷⁶⁵ Ibid.

⁷⁶⁶ Supra note 763 at 9; supra note 759.

⁷⁶⁷ Supra note 586 at 6.

regulations that are developed by governments or organizations that are subject to governmental or international authority.

6.4 Policy, Regulation, Patents and GURT

The interrelationship between policies and regulations is a vital component in assessing the viability of patents and GURT. Policies can be defined as general rules developed by organizations to achieve aims and goals and to carry out plans. In contrast, regulations, which are also rules, have the effect of a law and are restrictive such that they are intended to force compliance by individuals or organizations. Regulations can be used to develop or to support policies.

One might argue that many of the policies and regulations established to address patented non-GURT GE seeds could be applied to GURT seeds as well. After all, GURT seeds are essentially specialized GE seeds. Therefore, it seems reasonable that governments' abilities to regulate GURT or to develop particular areas of GURT policy should correspond to what has already taken place for non-GURT seeds, crops and foods.

To begin with, there is no reason to evaluate the safety of the GURT food end product differently than other food products produced from non-GURT GE seed. In fact it has been established that there is no scientific reason to evaluate the safety of food produced from either form of GE seed differently from non-GE seed.⁷⁶⁸ Governments should have no additional technical difficulty addressing, for example, labelling requirements for GURT foods just as they have done for foods derived from patented only GE crops. Although there are differences in national labelling requirements for GE foods, these differences often appear to be policy based rather than technology or science based. While GURT seeds have unique features such as the production of sterile seeds associated with them, the end food product that results from GURT seeds is fundamentally the same as that from non-GURT GE seeds. As previously discussed, both Canada and the U.S. consider food sourced from GE crops to be “substantially equivalent” to that from non-GE crops. GURT crops are simply another iteration of GE crops.

⁷⁶⁸ Marisela Rivera-Dominguez & Mari-Ernesto Tiznado-Hernandez, “Utilization of Omics Technology to Analyze Transgenic Plants” (2013) in Debmalya Barh, Vasudeo Zambare & Vasco Azvedo eds, *OMICS Applications in Biomedical Agricultural and Environmental Sciences* (CRC Press, 2013) at 418.

Where there can be meaningful differences in policy and regulation development between GURT and non-GURT GE seeds is first, whether to allow their use; second, how to compensate for the indefinite IP duration of GURT seeds; and third, in how to manage crop growth, sale and trade. It is here where differences in national priorities and the need to establish international agreements that allow for the smooth flow of trade have their greatest effect. Some of these issues, such as crop growth, sale and trade can be dealt with using the broad mechanisms already established for non-GURT GE seeds.

There is one area of IP policy and regulatory development, however, which has not been addressed by national and international regulators since there has been little need to do so previously. This involves the potential for GURT-based seeds to create an indefinite seed monopoly and the consequences of this on society's share of the benefits that accrue from GURT seed innovation.

It is in IP policy and regulation development where GURT is unique because the current IP system is not set up to address the possibility of an agricultural product with an endless monopoly that may require significant changes to the current IP protection model. This is because the self-protective nature of GURT seeds undermines the ability of governments to manage the IP regime for the benefit of society. This is a patent dependent IP regime that has been successfully modified over the years to meet the challenges of various innovative technologies that have one common theme. That theme is that they depend on legal mechanisms for IP protection.

The chief policy issue that differentiates patented-only GE seeds from GURT is not about the specific policies. Rather it is about the ability to establish policies for a product that is technologically under the control of the inventor to such an extent that then inventor does not require the help of the government to protect the IP. This is where the difference in IP protection methods plays a significant role in determining the viability of the two alternatives under discussion in this thesis. The private sector has historically depended on existing government developed and supported IP protection tools such as the utility patent as an incentive in order to offer up the societal benefit of invention disclosure. How then could government exert leverage on the private sector to enforce a time-limited monopoly in exchange for invention disclosure, if

firms are not dependent on governments to make the traditional patent bargain? The answer is that, under the current regulatory paradigm, there is no leverage.

Policies that government develops to maximize the benefits to society of a private sector initiative often depend on the government's ability to offer private firms something in exchange for this benefit. That something, for example, can be a specified period of monopoly to recoup R&D costs and to make a profit. GURT potentially eliminates the need for firms to depend on government for that monopoly. GURT, in fact, eliminates the absolute requirement to patent at all if a firm decides that the technology and a trade secret is sufficient protection.

The self-protective nature of GURT suggests that, should this technology be commercialized, patents will be of secondary importance in protecting GURT-based GE seed IP. If this is so, new policy may lack the leverage that the current patent regime gives to governments to influence this industry. Furthermore, one can speculate on the impact that this will have on established regulatory regimes that support those policies.

The legal protection afforded to GE seeds through the patent system gives governments significant control when designing IP laws. The many benefits that this affords society have been enumerated earlier. Such social benefits as invention disclosure; time limitations on monopoly; control over the breadth of patents; and the ability for governments to match IP laws to national policy demands are the basis for private and public sector cooperation. This would be difficult enough if nations agreed on all aspects of policy and regulation related to the new GURT technology. However, governments already have significant differences in their response to non-GURT GE seeds as has been shown by the differences in the U.S. and EU responses to these products. The added new attributes of GURT seeds can only make this situation more contentious.

That said, there are well-established national and international organizations existing that assess, regulate, modify, and manage IP associated with the genetic engineering of agricultural seeds. At the national level, organizations such as the United States Patent Office (USPO) and the European Patent Office (EPO) play a crucial role in patent evolution to meet the challenges of new biotechnologies. Internationally, WIPO, the OECD and other organizations play a similar policy development role. Also, there are hundreds of national and international organizations

dealing with the agricultural, environmental and economic aspects of GE seeds, crops and foods.

As an example of the difficulties that already exist for GE seeds and will only become more complex with the commercialization of GURT one can look at risk management. If this is an international bone of contention for traditional GE seeds as the disputes between the U.S. led pro-GE seed group of nations [U.S., Canada, Argentina, Brazil] and the EU-led anti-GE seed group clearly demonstrate, how can this not be at least as significant an issue for GURT. Among other differences, these two groups view risk management differently.

Attempts at risk management for existing traditional GE seeds demonstrates how difficult it is to develop internationally uniform policies and regulations for seeds where governments do have leverage [i.e. control over the granting of patents]. Policies for risk management exist but, because they have evolved differently in the U.S. and Europe, they are not internationally uniform.

GE product risk is addressed in a paper titled, “The Regulation of GMOs in Europe and the United States: A Case-Study of Contemporary European Regulatory Politics” prepared for a Council on Foreign Relations Workshop in 2001. According to this paper, the divergence that developed between European and American regulation of GE crops and foods is influenced by Europe’s more risk-sensitive policies. This is attributed to “three interrelated factors: the emergence of a European civic culture, the growing regulatory role of the EU, and a series of regulatory failures that undermined public confidence in regulatory institutions and policies”.⁷⁶⁹

So, even before the subject of GURT commercialization enters the discussion, the U.S. and the EU already base GE food policies and regulations on two entirely different risk management criteria. The U.S. looks at the final product of genetic engineering and has concluded through the FDA that if the final product is “substantially equivalent,” the process that leads to it is not relevant. On the other hand, the EU places a great deal of emphasis on the process that creates the final product. As noted earlier, the EU’s contrasting view of GE products was established in 1990 when the European Council adopted Directive 90/220/EEC on the

⁷⁶⁹ Diahanna Lynch & David Vogel. *The Regulation of GMOs in Europe and the United States: A Case-Study of Contemporary European Regulatory Politics*, (2001) online: Council on Foreign Relations <http://www.cfr.org/genetically-modified-organisms/regulation-gmos-europe-united-states-case-study-contemporary-european-regulatory-politics/p8688> at 20.

Deliberate Release of Genetically Modified Organisms. This directive highlights process rather than product and was based on the Precautionary Principle. Before GURT was even on the radar screen, there was no consensus between the U.S. and Europe on the risks of GE products. Now, with the potential for GURT commercialization at some point in the future, the risk management issue is magnified, as the process of producing GE crops becomes an even more contentious issue for Europe's Precautionary Principle-based policy and regulatory development.

Unlike non-GURT GE seeds, which either express a trait or do not express a trait, GURT seeds present a new and more complex layer of potential "risk". That risk is not the academic version of risk, which depends on the existence of statistical data for probability calculations, but rather the risk associated with uncertainty. Uncertainty limits government's ability to manage actual risk through regulation because the scientific basis for regulation is not clear. Instead, with the limited information available, the regulation of GURT can only be based on speculation, unsupported assumptions, and fear of the unknown.

The ability to develop and commercialize GURT seeds leads to a number of policy considerations that may not be present or would be present to a lesser degree with traditional patented only non-GURT GE seeds. First, the additional input requirements of GURT, such as the use of inducers to activate or deactivate genes, would affect high-intensity farming systems and formal seed systems.⁷⁷⁰ These are systems in which GURT could increase the ratio of inputs to land while presumably maintaining or increasing profitability. This could, however, widen the gap between poor, often low-intensity farms, and rich high-intensity farms. The public policy response to this would require an increase in public investment in the type of breeding that would benefit the resource-poor farmers. The problem here is that to accomplish this goal, public investment in R&D, which this thesis has previously shown to be fairly static at best, might need to be diverted away from other areas such as cutting-edge technologies. If this reallocation of resources did not occur, innovative technologies such as GURT would increasingly be left to the private sector.

Another consideration is control over IP protection, which GURT can potentially take out of the hands of governments. This would need to be addressed for governments to be able to

⁷⁷⁰ Supra note 586 at 5.

develop effective economic and social policies. GURT provides an increased level of protection for the GE seeds traits and no doubt the inventor would be pleased to have this enhanced protection. However, would governments find this type of protection desirable? Most governments, especially those supporting the OECD, would likely be supportive of the increased R&D and the economic benefits from innovation, if this were encouraged by GURT. This is supported by the earlier discussion identifying the OECD as an organization with goals that include innovation promotion for economic growth. On the other hand, these same governments might find that the endless monopoly that GURT provides to be a hindrance to innovation and detrimental to consumers.

Unlike patents, GURTS are neither territorial nor time limited, and this can present a serious policy and regulation problem for national governments. For example, if a GE seed is patented and employs GURT technology, the time limited nature of the patent is of little advantage to farmers who may wish to use the seed when the patent expires since, even though the seed has lost its legal protection, it still retains its technological protection indefinitely.

Governments, particularly those in the developing world, depend on the ability to differentiate between various types of uses for protected seed. This ability allows for flexibility based on the differing farming systems leading to varying degrees of breeder's rights and farmer privileges. The established patent system in conjunction with TRIPS, UPOV and other international agreements allow for this flexibility. As such, developing world countries that depend on this flexibility may reject or restrict GURT.⁷⁷¹ This represents somewhat of a "sledgehammer" approach to policy and regulatory development but it may be all that is available to developing countries when it comes to such a highly self-protected product.

A further policy and regulatory concern arises if commercialization is allowed and GURT seeds become so successful that they replace non-GURT GE seeds. This would affect a country's ability to manage value capture mechanisms in a manner that promotes that country's economic and social policy needs unless some form of national or international regulatory intervention were to take place. For example, the benefits of the "suis generis" feature of the TRIPS agreement whereby a country could circumvent specific patent requirements by offering an

⁷⁷¹ Ibid at 8-9.

alternative means of protection would become irrelevant. Also, other provisions such as breeder's exemption or farmer's privilege, which are available with plant patents or PVPs would become meaningless with GURT seeds. Furthermore, the technological makeup of GURT seeds would in effect be deciding policy issues and ultimately the design of IP laws rather than the complex set of negotiations that take place among stakeholders.⁷⁷²

Rather than policy/regulatory control, GURT would create a higher level of market control than is available through the use of patent only GE seeds. To counteract this increased market level control, according to the 2002 CGRFA-9/02/17 Technical Study ("Potential impacts of genetic use restriction technologies (GURTs) on agricultural biodiversity and agricultural production systems") regulatory bodies would have to consider establishing some form of patent-like temporary monopoly for GURT.⁷⁷³ Otherwise, the permanent monopoly that GURT establishes could eliminate much of the public benefit that is associated with the temporary monopoly that is a feature of patents. This is especially of concern because GURT could also eliminate the knowledge disclosure requirement of the patent if GURT were not patented. The resulting ability for others to take the next step in innovation based on that disclosure could suffer as a result.

Further to the point that GURT would create a permanent monopoly is the question of how governments might deal with this issue. One way could be through enhanced antitrust laws to prevent farmer dependence on a limited number of suppliers of GURT seeds.

From a policy perspective, governments may wish to reap the economic benefits of increased R&D from GURT while limiting its negative impact on IPR regimes. This could be accomplished by differentiating between GURT that promotes increased productivity [i.e. T-GURT] and GURT that acts purely as a value capture mechanism [i.e. V-GURT].⁷⁷⁴ One could then regulate on that basis to maximize societal benefits of the former and minimize societal costs of the latter.

⁷⁷² Stephen Hubicki & Brad Sherman, "The Killing Fields: Intellectual Property and Genetic Use Restriction Technologies" (2005) 28:3 UNSW Law Journal at 749.

⁷⁷³ Supra note 586 at 11.

⁷⁷⁴ Ibid at 10.

Of course, governments may wish to deal with this issue by restricting or eliminating the use of GURT altogether. So far, the moratorium on GURT commercialization has done that very thing. Would it be reasonable to forgo the potential benefits of GURT because of an inability on the part of governments to maintain the level of control over the technology that they demand?

On what basis would or could countries restrict the use of GURT? Certainly, if scientific evidence showed that GURT was harmful to the environment or to human, animal or plant life, a case could be made for restricting or banning the technology.

If the GURT technology is patented it would fall under the TRIPS agreement, and aspects of Article 27.2 of TRIPS allow the exclusion of patentability for inventions that a country considers a threat to *ordre public* or morality.⁷⁷⁵

But even if the product can be shown to be safe, would this be enough for the EU where the process used to create a product and the Precautionary Principle hold sway? It seems unlikely, since the Precautionary Principle allows for *uncertainty* as a basis for rejection. The arbitrariness of this measure removes the decision to allow or disallow GURT from the scientific realm and places it squarely in the political realm where opinion or belief is often the deciding factor.

If the right to patent GURT cannot be withheld for reasons just stated, or for any specific reason, the fact that an invention is patented does not automatically provide a positive right to commercialize it. To date GURT seeds are patented not necessarily because the fear of unauthorized use exists. Rather, as in most high technology industries, firms are protecting these inventions from rivals in the crucial initial development stage of the product by the most effective currently available method. Phillips and Dierker, Schenkelaars et al., Chesborough, Mansfield, Lerner, and Phillips and Gustafson all highlight the importance of this strategic patenting.

Once commercialization occurs, it is the users [farmers] of the product who are of greatest concern to the GE seed firms. The users have little or no ability to turn GURT traits on or off and therefore patents are of little use in protecting GURT IP from farmers' misuse.

⁷⁷⁵ Supra note 10.

To deal with these difficult issues if GURT is commercialized, new regulations may be needed, not to replace the existing patent regimes but rather, to enhance their capacity to address the absolute technological protection that GURT gives to firms.

Even though GURT seeds are patented, this thesis has repeatedly maintained that this technology does not require patent protection to prevent its unauthorized use by farmers. Should there be instances in which GURT seeds are not patented, the existing IPR system will not be able to provide a method for the regulation of this technology. If governments wish to regulate this technology, there must be a policy developed and regulations put in place that can allow this to occur.⁷⁷⁶

The “Genetic Use Restriction Technologies” Expert Paper notes on page 36 that the impact of GURT may be broader than its ability to fully enforce IP rights. The report reiterates that to obtain a patent the requirements of novelty, inventive step and non-obviousness must be demonstrated. In contrast, GURT can be applied to any seed without the need to claim anything as long as no attempt is made to patent the product.⁷⁷⁷

GURT would also affect other rights that have been established to limit seed firm control over seed IP such as plant breeders’ rights and farmers’ privilege.⁷⁷⁸ Even though plant breeders’ rights allow for farmers’ privilege, V-GURT, for all practical purposes, would make this privilege meaningless because the seed produced by a V-GURT plant is sterile.

Existing national and international GE seed regulation can be a framework for the regulation of GURT since GURT is, at its heart, an iteration of GE seed technology. However, T-GURT will be reliant on the use of inducers. There is the question whether these inducers require specific regulation and if so how and under what circumstances. This is a concern because, as is stated in the technical study on the potential impacts of GURT on agricultural biodiversity and agricultural production systems [CGRFA-9/02/17] prepared for the Commission on Genetic Resources in Food and Agriculture, small quantities of these inducers will have significant

⁷⁷⁶ Supra note 586 at 9.

⁷⁷⁷ Supra note 464 at 36.

⁷⁷⁸ *Plant Breeders' Rights (PBR)* gives exclusive rights to new varieties of some plant species. Protection is available to citizens of countries that are members of the International Union for the Protection of New Varieties of Plants (UPOV). *Farmers Privilege* allows farmers to use a part of the material produced on his farm, from a protected variety, for planting his own fields without any obligation to the PBR title holder. The member states of UPOV make provision for the farmers privilege.

commercial value due to their ability to activate or deactivate valuable GE seed traits. Certainly there is the possibility of patenting inducers. However, there are two problems associated with this method of control. First, patents will represent a legal method of control over this IP and will suffer from all of the disadvantages and problems associated with patenting including high transaction costs and monitoring problems. Second, as previously noted, the ability to patent an inducer may be problematic if that inducer already exists and has another recognized use as a product under IP laws. Third, the high value of these inducers will likely make them subject to unauthorized production and sale resulting in value leakage for the GE seed firms and loss of regulatory control by those responsible for that regulation.

6.5 Consumer Acceptance

The importance that consumer acceptance of a new technology has on the ultimate long-term success of that technology cannot be underestimated. Consumer acceptance will determine whether farmers select the seed for their crops and farmer demand will determine whether the GE seed firms have a market for the product.

In reviewing the literature on the acceptance of technology by consumers, one finds that perceived risks and benefits; personal values and attributes; and knowledge of the topic are among the primary variables that shape consumer views. In this regard, genetic engineering technology is no different than any other technology. Considerations such as the Precautionary Principle discussed earlier in this thesis reflect and affect consumer acceptance of GE seeds whether they are GURT-based or non-GURT-based. Jonathan Adler's paper for the *Texas International Law Journal* titled, "More Sorry than Safe: Assessing the Precautionary Principle and the Proposed International Biosafety Protocol" addresses consumers' willingness to accept risk associated with GE food and concludes that consumers must make their own judgement on acceptance of these products.⁷⁷⁹ In this thesis, one is attempting to compare the potential consumer acceptance of a new disruptive technology that has no track record with an existing commercialized non-GURT GE seed technology.

⁷⁷⁹ *Supra* note 103 at 179.

Attempts have been made to quantify this comparison with models such as that created by Khachatryan and Yiannaka and reported in their 2008 paper, “The Market Acceptance and Welfare Impacts of Genetic Use Restriction Technologies (GURTS).” Unfortunately, the assumptions that are required to give some veracity to their mathematical formulas are at times questionable. Problems with the Khachatryan and Yiannaka paper include assumptions on price differentials between conventional crops and GURT crops and the contention that new GE varieties will push old GE varieties out of the market.⁷⁸⁰ Assumptions such as these may have significant value in assessing economic acceptance of GE technology by GE seed firms and farmers. However, consumers, especially those in the developed world might look to factors beyond economics to judge the acceptance of this type of new technology. These factors include the perceived safety of the technology; an understanding of its mechanisms; and the ethics of its development and implementation.

Most data about consumer attitudes concerning GURT is not actually about GURT but rather about technology in general, and GE seeds, crops, and foods in particular. From this data, consumer attitudes regarding GURT may be predicted to some degree based on the specific attributes of GURT that differentiates it from non-GURT GE technology.

Numerous surveys have been carried out to weigh consumer attitudes towards GE seeds, crops and foods. Unfortunately, investigation of the groups conducting these surveys often finds that they are supported or associated with proponents of a particular view of this topic that may be self-serving. This does not necessarily mean that the survey/research that they conducted or their interpretation of the results is biased. However, it does suggest that the potential for bias exists in the design of the questions, populations surveyed, and the interpretation of the results. To limit potential survey bias two primary surveys are used in this thesis. They are from well-known, reputable sources independent of obligation to those with a stake in one side of the GE debate or the other.

⁷⁸⁰ Marianna Khachatryan & Amalia Yiannaka, “The Market Acceptance and Welfare Impacts of Genetic Use Restriction Technologies (GURT)” (2006) a selected paper prepared for presentation at the International Association of Agricultural Economists (IAAE) Triennial Conference (Foz do Iguacu, Brazil, 18-24 August 2012)), online <<http://ageconsearch.umn.edu/bitstream/126880/2/Yiannaka.pdf>> at 8.

The principal selected surveys are the EU Eurobarometer Biotechnology Report of 2010 and the Pew Research Center Study of 2015 on Public and Scientists' Views on Science and Society in the U.S. The Pew study is selected because it primarily surveyed consumer and scientist views on science and technology, which are broadly applicable to most areas of technological innovation. The Eurobarometer survey has similar components to the Pew survey but with added biotechnology components that are more detailed than those in the Pew survey. The other reason for the choice of these two surveys is that Eurobarometer survey is an EU survey, and Pew is a U.S. survey. These two surveys represent consumer viewpoints from the two major international blocks with conflicting GE biotechnology positions.

In addition, a 2004 FAO Agricultural and Development Economics Division working paper on "Public Attitudes towards Agricultural Biotechnology"⁷⁸¹ is also a useful secondary tool for this thesis. This latter publication summarizes a number of surveys, two of which are from organizations with industry backing. These two organizations are the International Food Information Center (IFIC) and the Asian Food Information Centre (AFIC). The data that they produced was very similar to that produced by the Eurobarometer and Pew surveys. This combined with the fact that the FAO found them to be worthy of publication by the FAO Agricultural and Development Economics Division suggests that these surveys have a high level of international scientific acceptance even though they are industry-based surveys.

Many consumers in North and South America, and to a greater extent those in Europe, already have a negative perception of GE food, which the literature indicates is the result of a personal evaluation of perceived risks and benefits of these products. So, whether the overall technology is protected legally by patents or technologically by GURT may have little impact on whether consumers have a favourable or unfavourable opinion of the technology. It may, however, affect some of the ethical issues around the specific attributes of GURT, such as its potential for increased monopolization by industry or that V-GURT results in the creation of sterile second generation seeds.

⁷⁸¹ Thomas J Hoban, "Public Attitudes towards Agricultural Biotechnology" (2004) ESA Working Paper No. 04-09 online: UNFAO, Agricultural and Development Economics Division <<ftp://ftp.fao.org/docrep/fao/007/ae064e/ae064e00.pdf>>.

The surveys discussed here all look at GE food and agricultural biotechnology as a broad category. These surveys do not directly address GURT. What these surveys and studies identify are consumer attitudes towards non-GURT GE biotechnology; the public's general scientific knowledge; and the sources of public trust for scientific information. The results of these surveys create a foundation for understanding where consumer attitudes are situated with respect to agricultural biotechnology and why this may be so. With this in mind, one can project how consumers may assess the acceptability of GURT, a subset of GE seed biotechnology. GURT's added complexity and specific unique attributes may exacerbate the level of concern that consumers may have with some of the attributes it shares with non-GURT genetic engineering such as the artificial transfer of genes. On the other hand, some attributes may alleviate concerns, such as GURT's capacity to limit the spread of transgenes.

In 2004, the Agricultural and Development Economics Division of the FAO produced a study of public attitudes towards agricultural biotechnology titled, "Public Attitudes towards Agricultural Biotechnology." This study involves all available earlier Pew, Eurobarometer and Environics surveys in the U.S., EU, Latin America, Asia and Africa. Although the number of internationally comparable public opinion surveys is limited, available data from this 2004 study indicates that public attitudes on this subject differ in various parts of the world and even within countries.⁷⁸²

The referenced surveys in this publication usually involved 1000 interviews per country. The largest of these surveys is the Environics International Survey, which conducted a wide-ranging study of consumer attitudes towards biotechnology in 2000. There were 35,000 respondents from 35 countries in this study. The statement of interest posed to survey participants was, "The benefits of using biotechnology to create genetically modified [GE] food crops that do not require chemical pesticides are greater than the risk."⁷⁸³ The 2004 FAO study on "Public Attitudes towards Agricultural Biotechnology" indicates that the Environics survey claims that consumers in North and South America and most of Asia agree with this statement.

⁷⁸² Ibid.

⁷⁸³ Environics International, *Food Issues Monitor 2001* as cited in Thomas J Hoban, *Public Attitudes towards Agricultural Biotechnology* (2004) ESA Working Paper No. 04-09 online: UNFAO, Agricultural and Development Economics Division < <ftp://ftp.fao.org/docrep/fao/007/ae064e/ae064e00.pdf> > at 1.

In contrast, European consumers and those in Australia, Japan, and Korea disagree.⁷⁸⁴ The problem with the statement posed to consumers is that it includes a claimed benefit of GE technology in the statement [i.e. "...that do not require chemical pesticides..."]. This certainly adds some level of bias to the statement.

While the 2000 Environics survey is revealing, a more detailed Environics GE food survey followed in 2001. The results of this survey are along the lines of those in the 2000 survey yet because these two surveys were conducted some years ago the debate over the effects of GE seeds, crops and foods was in its infancy. For this reason, data from more recent significant surveys by Pew Research and Eurobarometer have been utilized to give a more up to date view of attitudes in the U.S. and Europe.

These are attitudes that have formed over time for very specific reasons. As noted in the policy and regulation portion of this thesis, the case study produced for the Council on Foreign Relations⁷⁸⁵ suggests that the difference between European and American regulation of GE crops and foods is influenced by Europe's more risk-sensitive policies. The study attributes this to three interrelated factors previously noted: "the emergence of a European civic culture, the growing regulatory role of the EU, and a series of regulatory failures, which have undermined public confidence in regulatory institutions and policies."⁷⁸⁶ This study points to major and highly publicized regulatory failures as one reason for the current lack of consumer trust in GE biotechnology. Although these failures were more significant in Europe, the damage done to consumers' trust in science and its regulation has been broad. As stated in the 2000 report by the collection of national science academies, "Ultimately, not credible evidence from scientists or regulatory institutions will influence popular public opinion unless there is public confidence in the institutions and mechanisms that regulate such products."⁷⁸⁷ In addition, as mentioned earlier, Phillips and Dierker reflect on the growth of this regulatory consumer confidence deficit,

⁷⁸⁴ Supra note 781 at 1.

⁷⁸⁵ Supra note 769.

⁷⁸⁶ Ibid at 22.

⁷⁸⁷ Supra note 618 at 10.

which they suggest is further enhanced by the potential for regulatory capture from the partnering of public institutions and the private sector.⁷⁸⁸

A good example of the mixed signals from the regulatory apparatus is the recent Ebola issue in the U.S. where the Center for Disease Control (CDC) continued altering the protocols for quarantine in the midst of the crisis. What is particularly concerning about this is that throughout the crisis the scientific understanding of Ebola did not change, but the political and social pressures brought on by the crisis continued to intensify. As a result of these pressures, Ebola quarantine protocols changed to match non-science-based concerns rather than as a result of changes to the scientific basis for those protocols.⁷⁸⁹ What the public perceived was confusion and uncertainty, and the result was a growing lack of trust in the institutions that were tasked with keeping the public safe. There appeared to be a difference in how the public and scientists viewed the risks associated with the scientific issues. In this case, the gap between the public's view of perceived risk and the scientists' view of actual risk grew wider as safety protocols changed.

As recently as Jan 29, 2015, the Pew Research Center in the U.S. in collaboration with the American Association for the Advancement of Science (AAAS)⁷⁹⁰ conducted a survey that elicited the views of the general public and scientists on major scientific issues and the responsibility that science should have in creating public policy.⁷⁹¹

A common thread in the survey results is the high esteem in which both scientists and the public hold science in America.⁷⁹² However, the survey results for specific issues shows a gap

⁷⁸⁸ Supra note 325 at 9-10.

⁷⁸⁹ WHO, "Ebola response: What needs to happen in 2015" (2015) online: WHO <<http://www.who.int/csr/disease/ebola/one-year-report/response-in-2015/en/>>.

⁷⁹⁰ The American Association for the Advancement of Science (AAAS) is the world's largest general scientific society, and as such, encompasses all disciplines in the scientific community. Founded in 1848, AAAS publishes *Science*, one of the most widely circulated peer-reviewed scientific journals in the world. It is an international non-profit organization whose mission is broadly defined as seeking to "advance science, engineering, and innovation throughout the world for the benefit of all people."

(<https://www.aaas.org/about/mission-and-history>)

⁷⁹¹ Pew Research Center, "Public and Scientists' Views on Science and Society" (2015) a Pew Research Center study conducted in collaboration with the American Association for the Advancement of Science (AAAS) online: PewResearch Center <<http://www.pewinternet.org/2015/01/29/public-and-scientists-views-on-science-and-society/>>.

⁷⁹² Ibid at 26.

between U.S. adults and scientists in perceived risk and belief in the veracity of scientific conclusions. The issues surveyed are divided into two broad categories: one is biomedical sciences, and the other is climate, energy and space sciences. The latter category has one result of note that is valuable for this thesis. That is that the differences between the opinions of scientists and the public are less at odds in this category except in the area of climate change. In this area, there is a significant discrepancy between scientists and the public over the impact of human activity on climate change. On this issue, 87% of scientists but only 50% of the public agree that climate change is caused by human activity.⁷⁹³

The other category, biomedical sciences, is noteworthy in that it has the greatest average spread between scientist and public opinion. The average opinion spread for the biomedical sciences is 36.8% whereas that for the climate, energy and space sciences category is 19.3%. See Table 7 below for the specific spreads in subcategories.

Table 7: Opinions: % of U.S. Adults and AAAS Scientists⁷⁹⁴

Biomedical Sciences	U.S. Adults(%)	GAP Between U.S. Adults And AAAS Scientists(%)	AAAS Scientists(%)
Safe to eat genetically modified foods	37	51	88
Favour use of animals in research	47	42	89
Safe to eat foods grown with pesticides	28	40	68
Humans have evolved over time	65	33	98
Childhood vaccines such As MMR should be required	68	18	86
Climate, Energy, Space Sciences			
Climate change is mostly due to human activity	50	37	87
Growing world population will be a major problem	59	23	82
Favour building more nuclear power plants	45	20	65
Favour more offshore drilling	32	20	52
Astronauts essential for future of U.S. space program	47	12	59
Favour increased use of Bioengineered fuel	68	10	78
Favour increased use of fracking	31	8	39
Space station has been a good Investment for U.S.	64	4	68

Survey of U.S. adults August 15-25, 2014. AAAS scientists survey Sept. 11- Oct. 13, 2014. Other responses and those saying do not know or giving no answer are not shown.
Opinion Differences Between Public and Scientists

⁷⁹³ Ibid at 6.

⁷⁹⁴ Ibid.

The Pew survey becomes particularly poignant where it shows that 88% of AAAS scientists but only 37% of the public consider GM (GE) foods safe to eat. Upon further questioning, the reason for this large difference is that 67% of the public do not accept that science understands the health effects of GE foods.⁷⁹⁵ So, while the public holds U.S. scientific knowledge and scientists in high regard, there is a public belief that scientists lack a clear understanding of this topic. In essence, the public suggests that scientists are willing to say that GE foods are safe in spite of not having a clear understanding of this topic. One has to wonder on what basis the public would come to such a conclusion. Perhaps it is science's inability to convey the understanding that it has on this issue that is the problem. Or perhaps it is the public's level of science background that is the problem.

Two questions in the GE portion of the U.S. Pew public survey seem to be contradictory. Question #37 and Question #38 begin with the following preamble: "Scientists can change the genes in some food crops and farm animals to make them grow faster or bigger and be more resistant to bugs, weeds, and disease."⁷⁹⁶ Then question #37 asks, "When you are food shopping, how often, if ever, do you LOOK TO SEE [capitalization in the question as presented to consumers] if the products are genetically modified?"⁷⁹⁷ The responses were as follows:

- 25% Always
- 25% Sometimes
- 17% *Not too often***
- 31% *Never***
- 1% Someone else does the shopping
- 1% Don't know/refuse to answer⁷⁹⁸

Question #38 then asks, "Do you think it is generally safe or unsafe to eat genetically modified foods?"⁷⁹⁹ The responses were as follows:

- 37% Generally safe

⁷⁹⁵ Ibid at 8.

⁷⁹⁶ Ibid at 91.

⁷⁹⁷ Ibid.

⁷⁹⁸ Ibid.

⁷⁹⁹ Ibid at 92.

57% *Generally unsafe*

6% Don't know/refuse to answer⁸⁰⁰

So, from Question #37, we have 48% or about one-half of the public respondents never or not too often examine whether products are GE. From Question #38, 57%, or more than one-half of respondents, consider eating GE foods to be unsafe.

The obvious question that arises from this is, how strongly held is the belief that GE food is unsafe? Why, if more than one-half of the public regards GE food to be unsafe, do almost one-half of the public rarely or never check labels to see if the food they are purchasing contains GE material? One suggestion could be that this topic is simply not frequently on the minds of consumers. They must be prompted to think about it, and when they do think about it, they worry.

We know that in Canada and the U.S. there is no requirement to label foods as to their content of GE ingredients [recall the earlier discussed concept of substantial equivalence]. As such, this information is rarely found on the labels of food products. There does not seem to be a significant demand for this information since one half of the public does not seem to care to look.

The Pew survey does not address the level of conviction that the public has about the safety of GE foods. A useful survey question to flesh out this issue would have been: "If you saw that a food product you were about to purchase contained genetically modified products, would you still purchase it?" Looking at GURT and the often-used dysphemism "terminator seeds," how might the public answer the question, "Would you purchase a food product grown from "Terminator seeds"? It is likely that most of those questioned would have no idea what "Terminator seeds" are, however, it might be a safe bet that they would answer NO to that question simply because "Terminator" is a frightening term. After all, phrasing and word selection can make a difference in the response one can expect to a survey question or assertion.

The GE food debate seems to be filled with such polarizing language. A V-GURT seed can be a "biotechnologically protected seed" if one is a proponent of GURT or it can be a "terminator seed" if one is an opponent. It seems fair to suggest that the use of such inflammatory language as "terminator seed" adds to consumers' perceived risks of this product

⁸⁰⁰ Ibid.

and therefore encourages those consumers who are undecided to tilt away from the new technology.

Interestingly, in the Pew survey, 84% of scientists state that the lack of scientific knowledge among the general public is a major problem when it comes to the public making decisions on scientific matters or even knowing that there are specific scientific issues being debated. Three-quarters of scientists indicate that insufficient K-12 STEM (kindergarten to grade 12, science, technology, engineering, mathematics) education is a major factor in this lack of scientific knowledge.⁸⁰¹ However, the survey suggests that there are other factors that add to this problem. See Table 8 below.

Table 8: Major/Minor Reasons for the U.S. Public Having Limited Knowledge About Science: Opinions of AAAS Scientists (%)⁸⁰²

Reason	A Major Reason(%)	A Minor Reason(%)
Not enough K-12 STEM	75	22
Lack of public interest in science news	57	35
Lack of media interest in science	43	46
Too few scientists who communicate findings	40	49

AAAS Scientists Survey Sept 11 – Oct 3, 2014 (Q6a-d) Those saying not a reason or giving no answer are not shown. (Pew Research Center) Scientists' Perspective: Too Little K-12 STEM Linked to Limited Public Science Knowledge

According to the Pew survey, both AAAS scientists and the public are not highly complementary of the U.S. K-12 STEM education. Only 29% of U.S. adults consider this education to be the best in the world whereas only 16% of AAAS scientists have this opinion.⁸⁰³

This outcome is shown in Table 8. From this it would not be unreasonable to conclude that perhaps the U.S. public does not have a clear grasp of the concept of genetic engineering. This would not be surprising since genetics is a highly complex topic and the ability to manipulate genes artificially is a relatively recent development. The ability to do so

⁸⁰¹ Ibid at 10.

⁸⁰² Ibid.

⁸⁰³ Ibid at 30.

commercially in agriculture is an even more recent development. So, how does the public make decisions on the safety of our subject of interest, GE seeds, crops and foods?

A scientist will use peer-reviewed research to judge the risks associated with a research target such as GE seeds, crops and food. In contrast, the public does not have the capacity to evaluate research techniques as either good or bad and, therefore, cannot judge the quality of the results of research in the same manner, as would a scientist. The public must rely on the trusted opinions of others. Where then can the public get answers to the important scientific questions such as the safety of GE foods and more to the point the safety of GURT? The answer is that the public will get those answers from a variety of sources that include scientists; governments; special interest groups; and today, from anyone with access to the internet who wishes to espouse a point of view that may be based on less than rigorous scientific evaluation.

However, these sources are obviously not all equally valid. If one is questioning the safety of GE seeds, crops and foods or that of GURT, then one is proposing a scientific question best answered by scientists. On the other hand, if one is questioning policy, regulation or ethics associated with this subject, there may be valid ethical or political questions that are not related to science that require input from non-scientists.

Science provides the best available answers to the questions that can be scientifically determined. While scientific conclusions may be a foundation for the development of policy and regulation, there are other important considerations. There may be overriding political or social concerns that need to be addressed. One would think that scientific consensus is respected across the board by all sides of any debate, yet other factors such as political or social outlook may colour one's view of the science. The climate change debate seems to demonstrate such a situation.

A common phrase in the climate change debate by those who are convinced that human activity is responsible for climate change is that "the science is settled". In fact, as previously noted, the Pew survey shows 87% of AAAS scientists accept that climate change is caused primarily by human activity.⁸⁰⁴ Many environmental organizations, such as Greenpeace International agree with this position and point to this scientific consensus to bolster their

⁸⁰⁴ Ibid at 47.

position.⁸⁰⁵ However, Greenpeace also considers GE foods to be unsafe. A quick look at their website confirms this.⁸⁰⁶ Yet 88% of AAAS scientists in the Pew Research Survey state that it is safe to eat GE foods. Why is the science related to GE foods not “settled” when the same percentage of scientists consider GE foods to be safe as those that consider climate change to be due primarily to human activity?

Perhaps for some advocacy groups, it is often not about the science but rather it is about beliefs that they have formed concerning the motives of those who create or promote the science; regulate the science; or profit from the science. It may be that beliefs preceded the evidence and as Bertrand Russell suggests, it is sometimes very difficult to have one’s beliefs correspond to the evidence. Russell noted in his 1941 book, “Let the People Think”⁸⁰⁷ that often the stronger the belief and the less evidence supporting it, the greater the passion of those beliefs. Some may consider this to be an overly simplified generalization. However, it does appear to be a common occurrence today when viewing the hundreds, if not thousands, of anti-GE websites that proliferate on the Internet. The idea that beliefs precede the evidence may be very important in predicting the degree to which GURT will find consumer acceptance. Beliefs about the harm from GURT GE seeds are already quite passionate in some circles and yet there is a paucity of evidence to support those beliefs.

Another issue that affects consumer attitudes toward science is the consumer’s inability to understand what constitutes expert opinion. Russell suggested in 1941 that when it comes to beliefs and evidence, the following principle should be adhered to: “It is undesirable to believe a proposition when there is no ground whatever for supposing it true.”⁸⁰⁸ To support this proposal he claimed that we should accept the following propositions:

- (1) that when the experts are agreed, the opposite opinion cannot be held to be *certain* [my emphasis];
- (2) that when they are not agreed, no opinion can be regarded as certain by a non-

⁸⁰⁵ *Climate Change* (2016) online: Greenpeace< <http://www.greenpeace.org/international/en/campaigns/climate-change/>>.

⁸⁰⁶ *Genetic Engineering* (2016) online: Greenpeace< <http://www.greenpeace.org/international/en/campaigns/agriculture/problem/genetic-engineering/>.

⁸⁰⁷ Bertrand Russell, “On the Value of Scepticism” (1928) in Bertrand Russell. *Let the People Think: A Selection of Essays* (London: Watts & Company, 1941), online: Panarchy< <http://www.panarchy.org/russell/scepticism.html>>.

⁸⁰⁸ *Ibid.*

expert, and (3) that when they [experts] all hold that no sufficient grounds for a positive opinion exist, the ordinary man would do well to suspend his judgement.⁸⁰⁹

Unfortunately, passion is a difficult emotion to overcome, and those who are subject to its most extreme forms are least likely to succumb to a rational approach to evidence and belief. The recent and still ongoing vaccine/autism debacle is ample proof of the inability of the poorly informed to suppress belief in favour of evidence.

GE seeds, crops and foods provide a similar model for belief and evidence and GURT magnifies the anti-GE beliefs of those already so inclined. The dysphemism, “Terminator Seed” represents the beginning of the demonization of GURT. The Rural Foundation Advancement International (RAFI) first coined the expression “terminator” in 1998.⁸¹⁰ This organization, which no longer exists, was a Canadian based rural advocacy organization found on the Internet that was opposed to GE crops. “Terminator” refers to the robotic character in the 1984 Arnold Schwarzenegger feature film, “Terminator” whose sole purpose is to kill its assigned target at all costs and with no mercy. This term has become synonymous with GURT seed sterility even though only V-GURT produces sterile seeds. T-GURT seeds are quite viable yet Internet discussions rarely discuss these seeds since they simply do not have the same shock value as “Terminator Seeds.”

The Internet is a powerful media outlet for those with opinions on many scientific subjects. The Pew survey has produced some significant results about scientists’ views on how the public and the media affect science in 2015. See Table 9 below.

⁸⁰⁹ Ibid.

⁸¹⁰ Luca Lombardo, “Genetic use restriction technologies: a review” (2014) 12 *Plant Biotechnology Journal* 995, online: Wiley Online Library <<http://onlinelibrary.wiley.com/store/10.1111/pbi.12242/asset/pbi12242.pdf;jsessionid=3A68A8FA163B9E2F8A620CDA72CFEDC8.f03t01?v=1&t=iqquyt6&s=3645c0ae73c735f57cffe202d4fee64dfd66b1cc>> at 995.

Table 9: % of AAAS Scientists Saying Each is a Problem for Science in General⁸¹¹

The Problem	A Major Problem(%)	A Minor Problem(%)	Not a Problem
Public does not know much about science	84	14	1
News reports do not distinguish well-founded findings	79	20	2
News media oversimplify findings	52	43	5
Public expects solutions too quickly	49	44	7

Scientists Fault Public Knowledge and Media Reports as Problems for Science
AAAS Scientists Survey Sept 11 – Oct 13, 2014 (Q5a-d) Those giving no answer are not shown

This survey was also carried out in 2009 with the same questions. Interestingly, there was a small increase (79% 2015; 76% 2009) in scientists indicating that it is problematic for science that the news media is not differentiating between good and poor research. In addition, there is a rise in scientists suggesting that the media is glossing over some of the complexities in their research findings that are vital in establishing a realistic perspective on those findings (52% 2015; 48% 2009).⁸¹² This is problematic because many caveats that accompany the scientific findings are absent from the reporting. The Pew Research survey provides a clear window into scientists and public views on science in general with some specific notes on agricultural biotechnology. The 2010 Eurobarometer survey does much the same for the EU but with a heavier emphasis on GE biotechnology.

The biotechnology aspects of the 2010 Eurobarometer survey is used in this thesis to compare the European public's views on biotechnology to those of the U.S. public as demonstrated in the 2015 Pew Research survey discussed above. While the Eurobarometer survey is more focused on biotechnology, it covers many of the same important GE biotechnology issues as the Pew survey. Of the areas covered by Eurobarometer survey, those of particular interest are the public's understanding of biotechnology, its benefits, and those

⁸¹¹ Supra note 791 at 61.

⁸¹² Ibid.

responsible for carrying it out.⁸¹³ The analysis in this survey occurs at the EU level and by country but because the EU is often looked at as a block when it comes to the regulation of biotechnology, an EU level of analysis is used to compare and contrast with the U.S. Pew survey. Although the survey responses identify some significant country differences within the EU, this fact is of little value for this thesis.

In addition, the primary area of interest in the Eurobarometer survey is agricultural biotechnology as it relates to seeds, crops and food. A key finding in this survey is that Europeans see little benefit in GE foods and consider them to be unsafe.⁸¹⁴ Furthermore, Europeans trust that scientists are the best advisors about issues concerning biotechnology and that there should be strong regulation by government that reflects the opinions of these scientists.⁸¹⁵

Key consumer survey results with respect to “Awareness of and Attitudes towards Biotechnology” are:⁸¹⁶

- 1) ****53% agree that biotechnology and genetic engineering will have a positive effect on our way of life in the next 20 years; 20% say a negative effect; 7% no effect; 20% do not know.
- 2) 84% of Europeans have heard of GE foods
- 3) 38% of Europeans have themselves searched for information on GE foods
- 4) ****61% disagree that the development of GE food should be encouraged
- 5) ****59% disagree that GE food is safe for their health; 63% of Europeans who had heard of GE food prior to the survey do not consider it to be safe; 44% who had not heard of GE food prior to the survey do not consider it to be safe. In the 2015 Pew survey, 57% of the respondents indicated that GE food was unsafe for their health.
- 6) 58% disagree that GE food is safe for future generations
- 7) 57% agree that GE food benefits some people but puts others at risk

⁸¹³ EC, *Biotechnology, Special Eurobarometer (341/Wave 73.1) a survey conducted by TNS Opinion & Social on Request of European Commission, Co-ordinated by Directorate General Research* (Fieldwork 2010 January – 2010 February, Publication 2010) at 4.

⁸¹⁴ Ibid at 206.

⁸¹⁵ Ibid at 207.

⁸¹⁶ Ibid.

- 8) ****61% agree that GE food makes them uneasy
- 9) 53% disagree that GE food does not harm the environment; 23% agree that GE food does not harm the environment; 24% do not know
- 10) 61% disagree that the development of GE food should be encouraged; 23% agree
- 11) 43% agree that artificially introducing a resistance gene from another plant or animal (horizontal transfer) into another plant is a good idea; 45% disagree
- 12) 50% disagree that eating apples produced using the technique in (11) is safe; 30% agree that it is safe

In the 2010 Eurobarometer survey, when Europeans were asked who they thought is doing a good job for society, respondents looked favourably upon medical doctors (81%); “university scientists (77%); consumer organizations (73%); environmental groups who campaign about biotechnology (66%);”⁸¹⁷ and the media which report on biotechnology.⁸¹⁸ Unfortunately, this question was not asked about Internet sources, which are likely a significant source of “information” on biotechnology for many people because of the ease of information access.

Considering the recent regulatory failures in the EU and the reported diminishing of confidence by the EU public in the quality of regulation noted earlier, the public survey response with respect to EU lawmakers, national lawmakers and industry is quite surprising. When asked if they thought these three groups are carrying out their functions in a manner that benefits society, the responses were as follows:⁸¹⁹

- 60% of respondents said that the EU is doing a good job-making laws about biotechnology for all EU member states
- 55% of respondents said that national governments are doing a good job- making laws about biotechnology
- 58% of respondents said that industries which develop new products with biotechnology are doing a good job

⁸¹⁷ Ibid at 153.

⁸¹⁸ Ibid.

⁸¹⁹ Ibid at 162.

How do these survey results compare to those of the 2015 Pew Research survey in the U.S.? Both the 2015 Pew survey and the 2010 Eurobarometer survey indicate that the majority of the public agree that GE food is unsafe (EU 61%; U.S. 57%). The surveys suggest that the respondents in the EU and those in the U.S. come to this conclusion in different ways and with differing degrees of conviction. While Americans consider GE food to be unsafe, the survey states that they do not place much emphasis on searching out food label information to back up their concerns. Much of this could be because the labelling of GE food is optional in the U.S. and is mandatory in Europe. The U.S. results suggest that a lack of basic science knowledge has put Americans in the position of being more susceptible to media influence when making decisions on scientific matters. Add to this the fact that the USDA indicates there is no need to label GE food and that this position is supported by the industry; one can understand why Americans would be influenced not to support labelling of GE food.

Many articles appear in newspapers or are available online providing facts, pseudo-facts and opinions on GE foods. One that appears to accurately reflect the political aspects of the thesis topic appears on the New York Times website. It was written by Michael Pollan, who has authored a number of books and articles about the intersection of nature and culture with a particular emphasis on food. Titled, “Vote for the Dinner Party”, it addresses California’s Proposition 37, an initiative that would have required the labelling of GE foods. This initiative represented the first large coordinated attempt by the food movement in the U.S., as Pollan refers to it, to impact the political arena.⁸²⁰ Pollan saw this initiative as a way to impress upon “Big Food” that consumers dislike the, “corporate control of the regulatory process; lack of transparency (for consumers) and lack of choice (for farmers); an intensifying rain of pesticides on ever-expanding monocultures; and the monopolization of seeds, which is to say, of the genetic resources on which all of humanity depends.”⁸²¹ Given the tone of his article, Pollan expected that given the choice the public would follow the path of Europe and demand labelling of GE food.

⁸²⁰ Michael Pollan, “Vote for the Dinner Party: Is this the year that the food movement finally enters politics?”, *The New York Times* (10 October 2012) online: The New York Times <<http://www.nytimes.com/2012/10/14/magazine/why-californias-proposition-37-should-matter-to-anyone-who-cares-about-food.html>>.

⁸²¹ Ibid.

Proposition 37 represented the first time North American consumers were given a choice in the GE food labelling debate. Previously, voluntary labelling was the only alternative that was supported by the industry and the regulatory agencies in the U.S. On Election Day, November 6, 2012, Proposition 37 failed. The result was 53% opposed and 47% in favour. In an op-ed in the *New York Times* on November 7, 2012, Andrew Revkin stated that he was “glad that the sloppy, unscientific and protectionist initiative failed, but glad an important discussion of transparency in food sourcing has begun.”⁸²² Revkin noted that before the vote, the *Los Angeles Times* editorial recommended rejecting the initiative stating that, “What’s needed is a consistent, rational food policy, not a piecemeal approach based on individual groups’ pet concerns.”⁸²³

For this issue, the debate was not specifically about GE foods themselves but rather over the labelling of GE foods. It was a debate over the right to be informed about what consumers consume. The polarization of attitudes was extreme in this case, and one can only speculate how a debate over “Terminator Seeds” (V-GURT) would progress.

From the perspective of consumers, GURT can only add to the confusion around food safety. To this one can add the ethical issues associated with V-GURT. These include consumer attitudes to farmers’ rights to save seed and predictions that GURT will add to the loss of traditional knowledge by indigenous and local communities.⁸²⁴ Based on these concerns, one can be excused for suggesting that V-GURT will be a tough sell to consumers and the many NGOs that have already staked out a negative position on GURT. Some examples of NGOs opposed to GURT are Friends of the Earth, Consumer’s Union, Organic Consumers Association, Center for Food Safety, and EarthOpenSource.

So far most of the discussion of consumer attitudes towards GE seeds, crops and foods has focused on developed countries. How do developing world consumers view this subject and does it matter? First, yes it does matter, and the reason is that global food security is at its highest priority where it is at greatest risk; that is in the developing world. Furthermore, food security depends on the availability, access, utilization and stability of food. GE seeds, crops and food

⁸²² Andrew Revkin, “California Votes No on 37: Flawed Proposition on Food labeling”, *The New York Times* (7 November 2012) online: *The New York Times* < <http://dotearth.blogs.nytimes.com/2012/11/07/california-votes-no-on-37-flawed-proposition-on-food-labeling/>>.

⁸²³ Ibid.

⁸²⁴ *Supra* note 496 at 8.

already strongly affect three of these attributes of food security: availability, access and stability. GURT impacts these three attributes to an even greater extent because of its unique no seed saving characteristics. This latter attribute affects short-term food security by directly impacting the next season's crop and therefore food security. Since short-term food security is of more immediate concern in the developing world the acceptability of GE seeds or GURT seeds is of more immediate concern there.

The Agricultural and Development Economics Division of the FAO reported in "Public Attitudes towards Agricultural Biotechnology" (2004) that the Asian Food Information Centre Survey is the most useful survey assessing current public attitudes toward biotechnology in Asia. There is some reason to at least initially question the results of this survey since, as Lobbywatch notes on its website, AFIC is funded by 'the food, beverage and agriculture industries. Lobbywatch suggests there is a connection between the AFIC and the US-based International Food Information Council (IFIC), which also states on its website that it is "supported primarily by the food, beverage and agricultural industries."⁸²⁵ However, Lobbywatch does not necessarily enter this discussion as an unbiased observer. This organization identifies itself on its website as an offshoot of GMWatch, an organization that was established as an anti- GMO (anti-GE) advocacy group. The GMWatch website states that "GMWatch is an independent organization that seeks to counter the enormous corporate political power and propaganda of the GMO industry and its supporters."⁸²⁶

In spite of concerns by some over potential bias of AFIC, its survey was deemed sufficiently useful to be included in the "Public Attitudes towards Agricultural Biotechnology" paper developed for the Agricultural and Development Economics Division of the FAO. There are many similarities in the results of the AFIC Survey and the Environics, Pew, and Eurobarometer surveys. In 2002, the AFIC Survey interviewed 600 consumers in China, Indonesia, and the Philippines.

This survey found that the majority of consumers in Asia are aware of, but largely unconcerned by, GE-derived foods in their diets. Most consumers accept that they have eaten

⁸²⁵ *Profiles: Asian Food Information Centre*, (2015) online:>Lobbywatch.org<
<http://www.lobbywatch.org/profile1.asp?PrId=290>>.

⁸²⁶ *About GM Watch*, online: GM Watch < <http://gmwatch.org/about>>.

GE foods and do not attempt to avoid these foods.⁸²⁷

For 90% of Asians surveyed, nutrition and food safety (chemical residue and microbial contamination) are the greatest concerns. However, GE foods are of little concern and are seen as a source of potential benefits. Improved nutritional value, identified by 55% of respondents, and reduced cost, identified by 48%, are the most popular benefits that are associated with GE foods. Also, 66% of respondents report that during the next five years, food biotechnology will benefit their families.⁸²⁸

These results are very consistent with similar studies done in the US over the past five years according to the 2002 IFIC survey and the 2010 Eurobarometer survey where 53% agree that agricultural biotechnology will improve life over next 20 years.⁸²⁹

The AFIC Survey reveals that the mass media is the preferred source of consumer information on biotechnology, food safety and nutrition. Government agencies and other public sector sources are less popular as sources of information. This lack of confidence in public information sources is in sharp contrast to the positive attitude toward these information sources in the U.S. and EU as indicated in the 2015 Pew survey and the 2010 Eurobarometer survey. This lack of confidence is troublesome since it is government agencies that are responsible for both policy development and the implementation of a regulatory environment that both protects the public and supports the promotion of innovation. Beyond information, however, public sector bodies are seen in the AFIC Survey as trustworthy protectors of health and safety.⁸³⁰ This does seem somewhat contradictory.

Unlike EU respondents in the Eurobarometer survey, AFIC Survey respondents do not look for biotechnology information on food labels. These respondents are concerned with expiration date, ingredients, and nutritional information. Biotechnology is not named as an information item that these consumers wish to see on their food labels.⁸³¹ Although Asian consumers, like most consumers, have little knowledge about the workings of biotechnology,

⁸²⁷ Supra note 781 at 5.

⁸²⁸ Ibid.

⁸²⁹ Supra note 813.

⁸³⁰ Supra note 781 at 5.

⁸³¹ Ibid.

they are aware and accept that approved biotechnology foods are widely available.⁸³²

The more relaxed attitude of Asian consumers toward agricultural biotechnology indicated by the AFIC Survey suggests that GURT would also face less resistance in Asia than in the U.S. and most certainly than that in the EU.

The FAO “Public Attitudes towards Agricultural Biotechnology” paper concludes that “consumer attitudes towards biotechnology”... [vary]... “across and within countries”... [and stresses that]... “comparisons of results from different studies must be made with caution, because of the sensitivity of such studies to the particular circumstances surrounding their design and administration.”⁸³³

The FAO paper highlights the fact that the studies reviewed for the United States, Europe and Asia confirm the somewhat dated internationally comparable Environics International studies. The Environics International studies show that, in general, consumers in the United States and Asia value the benefits that biotechnology offers the food sector more than Europeans.⁸³⁴ Many consumers in all countries value the benefits that these technologies provide regarding choice, quality and safety of foods.⁸³⁵

Interestingly, the surveys identified in the FAO paper also indicate that technical knowledge is not a prerequisite for consumer acceptance. What is essential for consumer acceptance is the clear communication of actual, as opposed to theoretical, risks and benefits associated with foods that incorporate GE products.⁸³⁶

⁸³² Ibid.

⁸³³ Ibid at 7.

⁸³⁴ Ibid.

⁸³⁵ Ibid.

⁸³⁶ Ibid at 6.

Chapter 7

Evaluation and Conclusion

7.0 Innovation Protection: Patents and GURT

Referring to the specific questions that were posed to assess the innovation protective capacity of patents as they pertain to GE seeds:

Do patents exclude those, other than the inventor, from making the invention?

This question must be answered for both rival firms and the farmer end user. From a theoretical perspective, the answer is yes, patents *legally* exclude other biotechnology/seed companies and end users [farmers] from making the invention. Patents are an effective method of protecting innovation in developed nations with a well-established and strong IP environment. The effectiveness of this method of innovation protection in a business setting is very much as it would be for any other invention. The degree of legal protection within the agricultural industry is robust, especially in jurisdictions such as North America and Europe where the IP regime supports this protection. For the most part, both industry rivals and end users adhere to the law. Inventors of GE seeds have effective legal recourse to protect their IP.

However, under this patent paradigm, non-GURT GE seeds can be “made” by farmers through the normal course of using the invention as intended. Farmers growing the GE seed into a GE plant and harvesting the resulting seeds for food is the intended use of the GE seed. It is at the point of harvest where problems arise for the GE seed firm if there is an illegal intention, on the part of the end user, to use those seeds for planting. Technically, this process can be repeated endlessly. However, because the resulting GE seed is an identical copy of the original GE seed, courts have concluded that progeny seeds are also patent-protected.

The research provided in this thesis highlights significant weaknesses of the utility patent as a form of innovation protection for GE seeds. The *Schmeisser*, *Bowman* and *OSGATA* cases demonstrate this problem at the individual domestic farmer level. The *Argentina* case focuses on the same problem at the international farmer level and reveals that patented-only GE seed

protection can evolve from an individual farmer issue into an industry-wide issue with considerable domestic and international market failure repercussions.

Here the patent lesson is that patents can legally exclude others from making or copying the invention. However, the patent cannot physically prevent a farmer from easily reproducing the GE seed invention in the course of using the product as intended and then illegally acquiring all of its benefits.

Do patents exclude those, other than the inventor, from using the invention?

The only parties who use GE seeds in such a manner as to take advantage of the value-added traits that are the basis for patenting this invention are farmers. Because GE seeds are patented, GE seed firms can successfully insist that farmers sign a contract to be allowed to use the seeds. An example of this contract is the previously discussed Monsanto TSA. Here again, the degree to which farmers are willing to obey the law determines the effectiveness of the patent in preventing the unauthorized use of the product.

In jurisdictions such as North America and Europe where law enforcement is rigorous, and penalties for non-compliance are arguably fairly applied, the problem of legally excluding unauthorized individuals from using the product is limited. However, there is an issue for GE seed firms in developing countries where the laws or their enforcement are lax or there are international agreements (e.g. TRIPS) that offer users a legal workaround to avoid patent enforcement. There is no cost effective manner in which GE seed firms can either monitor or enforce patent compliance in weak IP environments where millions of farmers can easily and cheaply use GE seeds illegally if they so wish.

Do patents exclude those, other than the inventor, from selling the invention?

Farmers primarily sell seeds as food and occasionally in some circumstances to be planted for the creation of a new crop. Patents erect a legal obstacle to the sale of GE seeds as a source of initial or subsequent crop planting. This is clearly outlined in the Monsanto TSA, which is representative of the industry. Selling patented GE seeds as food is not prohibited,

controlled, or regulated differently than is the selling of the non-patented non-GE product. That is, the existence of a patent is not a factor in determining whether a GE seed can be sold for food.

Both the GE seed patent and the TSA legally prevent farmers from selling GE seeds from their harvested crops for the purpose of planting subsequent crops. This is a legal restriction, which is again most enforceable in a strong IP environment. The Argentina case, where Brazilian farmers illegally purchased and used legal, unpatented, Monsanto GE seed from across the border in Argentina, clearly demonstrates the weakness of patent protection in weaker IP environments. The Argentina case also exhibits the degree to which a patenting error by a firm can be magnified to create a massive value capture disaster for the firm. In this case, what should have been patented GE seeds were legally sold for planting within Argentina by those who would otherwise have been legally restricted from doing so had the seeds been patented in a timely manner.

The outcome of the Bowman case is also instructive with respect to using or selling the GE seed invention. By unanimously concluding that the exhaustion principle does not apply to GE seeds, the U.S. Supreme Court acknowledged that not only can a farmer not sell second-generation GE seeds to another for use as planting seed, but also that the farmer could not use the seed himself for that purpose. That is, seed saving of patented seeds is not allowed even though, historically, this is a “traditional” farming practice.

How then does a GE seed firm determine that its patented seed is not being illegally used? The cases of patent infringement cited earlier all depend on the monitoring of farmers’ fields by GE seed firms to protect the patent. In a strong IP environment, the monitoring of crops by GE seed firms or their agents is an effective although costly method of protecting firm IP. In a weak IP environment that often exists in the developing world, this requirement becomes not only a practical impossibility but also a wasted effort leading to the potential for significant loss of value capture by the GE seed firms.

However, the question in the strong IP environments of developed countries is how much monitoring is enough and at what cost. It is obviously not practical to monitor all fields. As such, for GE seed firms, a law-abiding farmer is the best source of innovation protection not only from the perspective of his/her behaviour but also as a source of information about the actions of other

farmers. Yes, GE seed companies do depend on farmers to inform on other farmers. Companies, such as Monsanto, frame this as a method of preventing “free riding”⁸³⁷ by some farmers at the expense of others. According to the Monsanto web site, law-abiding farmers are protecting the level playing field on which all farmers depend to be competitive. Some might consider this position by a GE seed firm to be little more than self-serving rationalization.

Unfortunately, for GE seed firms the effectiveness of the patent is dependent to a large degree on the cooperation of the user of the product. While this is the case with many patented products, a self-replicating product such as a GE seed magnifies the problem by creating a unique patent-stressing situation.

Patents provide effective legal protection against appropriation in jurisdictions where the rule of law is part of the “DNA” of the society. Otherwise, patents are at best only partially effective. Patent monitoring is costly in developed countries and more so if attempted in developing countries because of the vast number of small farmers, many of who may live in remote areas. Monsanto’s ongoing public relations challenges that arise from their farmer field monitoring activities demonstrate that patent protection has more than a short-term financial cost. There is also a long-term reputational cost that can lead to a long-term financial cost.

The many online websites that deal with the criticism of GE seeds invariably excoriate Monsanto for abusing small farmers by surreptitiously monitoring their fields. The truth of the covert monitoring allegations is debatable, as no amount of contrary evidence appears to sway either side. As the online debate demonstrates, the damage to Monsanto’s reputation created by this David and Goliath confrontation is challenging to overcome.

The same questions that assess the protective capacity of patent-only non-GURT GE seeds apply to GURT GE seeds. Referring to the specific questions that were posed to assess the innovation protective capacity of GURTS:

Will/can GURT exclude those, other than the inventor, from making or using the invention?

At the farmer level, the relevance of GURT as a GE seed innovation protection mechanism is directly related to the control that GURT gives the innovator over the farmers’

⁸³⁷ Free riding in this context refers to farmers using GE seed for the purpose of acquiring the GE value-added attributes without paying for the right to do so.

ability to make the invention [i.e. subsequent generations of GE seed]. Currently, GURT GE seeds are patented just as any other GE seed so that from the perspective of industry rivals, there is no difference in the legal protection required or the legal protection achieved. This is the case for both V-GURT and T-GURT GE seeds.

Unlike GE seeds without restriction technology, second generation seeds that are a result of V-GURT and T-GURT cannot be used for planting a new crop of GE plants, or at least one that has active value-added traits, unless the GE seed firms allow this to occur. The seeds either will not grow (as is the case with V-GURT) or they will grow but without exhibiting the desired value-added GE trait(s) (as is the case with T-GURT). Farmers using GURT will only be able to use it as intended by the GE seed firm; that is, as seed to be sold for food or in the case of T-GURT as seed to be sold as food or planted as a conventional non-GE crop if planted without the use of the inducer.

One fundamental weakness of T-GURT, the requirement for an inducer, is also one of its strengths. That inducer gives access to the value-added trait(s) if applied by the GE seed firm at a time and in an amount that has been determined by the seed firm. The weakness of T-GURT is that the inducer may be patented. If it meets the requirements for patenting and it is, in fact, patented then disclosure is required. This creates a potential for an unscrupulous individual to violate the patent and defeat the restriction technology built into the T-GURT seed. Alternatively, the inventor can maintain the inducer process as a trade secret, in which case if it is a well-kept secret, the technological protection built into the T-GURT is highly effective.

So, GURT has the potential to exclude those, other than the inventor, from using the invention under the right circumstances for T-GURT or under any circumstances for V-GURT.

Will/can GURT exclude those, other than the inventor, from selling the invention?

In the case of V-GURT, the seed company has physical control of the initial product and, therefore, can control to whom that product is sold and when. After that, the originally sold V-GURT seeds can be used for planting by the original purchaser. In this case, the seed firm has captured value from the original sale, and the product will be used as intended because the second-generation seeds are sterile and can only be used as food. One other possibility is that the

original purchaser of the V-GURT seed may wish to sell the seed to another farmer for planting. This could be disallowed in a company TSA signed by the original purchaser. Even if disallowed and the original purchaser illegally sells the seed to another grower, there is no danger of growing this crop illegally with the intention of producing copies of the original seeds since those copies would be sterile.

The case of T-GURT seeds is somewhat different. Again, the seed firm controls the initial product and the specifics of inducer application. Also, the initial sale can proceed just as it would with V-GURT seeds. However, the second-generation seeds will contain inactive value-added traits. If these seeds are sold for planting, they will produce a crop that does not display the value-added traits unless an inducer is properly applied at the appropriate time in the plant life cycle. As a result, there is again no loss of value capture for the seed firm.

GURT offers effective physical and technological protection that is currently supplemented by legal protection, which is secondary to the inherent technological protection. There are three types of protection required for GURT to be successful in their IP protective function: first, protection for the desired GE trait; second, protection of the GURT process; third, protection of the inducer technology. The first one, GE trait protection, is relevant to both seed firm rivals and farmers. Legal protection through patenting takes care of IP issues with the seed firm's rivals. Restriction technology protection takes care of the primary issue of farmer-saved seed. The second protection, GURT process protection, is only relevant to the seed firms since there is a high R&D and capital requirement cost to access this technology from first principles. Legal protection and high capital requirements take care of most of this issue. The third protection, inducer technology protection, is again relevant to both seed firms and farmers. Again legal protection adequately deals with the seed firms that must operate in strong IP environments. However, if the inducer is patented, there is a weak link at the farmer level since patent disclosure is required. It is technically possible that an unscrupulous firm, individual, or farmer can illegally overcome this protection unless the inducer application must occur at a time or by a method that is under the secure control of the GE seed firm.

Ultimately, GURT protection is primarily focused on the end users of GE seeds as opposed to industry rivals that may copy the invention. The invention that GURT strives to

protect is not the GURT itself but rather the value-added traits within the GE seeds that are in demand by farmers. Patents simply cannot match the physical and technological protection that is intrinsic to GURT. The legal protection offered by patents requires monitoring and enforcement and the cooperation of the farmer. GURT virtually eliminates the need for farmer cooperation in IP protection. The entire protective mechanism is in the hands of the inventor if the GURT is designed to maximize its protective capacity. Monitoring and enforcement by third parties is not required and this makes the protective power of GURT superior to patents from an enforcement perspective.

In summary, GURT has the potential to provide superior IP protection to that of patents in any IP environment. However, this GE seed firm benefit is greatest in developing countries where these firms currently have the least effective IP protection. This is protection that benefits seed firms directly by maximizing value capture with minimal requirement for monitoring and enforcement. At the same time, this superior IP protection has no obvious direct value to other stakeholders.

7.1 Innovation Promotion: Patents and GURT

Referring to the specific questions that were posed to assess the innovation promotion capacity of patents and GURT:

1) How does the legal protection of GE seeds, represented by the patent, compare to the technological protection of GE seeds, represented by GURT, when it comes to encouraging PRIVATE sector R&D?

In looking at this question, it is clear that the level at which agricultural biotechnology firms invest in R&D is correlated to the level of patent protection available for codifiable knowledge. It is also intuitive that this should be the case. Patents provide a legal means of R&D investment protection for firms. Data from international organizations such as the OECD shows that there is a high degree of private investment in agricultural biotechnology in strong IP jurisdictions and that private investment is limited where this protection is weak.

It is not surprising then that the patenting of agricultural biotechnology does, in fact, increase firm R&D expenditures for two important reasons. First, as noted, the IP protection that

patents provide encourages GE seed firms to invest in new products knowing that the products that result from their investments will be protected. Second, there is the patenting disclosure requirement that provides access to fundamental knowledge for those who would take the next inventive step. This latter patent feature is tempered somewhat by the protection that patents may offer to fundamental processes that are needed to advance research and which may be unavailable due to the patenting of those processes.

GURT provides a greater level of IP protection because that protection is technological as well as legal. However, GURT's IP protective capacity is not dependent on the degree to which the *user* of the product is willing to observe the legal status of the product. As a result, one might assume that, if an increased protective capacity is a significant driving force for innovation, as is suggested for patents, GURT should increase firm R&D expenditures to a greater extent than occurs with patents.

To date GURT does not exist as a commercial product and, therefore, whether GURT would increase R&D beyond that which occurs with patents requires an indirect approach. The history of the technological protection built into hybrid corn provides the closest approximation to GURT.

The research in this thesis shows that the technological protective capacity of hybrid corn and the dramatically improved traits of this hybrid strongly correlate with increased R&D in this specific crop. Furthermore, this correlation is unrelated to the IP environment. The high level of R&D in hybrid corn over a period of over seventy years and its extensive international commercialization and profitability for seed firms is a solid indicator of enhanced innovation promotion in agricultural biotechnology that hybrid corn has encouraged.

There are both positive and negative ways in which GURT can potentially alter R&D. First, GURT can increase R&D in mechanisms for control over gene expression. This includes not only IP protection issues but also specific value-added traits that impact nutritional content; drought resistance and temperature sensitivity; pharmaceutical application; and a virtually endless stream of other possibilities. Second, GURT can promote GURT R&D in weak IP environments by protecting the outcomes of that research.

2) How does the legal protection of GE seed IP, represented by the patent, compare to the potential technological protection of GE seed IP, represented by GURT, when it comes to encouraging PUBLIC sector R&D?

Patents can and do affect the public sector and its willingness to promote innovation through R&D expenditures. One reason that the public sector patents inventions is to allow for cooperative agreements with the private sector where the private sector licenses inventions for commercialization from the public sector. However, there are reasons other than short-term profit that encourages R&D investment in the public sector. One major goal of public sector R&D as revealed by numerous OECD documents is national economic development through industry support.

If one can demonstrate the ability of GURT to realize benefits that are of specific value to the public sector, then GURT should encourage an increase in R&D in the public sector to further these goals. Two particular areas where GURT has unique potential is environmental protection and food security. The potential ability to control the unintended spread of transgenes addresses one of the major concerns of non-GURT GE seed opponents. In addition, the potential to increase food security through the use of T-GURT to turn on and off genetic traits to manage crop life cycles more accurately to match existing environmental conditions can increase crop yield.

However, because of the high cost of GURT development, this area of R&D is likely to continue to exist primarily in the private sector in the developed world and in two key developing world nations, China and India. These two countries were previously identified as high growth areas with increasing public R&D environments.

The public sector is familiar with the established process of R&D that leads to licensing agreements with private firms that then further develop and commercialize products. As R&D costs associated with high technology products continue to rise, the limited budgets of governments will be hard pressed to maintain R&D at levels required to meet the demand for these new technologies. As indicated earlier, public sector R&D has been on the decline due to the many demands on public sector resources and at this time there is no reason to believe that this trend will be altered in the future.

3) How do patents compare to GURT when it comes to the creation and diffusion of fundamental knowledge?

Arguably, patents are notorious for hindering the diffusion of some types of fundamental knowledge often by restricting the availability of invented processes that if available would enable further scientific investigations. However, patents have always been an agreement between society and the inventor whereby society provides a time-limited monopoly to the inventor to recoup his investment. In return, the inventor provides full disclosure so that society may ultimately benefit from this invention by allowing others to use the knowledge made available from invention disclosure to take the next inventive step. On the other hand, by protecting some inventions involving processes, patents can be a hindrance to the diffusion of fundamental knowledge if this protection restricts the ability to use patented processes that are needed to take the next inventive step.

Currently, firms commercializing non-GURT GE seeds will patent those seeds. This requires that the invention details must be disclosed in the patent. As such, from this perspective, GURT and non-GURT GE seeds are equivalent from a knowledge diffusion perspective.

However, because of the built in technological protection inherent to GURT, it is possible that GE seed firms may find it beneficial to not patent this technology in the future. The dynamic nature of this field could convince GE seed firms that the lead time that results from not patenting the technology would be sufficient to recover costs and profits before the next iteration of the product occurs.

If this were the case, then GURT would be a detriment to the disclosure of the GE seed inventions. The result would be that fundamental knowledge would not be available for others to build upon in the short or long term. Furthermore, GURT technology even with the application of a time limiting patent would result in an endless monopoly from the farmers' perspective.

Patent expiration for a GURT product is all well and good at the firm level where patent expiration results in rival firms entering the market to produce GURT seeds using the previously patented technology. However, patent expiration does not help the farmer. For the farmer, the unlimited monopoly would remain since the control (viability) of the seeds is still in the hands of

the seed firms. That is, the technological control of the seeds remains in the hands of the seed firms.

4) How do patents compare to GURT when it comes to promoting innovation through the commercialization of GE seeds?

The research in this thesis indicates that the commercialization growth rate of GE seeds has been significant since their introduction in 1995/1996. The question one may ask is, why? The obvious reason is that there is demand for the product because the benefits that farmers see in the GE traits outweigh the added costs associated with their use. If GE seeds were free for anyone to use, there is clear evidence that there would be even greater use. The willingness of farmers such as Schmieser, Bowman and many others to flout the law to access freely GE seed technology clearly demonstrates the value of this technology to farmers. This is also highlighted by the Argentina case where Monsanto's GE seeds were not patented and their cost-free use exploded in that country.

However, without the patent, these GE seeds would not likely be commercialized to the degree that they are since there would be no incentive for the private sector to invest the vast resources needed to develop them. Furthermore, the innovation promotion that results from this commercialization and the firm profits that it produces would also be significantly reduced.

As has been described earlier in this thesis, one method of evaluating this question of commercialization is to ask those executives tasked with the responsibilities of making these decisions to provide an opinion based on a given scenario. As previously noted, the executives questioned are all quite clear in stating that appropriability is the key to commercialization, and they strongly suggest that it is patents that allow for this to occur.

The research clearly shows that commercialization is greatest in developed countries with strong IP environments. Here patenting provides sufficient legal protection to allow firms to confidently commercialize inventions knowing that they will at least have legal recourse should their legal rights be threatened. Certainly one other major reason for this commercialization in the developed world is that it is profitable. The trend toward increased use of GE seeds in the developing world indicates that there is significant profit potential there as well. While

commercialization in the developed world is legally protected, the developing world currently makes commercialization a riskier prospect since the legal protection is often questionable. This certainly also makes the value capture potential of the invention questionable and the high cost of commercialization a risky undertaking.

Can GURT increase the level of overall GE seed commercialization taking place based on its highly protected characteristics? One must look at the costs and benefits of GURT and make assumptions based on the successful commercialization of existing technologies such as hybrid corn to make these innovation promotion determinations.

There is also the question of limited R&D resources. If R&D focuses on developing GURT in the hopes that the technology will be approved for commercialization, then GURT may reduce the overall level of GE seed commercialization, at least in the short term, by absorbing limited resources from other areas. GE seed firms would not be faulted by shareholders for a business decision to invest in a technology that maximizes company profits.

A larger concern for commercialization success is the degree to which farmers will accept GURT seeds over traditional patented GE seeds. The potential for this acceptance is high if hybrid corn is any indication. Farmers worldwide look for seeds that are productive and easy to use. If farmers find the traits and the ability to turn them on or off beneficial and also determine that these benefits offset the cost of GURT, then commercialization of GURT can be highly successful. As a result of this successful commercialization, the potential for increased GE seed firm profitability should encourage additional innovation in this technology.

The qualitative answer for each of these innovation promotion questions is that a good case can be made that GURT will promote innovation at least at the same level as patents if the moratorium on commercialization is lifted. In fact, it is likely that as GE seed firms stress value capture, the commercialization of GURT-based GE seeds would be private industry's preferred solution to their value capture problem in the developing world.

In the developing world, the answer to the innovation promotion question is highly speculative. One can surmise that the protective capacity of commercialized GURT over that of patents would not lessen the potential for innovation promotion. One possibility in the

developing world is that GE seed firms would redirect innovation promotion to GURT at the expense of non-GURT GE seeds.

At this point two things are clear. First, innovation protection based on GURT is far superior to that of non-GURT patented GE seeds. This is a feature of GURT that primarily benefits the GE seed companies. Second, the innovation promotion differences between the two alternatives are speculative because only non-GURT GE seeds have a track record that can be assessed. GURT seeds depend on the hybrid corn track record or speculation to make their case for innovation promotion. While the hybrid corn model is convincing, it is based on a historical framework that no longer exists.

7.2 Viability: Patents v GURT

There are two primary GURT attributes that differentiate these seeds from non-GURT GE seeds. The first is that V-GURT seeds produce sterile second-generation seeds. The second is that T-GURT GE attributes can be turned on or off with the use of an inducer. Other than these two attributes, all other GURT attributes also exist in non-GURT GE seeds. The capacity of T-GURT seeds to *dynamically* adapt or be adapted to environmental conditions does offer the potential for greater food availability and stability. However, this advantage is limited to T-GURT seeds and not V-GURT seeds. T-GURT seeds have an added advantage particularly useful in the developing world. That is that farmers could save T-GURT seeds to grow a non-enhanced crop by using a seed with an inactivated or non-activated value-added trait. In contrast, although farmers could technically save non-GURT GE seeds to grow a value added crop, doing so would be illegal in cases where the seed patent was in effect.

In developed countries, there is little real prospect of increasing the availability aspect of food security using GURT seeds. In developed countries, non-GURT GE seeds are successfully addressing the availability issues. Some stability enhancements are possible as T-GURT allows for selective environmental activation or deactivation of traits that could improve yield.

Access issues are another matter. Patents provide a time-limited, legal, society-backed monopoly with all the features that accompany a monopoly such as higher prices combined with lower product quantities than would occur at competitive equilibrium. From a food access point of view, such a monopoly initially decreases access to food by increasing the resources required

to acquire that food; that is the price. This is more of an issue in the developing world where access to food can be tenuous. Access is less of an issue in the developed world where food is abundant, and there are often programs to help those who have food access issues.

Under the current regulatory environment, GURT could also decrease food access because the technology would infinitely lengthen the monopoly period for these unique GE seeds. This has the potential to lead to higher prices for longer periods of time. This would be an issue in both developed and developing countries, but the impact on the latter would be more severe. On the other hand, the development of a highly competitive environment in GURT seeds could decrease the price.

Environmentally, biosecurity can be improved by V-GURTS or T-GURTS that limit the negative environmental issues that are possible with non-GURT GE seeds such as the inadvertent spread of transgenes. The prevention or at least the limitation of the transgene spread is one area where GURT seeds are dramatically superior to non-GURT GE seeds. This quality is specifically related to V-GURT and the benefit is broad in that it can be advantageous for both farmers and the environment.

This same GURT advantage does not apply to biodiversity. Biodiversity issues, as they influence the choice between GURT and non-GURT GE seeds, are not a deciding factor since biodiversity is not a genetic engineering issue as much as it is a breeding issue. Traditional breeding has been the major source of alterations in biodiversity as farmers have manipulated crops for their best advantage for hundreds of years. Most crops have been developed for uniformity. GURT and non-GURT GE seeds do not change this dynamic; they simply continue it.

From a human or animal health perspective, there is no evidence that one alternative is superior to the other. To date, there is no scientific evidence that non-GURT GE seeds have negative human health effects. There is no basis to consider GURT GE seeds to be different in this respect since these seeds are simply another type of GE seed. One potential concern is that there might be issues with the inducer chemical that is specific to T-GURT seeds. However, like any other chemicals used in agriculture, they would undergo testing to maximize safety.

From an industry standpoint, the IP protective capacity of GURT is a major economic benefit. Economic well being of GE seed firms can be enhanced by the technological protection that GURT seeds provide. The long-lasting ability to capture value from the sale of GURT seeds to farmers increases the potential profitability of GURT seeds far beyond what is possible with non-GURT seeds.

GURT seeds can also alter industry structure by encouraging an increase in the level of horizontal and vertical integration that has been an ongoing feature of this industry. One reason for this alteration in industry structure would be the increased need for control of complementary products such as inducer chemicals to enhance value capture from T-GURT seeds. In addition, the more complex technology represented by GURT may raise the cost of R&D, putting it beyond the capacity of smaller firms. GURT would alter industry structure in a way that would encourage the restriction of new entrants in this market further increasing the profitability of existing players.

The economic well being of the industry also depends on whether farmers and consumers will accept GURT seeds? Acceptance by these two stakeholders is a delicate situation. If consumers are not willing to accept the new GURT technology, farmers will be hard-pressed to justify using it for their crops. So, whether farmers use this technology is dependent on more than simply the farming issues associated with it. If farmers refuse the new technology, firms will not supply it. The consumer surveys indicating what consumers “believe” about this GE seed technology should not provide industry or farmers with any confidence that GURT promotion will be free of controversy.

Both GURT and non-GURT GE seeds are ideal for a formal seed system that is subject to high-intensity farming. GURT seeds can only be accommodated in a formal seed system because they are subject to absolute industry control. This makes GURT ideal for farming in the developed world or in the more affluent parts of the developing world where formal seed systems are cost effective. In the developed and developing worlds, it is the physical attributes of GURT that fit the formal seed system so well. In both instances, GURT can only be used with the cooperation of the innovator. While designed for the formal seed system, non-GURT GE seeds can be used in the informal seed system both legally and illegally. However, in this case,

the legal use is not based on these non-GURT GE seeds being patent protected. Rather, non-GURT GE seeds are grown in the same way as non-GE seeds. That is, their use in the informal seed system is based on exemptions to patent protection provided by international agreements.

It is in the area of policy and regulation that GURT can begin to have significant negative repercussions unless some changes are made both nationally and internationally. The two key areas that would need to be addressed are the endless monopoly that the technology would give to GURT seeds and the potential lack of disclosure if these seeds were not patented. The former has obvious anti-trust and competition issues associated with it, and the latter has negative implications from the loss of societal benefit that can result from a lack of knowledge disclosure that is, in contrast, inherent to much of the patenting regime. Furthermore, GURT can weaken or alter a government's ability to use existing regulations as policy instruments since these existing regulations were simply not designed to deal with self-protecting IP. The policy control that patenting currently gives to governments is not present with GURT.

Well-established national and international organizations exist that assess, regulate, modify, and manage IP associated with the genetic engineering of agricultural seeds. At the national level, organizations such as the United States Patent Office (USPO) and the European Patent Office (EPO) play a crucial role in patent evolution to meet the challenges of the new biotechnologies. Internationally, WIPO, the OECD and other organizations play a similar policy development role. Again, the self-protective nature of GURT can diminish the influence of these organizations on the policy development and regulatory landscapes.

So, from a policy and regulation perspective, how does the viability of GURT compare to non-GURT GE seeds? The question comes down to whether governments are willing to give up some control over innovation and known societal benefits associated with the current patent model in exchange for gains in some benefits such as a potential increase in certain aspects of global food security or biosecurity. However, the answer to the overall viability issue may be based on the final viability concern; that is consumer acceptance of GURT.

It is evident from the vast amount of Internet-based information available on the subject of GE seeds, crops and foods that there is a large segment of the population that is fearful of genetic engineering. It may be that no matter what positive attributes GURT has for various

stakeholders, the fact that they are based on genetic engineering is sufficient to create public resistance to the technology.

One point is abundantly clear. There is no identified practical or scientific difference between the *food* resulting from non-GURT or GURT GE seeds; they both produce food from GE seeds. However, for some consumers, there may be uncomfortable ethical issues associated with GURT seeds that do not exist with non-GURT seeds. For example, V-GURT will produce sterile seeds, which some individuals perceive as unnatural or unethical. Also, GURT GE seed usage by farmers subjects them to economic control by GE seed firms to an even greater extent than is the case for non-GURT GE seeds. If some consumers place a great deal of importance on the economic and social well being of farmers, then the difference between these two types of GE seeds might be relevant for them.

Some experts have already staked a clear position on the ethics of the sterility issue. One widely disseminated publication is revealed in a 2001 FAO paper, “Report of the Panel of Eminent Experts on Ethics in Food and Agriculture.” In this report, the Panel was unanimous in its conclusion that “terminator seeds” are, “generally unethical, as it is deemed unacceptable to market seeds whose offspring a farmer cannot use again because the seeds do not germinate.”⁸³⁸ The Panel notes that GURT is not a fundamental requirement for success in the genetic engineering of crops, and by making this qualification they seem to be suggesting that it is not genetic engineering itself that is unethical but rather GURT that they consider to be so.

A fundamentally negative attitude by consumers towards the V-GURT sterility attribute may be the issue that determines consumers’ overall attitudes to GURT. Consumers may also be concerned that farmers will have no option to save V-GURT seeds notwithstanding the opportunities that international agreements such as TRIPS offer to national governments to tailor their IP regimes to local requirements.

Then again, consumers may be supportive of the improved restriction on the spread of transgenes intrinsic to V-GURT. This farmer complaint is one that has been taken up by farmer

⁸³⁸ UNFAO, *Report of the Panel of Eminent Experts on Ethics in Food and Agriculture: Biotechnology, Including Genetically Modified Organisms* (Rome: UNFAO Information Division, 2001), online: UNFAO<<ftp://ftp.fao.org/docrep/fao/003/x9600e/x9600e00.pdf>>12_at 14.

advocacy groups, environmental groups and specifically the vast array of anti-Monsanto special interest groups that number in the dozens if not hundreds.

If consumers are emotionally and/or ethically opposed to GE crops or the companies responsible for them or if they do not trust the scientific consensus that GE crops and foods are safe and beneficial, then they will likely avoid those “contaminated” GE crops and foods whether they are GURT or non-GURT.

The strong monopoly that GURT potentially offers to GE seed firms is yet another source of possible concern for consumers. The power this gives to the GE seed firms combined with the lack of societal benefits that may result should GURT seeds not be patented in the future, can be important negative issues in the eyes of consumers.

Unfortunately, high-quality public surveys of any significance have not been found that ask serious questions about GURT. This could be because the complexity of the issues with this subset of GE biotechnology is simply too difficult for the general public to grasp at this early stage of development. Or it could be that it is simply not useful to survey opinions on a non-commercial product with consequences that cannot be evaluated to the degree that some would consider necessary to answer survey questions.

Based on what is known to date, it can be expected that because T-GURT seeds are also GE, consumer resistance to them would be broadly the same as that for V-GURT seeds or patented-only non-GURT GE seeds. However, inactive T-GURT seeds would be the equivalent of non-GE seeds since they would grow as normal non-GE crops. The DNA manipulation exists but is inactive. This means that the proteins produced by the added trait genes that are the basis for the attributes designed into the technology would not be produced. This concept was described earlier with the analogy to the computer algorithm that bypasses inactive code.

One might surmise that anti-GE food consumers would potentially accept this type of T-GURT seed. However, the fact that DNA manipulation has occurred, active or not, could be a deciding factor for the avoidance of this product by diehard anti-GE consumers or those who could be swayed that this is an important issue. If this were the case, consumer avoidance of this product, because of perceived health and safety concerns, would be a decision with a non-scientific basis but one that a scientifically challenged public might find reasonable.

Consumers might ethically support the fact that farmers can grow inactivated T-GURT seeds and produce a basic non-GE crop. Although the farmers would not be able to access the high-value traits such as increased yield or drought resistance, they could still grow a saved-seed crop; there is no appropriation of IP rights by farmers in this case. A segment of consumers may be satisfied that farmers may prefer T-GURTS to V-GURTS.

In the end, if the public does not accept the desirability of existing GE seeds, it is unlikely that they will accept GURT seeds that are essentially GE seeds with added attributes that increase industry control of the product through a dramatic escalation of human interference in plant DNA structure and function.

Although the degree of acceptance of GE crops can vary whether the concerned individual is a farmer, environmentalist, regulator, policy maker or consumer, it is the consumer who ultimately determines the commercial success or failure of a product. So, it is a question of what the consumer “believes” about GE food and the seeds that produce it that is the key issue. If current attitudes toward GE food are any indication, this will vary by region (U.S. and Canada; EU; Asia) making the commercialization of GURT seeds an uphill battle in some regions.

From an IP perspective, it is not known whether the public would prefer the patent regime for IP protection over technological IP protection although the extended monopoly potential of GURT is not something that seed firms would find as a selling point for consumers. Policy-makers and governments may have strong opinions on this issue but those opinions are often reflections of public opinion. Regulators also often have opinions that not only reflect public opinion but also may be influenced by the industry that they regulate. Knowledge in this industry is highly specialized and complex and the addition of industry representatives to regulatory bodies can add expertise but can also result in regulatory capture.

7.3 Is GURT a Viable Alternative?

Currently, patents provide a superior level of innovation promotion since the promotion of innovation is highly dependent on the diffusion of knowledge that invention disclosure mandates. This knowledge diffusion capacity does not exist in the pure, non-patented GURT model. One possible solution that would solve this GURT knowledge diffusion deficiency is to make the commercialization of GURT dependent on a regulatory requirement that the underlying

invention(s) must be patented. This will not only encourage knowledge diffusion but also will support other societal benefits. One of these important benefits is the prevention of an infinite monopoly that an unpatented GURT GE seed would allow. This is a solution that can work well in developed countries where the rule of law is well established. Unfortunately, unless there is a method of permanently unlocking the GURT protection at the end of the monopoly period or specific agreements are made with the patent holders to do so, farmers will still be subject to the infinite monopoly.

The situation for developing countries is more complex. The increased difficulty in farm monitoring and the various IP regimes in conjunction with legal systems of varying abilities to protect IP would likely make the use of non-patented GURT a better choice than patents for innovation protection at the firm level. Once again, at the more important farmer level, GURT offers GE seed firms ideal protection whether patented or not.

While innovation protection associated with GURT is obvious, there is no definitive way to demonstrate that GURT would provide superior innovation promotion, especially in developing countries. Patented GURT may simply provide a more secure means of value capture for multinational seed firms with no guaranteed return on innovation for developing countries. Non-patented GURT could encourage the large GE seed firms to increase investment in R&D in developing countries since there would be no disclosure requirement and, therefore, no risk of value appropriation by rival firms in those countries.

It is abundantly clear that GURT is the best alternative for innovation protection at the farmer level where the threat of value leakage is the greatest and that this feature of GURT is most important for GE seed firms in developing countries where weak IP environments are most common. It is also clear that innovation promotion is greatest where value capture by the innovator, knowledge diffusion and the ability to commercialize is maximized.

From a purely innovation protection and promotion perspective one can draw three useful conclusions. First, GURT (patented or non-patented) is far superior to patented only GE seeds in protecting innovation. Second, GURT is superior in promoting innovation through maximizing value capture and thereby encouraging R&D expenditures. Third, patented only GE seeds or patented GURT are equally effective in promoting innovation by encouraging the diffusion of

knowledge through the disclosure requirements of patenting. Non-patented GURT is less effective at promoting innovation than either patented non-GURT GE seeds or patented GURT seeds since no disclosure is required.

From the perspective of innovation promotion, there is nothing to indicate that the level of innovation promotion that springs from patented GE seeds would be substantially different than that which would result from GURT. However, research shows that the potential for greater R&D in the developing world exists if firms can improve IP protection. The technological protection offered by GURT can accomplish this goal.

An important determining factor for GURT viability is the level of acceptance of this product by farmers. This acceptance would not be related to the farmers' ability to save or not save the seed. Both hybrid corn and non-GURT GE seeds have demonstrated that there are other factors that farmers consider crucial in seed selection. Farmers' seed choice is more a matter of a cost/benefit analysis on the part of farmers whether they are located in the developed or the developing world. Patented GE seeds have already shown this to be true since the developing world now grows more acreage in GE crops than the developed world. Farmers are making their choice. Increasingly this choice is to embrace cutting edge agricultural biotechnology.

The question that must be answered for developing countries is whether the viability issues will support the massive innovation protection (and not so much innovation promotion) ability of the GURT. The IP protection from GURT benefits GE seed firms most whereas that of patents, while less ironclad, benefits both the GE seed firms and society.

The answer to the original thesis question is much clearer than I had imagined that it would be at the outset of this thesis. Currently, GURT is not a viable alternative to non-GURT patented GE seeds for the promotion and protection of innovation if GURT is commercialized into the current environment of consumer attitudes; policy and regulatory models; farming and seed systems; food security imperatives; biosecurity and biodiversity demands; and GE seed firm industry structural evolution.

However, GURT has the potential to be a viable alternative if those with an interest in advancing global food security through agricultural innovation can maximize the advantages of this technology while minimizing or eliminating the disadvantages. This would require changes

to many of existing rules and regulations as well as to the models that have long sustained agricultural innovation. Only in this way can disruptive, game-changing technologies such as GURT be brought into the agricultural mainstream rather than forcing it to exist at the fringes of agricultural innovation.

The best approach for GE seed firms, regulatory supporters, and the vast majority of the scientific community begins by developing a strategy to promote the value of existing non-GURT GE seeds. The primary issues that exist with non-GURT GE seeds revolve around consumer acceptance and the differences in various national policy and regulations that are often dependent on consumer beliefs. Without greater consumer support for what already exists, it is difficult to imagine that consumers and governments will accept the more dramatic GURT form of GE seeds.

In the face of GURT commercialization, it is likely that those opposed to GE seeds would remain so. Those who are undecided are likely to be swayed one way or the other based on whether they see the GURT specific attributes as positive or negative for the viability criteria that they value most. Research indicates that it will not be consumers' knowledge of the science of GE biotechnology or the scientific basis for the potential benefits of GURT that will be the deciding factor for consumer acceptance or rejection of GURT. Rightly or wrongly, it will be what consumers "believe" are the important issues.

The importance of the consumer acceptance issue cannot be overemphasized because without consumer acceptance of GURT, any attempt at commercialization will fail and the potential advantages or disadvantages of this technology will remain untested.

If GE seeds or GURT had been developed in the 1950s or 1960s, it is very unlikely that the consumer controversy over their use would have become an issue in the way that it has today. After all, mutagenesis as a means of creating beneficial crop mutations began decades ago. This technique involves the irradiation of plants to develop useful crop mutations with little thought to the potential of introducing potentially harmful mutations. The new corporate social responsibility (CSR) paradigm that developed in the 1980s following the implementation of neoliberal economic policies and related firm management techniques provided a ripe

environment for enhanced civil regulation. The questioning of big business over GE seed and GURT safety and economic sustainability is an outgrowth of this new CSR.

GURT viability is both a national and an international question. However, the nature of globalization and the international trade in food and food products demands that there should be an international solution to this problem. The solution for all stakeholders whether regulators, farmers, GE seed firms, or consumers would best be accomplished through international cooperation through existing organizations such as the World Trade Organization (where TRIPS originated), the Food and Agriculture Organization (responsible for global food security and crop analysis), and the World Intellectual Property Organization (responsible for IP information, resources and services). The use of these organizations as arbiters of any GURT/GE seed solution would create some international uniformity to any resolution of the issue.

Although this thesis has demonstrated the complexity of the GURT GE seed IP issue, it may be possible to go some way toward solving a portion of the problem by internationalizing the specific GE seed firm/farmer problem. I suggest that this could be accomplished in the same way that many national publically funded healthcare systems purchase pharmaceuticals for national distribution as part of their single-payer national health systems. However, rather than the beneficiaries being individual consumers, they would be farmers in developing countries. This appropriation of the bulk buying concept employed by national publically funded healthcare systems is how GURT could be most useful in preventing IP value leakage while benefiting other stakeholders as well.

Seed firms would sell to governments under license allowing all farmers in the country to grow GURT crops with no additional fees. This would reduce the GE seed firm transaction costs of dealing with individual farmers. It would also eliminate the issue of some poorer farmers being unable to pay for the latest seed technology. There would also be no need to introduce an alternate value capture system whereby the seed companies might extract value from individual farmers following harvesting on a fee per ton of crop basis. This latter solution would still require a firm-to-individual-farmer interaction and would, therefore, would be subject to high transaction costs. The former recommended method of government license fees has benefits for farmers, governments, seed firms, and consumers.

If governments decide to deal unfairly with the company(s), the companies could refuse to supply the next generation of seeds. And because these seeds are of the GURT variety, they remain under the control of the seed firms and the IP would have international backing. For governments, the ability to purchase high quality seed at a low cost would provide national economic benefits since all farmers in the country would have access to high quality seed to maximize yield. For the individual farmer, there would no longer be an annual cost/benefit analysis to determine the affordability of the latest GURT/GE seed. Also, the individual farmer would have no incentive to misappropriate IP. National regulators could find a more uniform, less confrontational domestic and international GE seed regulatory environment. Consumers would have a greater assurance of seed product safety since their governments would oversee purchases and would presumably make those purchases based on numerous factors such as quality and safety.

The primary disadvantage that I see with this solution is that it would likely increase the horizontal concentration in the industry leaving fewer seed firms to supply the market since the millions of small customers in the developing world would be replaced by their national governments.

It is my hope that the process of striving toward an answer to the thesis question creates a better understanding of the role of IP associated with GE seeds in the relationships among firm performance, public sector policy development, economic growth, and food security. This thesis has uncovered unique qualities of a potential alternative to the use of the utility patent that could redefine the way in which innovators address the protection and promotion of innovation in both the private and public sectors of the GE seed industry and perhaps in other life sciences.

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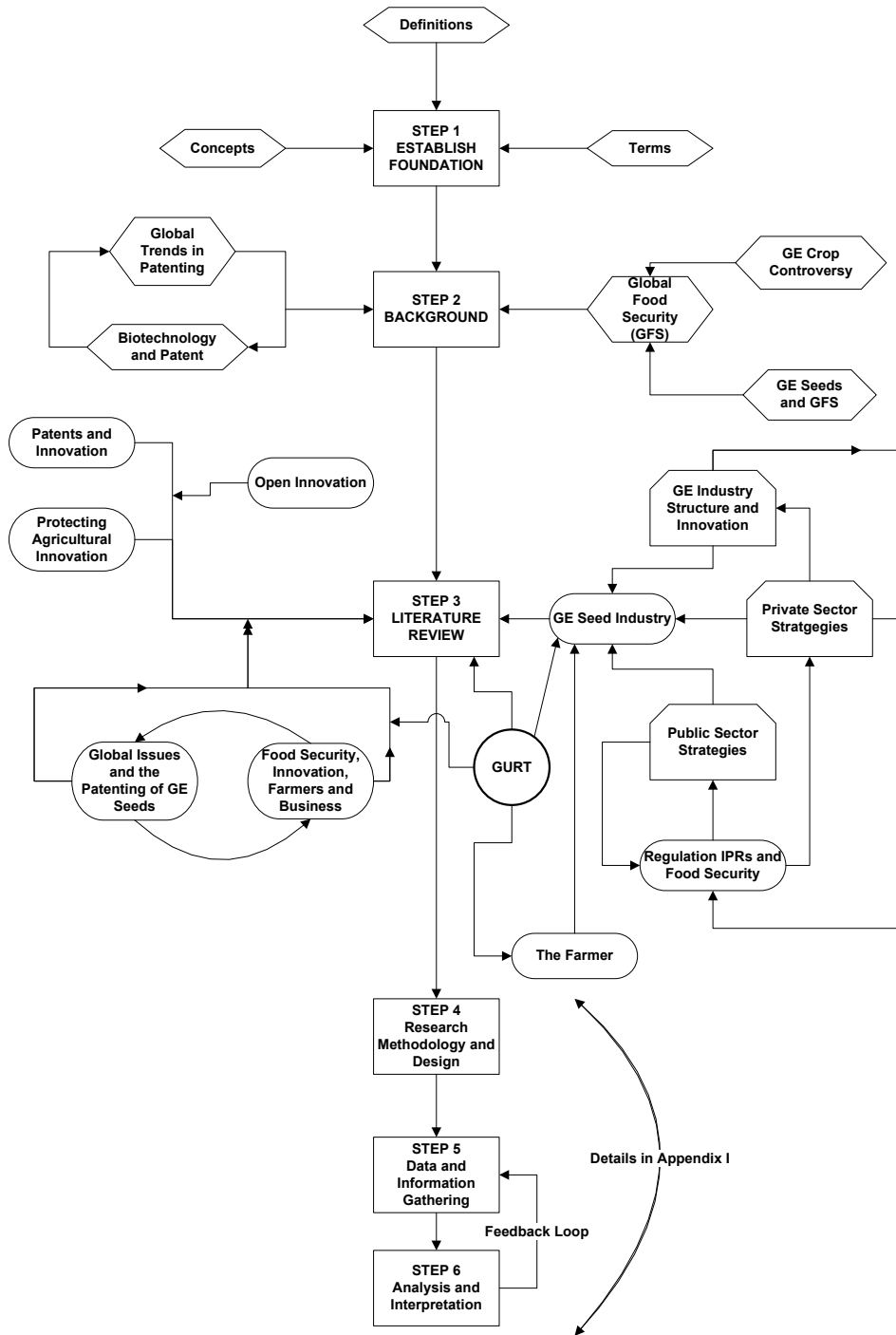
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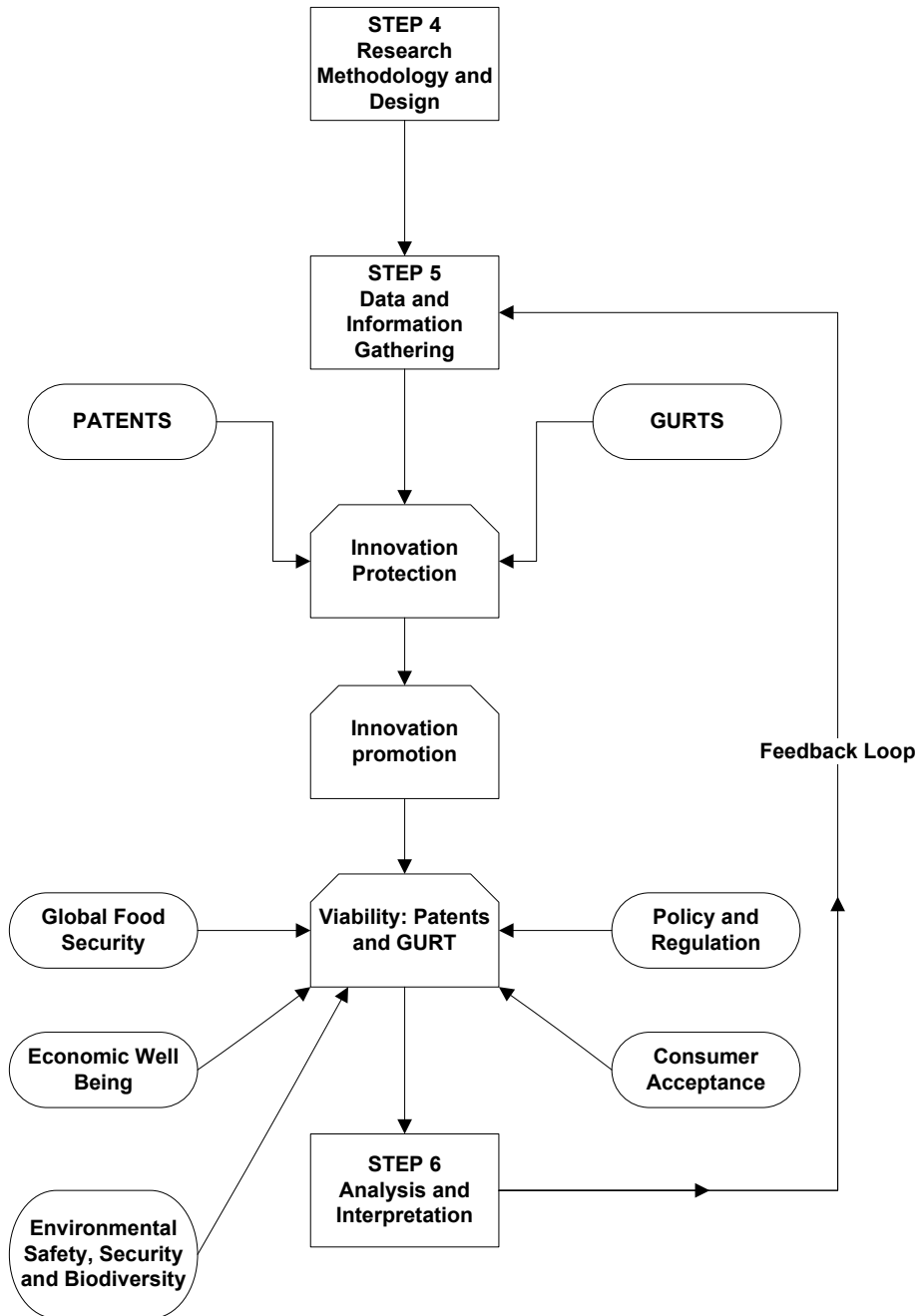
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Appendices

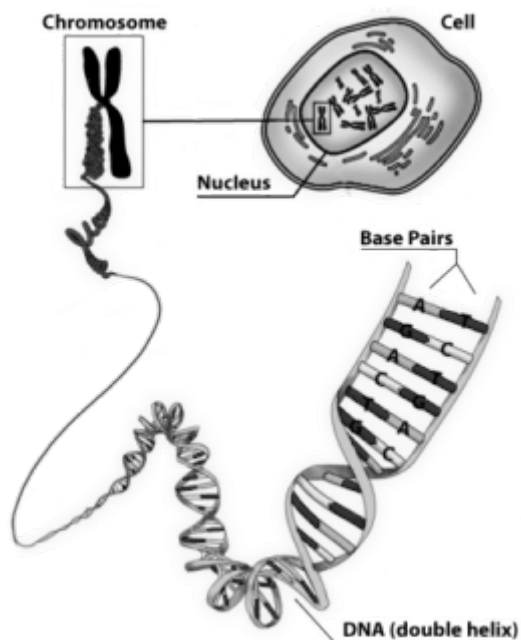
Appendix A: Overall Thesis Flowchart (Step 1 to Step 6)



Appendix B: Research and Analysis Procedure (Step 4 to Step 6)

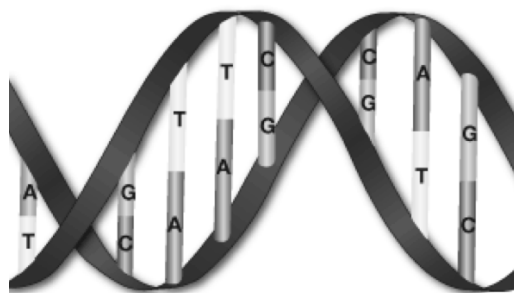


Appendix C: DNA: Gene Location and Arrangement



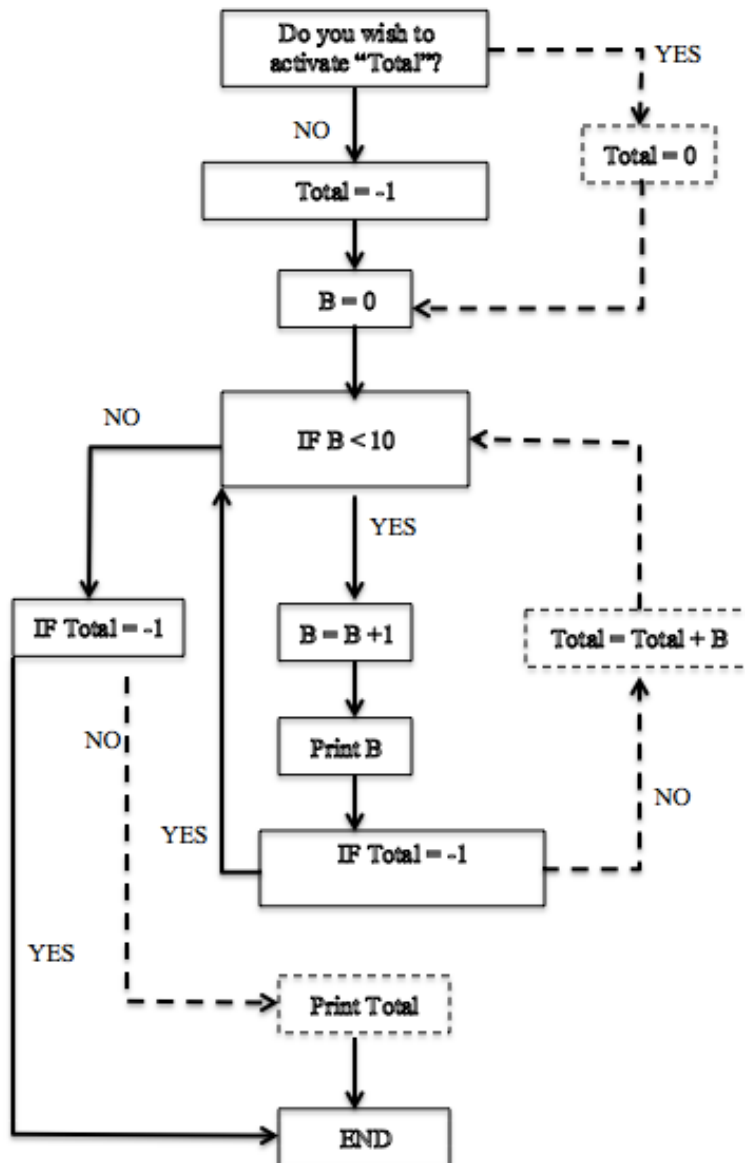
<http://www.genomnz.co.nz/Science/Science/tabid/92/Default.aspx>
Genomnz – DNA Testing Laboratory June 4, 2013

DNA Base Pairings



Thymine = T Adenine = A Guanine = G Cytosine = C
Note the base pairing combinations that exist between the two phosphate-sugar backbone structures that form the well-known DNA double helix configuration
<http://history.earthsci.carleton.ca/harvey/genealogy/dnabackground.htm>
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Appendix D: GURT-LIKE ALGORITHM



Computer Algorithm to add a series of numbers from 1 to 10 and print the numbers. The total is printed if the special attribute “Total” is activated by assigning the value of “0” to it

Appendix E: GE Seed Industry Analysis

(Appendix E is taken in its entirety from: Rosenblat, Joseph. “The Effect of Intellectual Property Rights Associated with Genetically Engineered Seeds on Global Food Security” (2012) A Major Research Paper in partial fulfillment of the requirements for the degree of Master of Laws, Osgoode Hall Law School, Toronto, Canada, Appendix C)

A Porter Five Forces Analysis is a standard tool used to aid in industry analysis. The purpose of the Analysis is to provide a description of the industry structure by assessing the strength of the five key elements of industry structure: rivalry in the industry, the threat of new entrants to the industry, the threat of substitutes for the industry products, and buyer and supplier power.

Rivalry Among Established Firms

Rivalry among established players in the GE seeds industry is a major determinant of overall competition and profitability. In this global industry, some of the top competing firms are Monsanto, BASF AG, Bayer CropScience AG, Syngenta AG, and DuPont. All are large firms, with annual revenues over \$10B US.⁸³⁹ These firms are multi-product, diversified companies in which GE seeds represent only one segment of their business. This diversification, which includes both vertical and horizontal integration, helps these firms reduce market risk.

Innovation strategy in this industry tends to be fairly uniform. One aspect of this strategy, and an area where the industry derives a substantial portion of its current profits is through incremental improvements (i.e. sustaining innovation) in existing products for current customers.⁸⁴⁰ However, these companies also use extensive R&D to develop new disruptive technologies on which to base future profits. For example, a disruptive technology that would fundamentally alter this industry and global food security could be, for example, a corn seed that creates a full yield crop in half the time. Such a product would have an extended development time at which point it would begin to enter commercial use by those who could immediately

⁸³⁹ *Monsanto Company* (2011), online: Mergent
< <http://www.mergentonline.com.ezproxy.library.yorku.ca/basicsearch.php>>.

⁸⁴⁰ This incremental improvement is the sustaining innovation previously discussed in the main body of this thesis where sustaining and disruptive innovation were differentiated.

benefit from it. At some point, when it became a mainstream product, research would continue to improve the product incrementally.

Another innovation strategy in this industry is the use of collaborative agreements with local research institutes. For instance, in February 2009, Bayer CropScience and the German Leibniz Institute of Plant Genetics and Crop Plant Research (IPK) entered into a research agreement to develop genetically engineered, high-yielding canola hybrids.⁸⁴¹ Collaborative initiatives are also common among the firms within the industry. One example is the 2007 joint R&D venture between Monsanto and BASF to develop GE crops to meet the growing demand for biofuel.⁸⁴²

The similarity in some product offerings and distribution methods among the major competitors is a primary reason for the intense industry competition. High capital requirements to enter the industry [specialized equipment and materials] and the resulting high *exit barriers* [Exit barriers are the costs associated with capacity leaving an industry. This is especially problematic where resources are durable and specialized. The assets of such a company are difficult or impossible to liquidate. The result is the high cost of leaving an industry can outweigh the cost of staying.] further increase the competitive pressures for these major players.

The overall lack of highly differentiated products in basic GE traits currently in demand such as herbicide or insect resistance also increases rivalry. However, at the same time, firms are constantly seeking new differentiating traits for their seeds that they can protect through patents. That ability to protect IP is a major factor responsible for growth and innovation in the GE seeds industry.⁸⁴³

Overall, rivalry in this industry is high. This does not suggest that there is no dominant player in the industry. Monsanto is dominant in GE traits, although other companies—including Dow AgroSciences, Syngenta, and DuPont—have competing GE traits that have been or soon will be commercialized.

⁸⁴¹ Bayer AG (2011) online: Datamonitor360<<http://360.datamonitor.com.ezproxy.library.yorku.ca/>>.

⁸⁴² Monsanto Company Profile (2010) online: Hoovers
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⁸⁴³ H Stein, “Intellectual property and genetically modified seeds: The United States, trade, and the developing world” (2005) *New Journal of Technology & Intellectual Property* 160 at 170.

Buyer (Farmer) Power

The level of buyer power in any industry depends on the buyers' price sensitivity and their relative bargaining power. Several factors increase buyer power in the GE seed industry. The fact that there is relatively little differentiation in mainstream products among the various major retailers increases buyers' price sensitivity, thereby encouraging the buyer to switch firms based on cost. However, any requirement for the buyer to use firm-specific complementary products and to invest in product specific capital assets can increase switching costs and, therefore, decrease buyer power. Competitors forming alliances that reduce rivalry can also reduce buyer power.⁸⁴⁴

In contrast, the availability and usefulness of substitute products such as GE seeds, herbicides, insecticides, and fungicides produced by other firms increase buyer power. Another potential substitute but one that varies in its "closeness" is the variety of non-GE seeds and complementary products available.

Taking all factors into consideration, buyer power is low to moderate depending on specific circumstances and geographical regions.

Threat of New Entrants

As in most other industries, the threat posed by new entrants in the GE seed industry is dependent on the existence and effectiveness of applicable barriers to entry as weighed against the potential for profit. Some of the barriers to entry in this industry include high initial capital requirements, economies of scale of existing competitors, access to distribution channels, incumbent brand reputation, government regulations, IP requirements, and retaliation from incumbents. Entry is made even more difficult by the occasional collaboration among firms through business and licensing agreements.⁸⁴⁵

The need for extensive, costly R&D represents a significant barrier to entry. One of the most significant additional entry barriers for this industry is government and international regulation on the use of GE seeds and the sale of GE foods. Another barrier is the large part

⁸⁴⁴ *Monsanto Company Profile* (2011)

online: Datamonitor360 <<http://360.datamonitor.com.ezproxy.library.yorku.ca/>>.

⁸⁴⁵ Ibid.

played by IP laws in the ability and cost incurred by firms to protect new discoveries against encroachment by competitors. The capability of a firm to patent an invention improves its competitive power by reducing the threat of new entrants. Other deterrents to entry include high capital costs that are magnified by the requirement of specialized and highly trained personnel and long time horizons for R&D. As a result of the challenges that need to be overcome by potential new entrants in this industry, the threat of new entrants is considered to be low.

Threat of Substitutes

While non-GE seeds may replace GE seeds, there are no direct substitutes for GE seeds. There are, however, limited substitutes for specific traits available from some competitors. GE seeds are currently more expensive than low-cost non-GE seeds due to high development costs associated with the value added benefits that they provide [i.e. drought resistance, pest resistance, high yield, etc.]. Costs to the purchasers are further magnified by the limited monopoly positions of the firms in the industry.

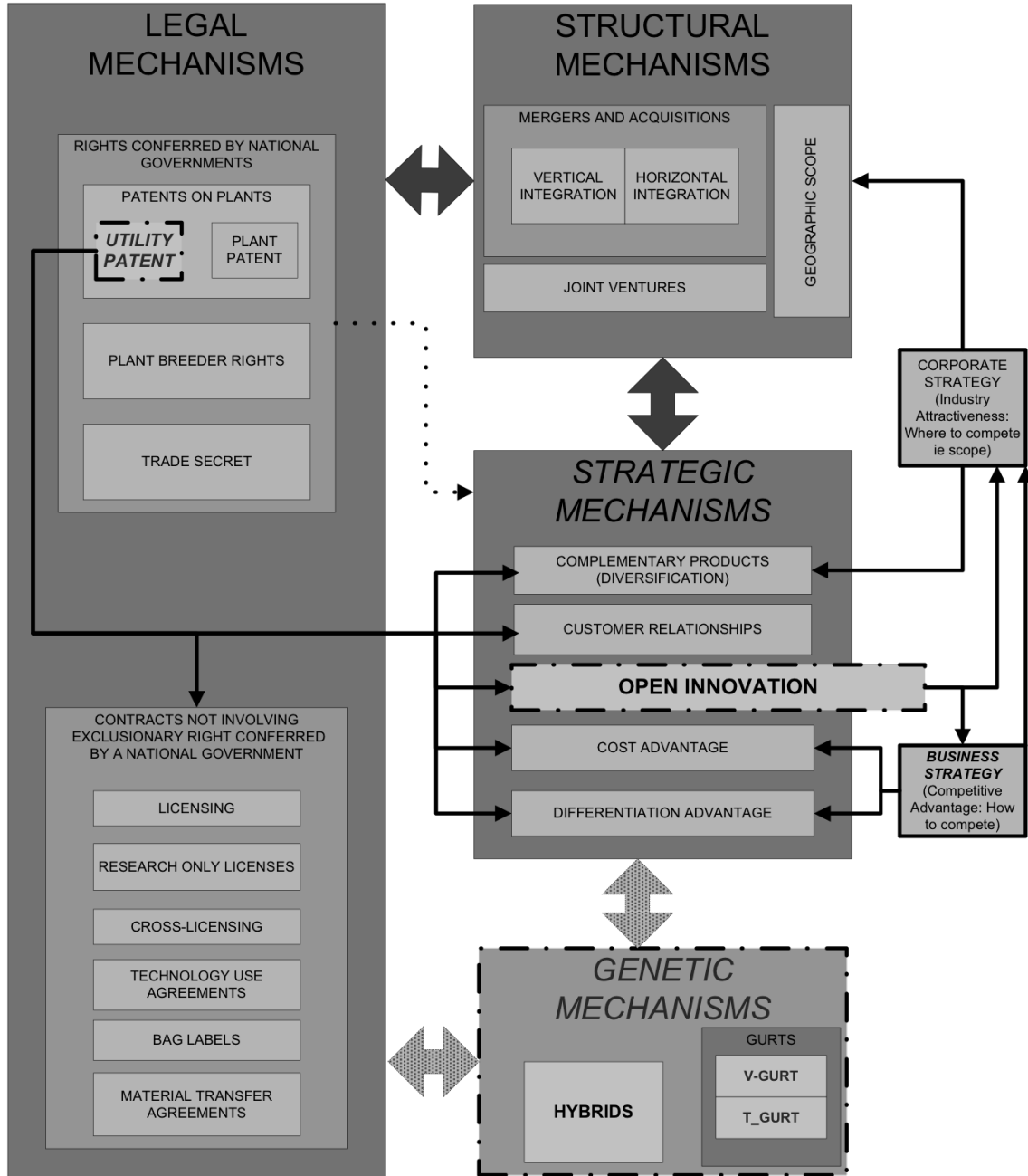
The buyer's cost of switching is also high, as previously mentioned. An added cost to buyers includes precautions to avoid the threat of lawsuits by the major competitors such as Monsanto, which have brought allegations of patent infringement against farmers.

A substitute does not have to be a "direct" [i.e. perfect] substitute to have a market effect. The use of external materials can be considered to be a substitute for GE seeds. For instance, the use of herbicides and pesticides with non-GM seeds would be a substitute for GE seeds that have those attributes. While these products have the disadvantage of possible secondary environmental effects, they do have the advantage of lower cost [a significant area of concern in third world countries].

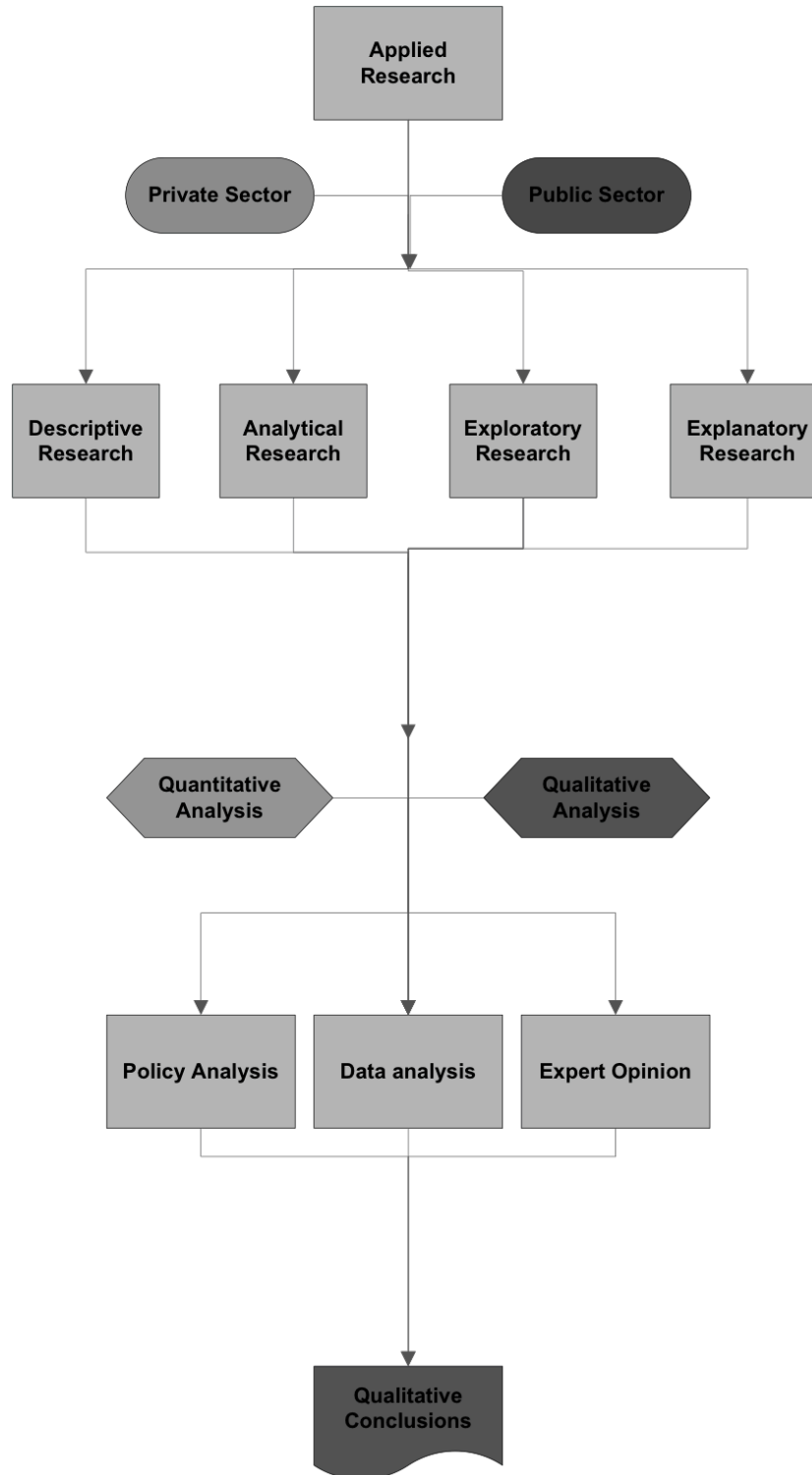
Also, the traditional breeding of plants would be a substitute for GE seeds although disadvantages include the extended timeline for development and that the required traits may be impossible to duplicate naturally.

The threat of substitutes is trait and geographical region specific and ranges from low to moderate.

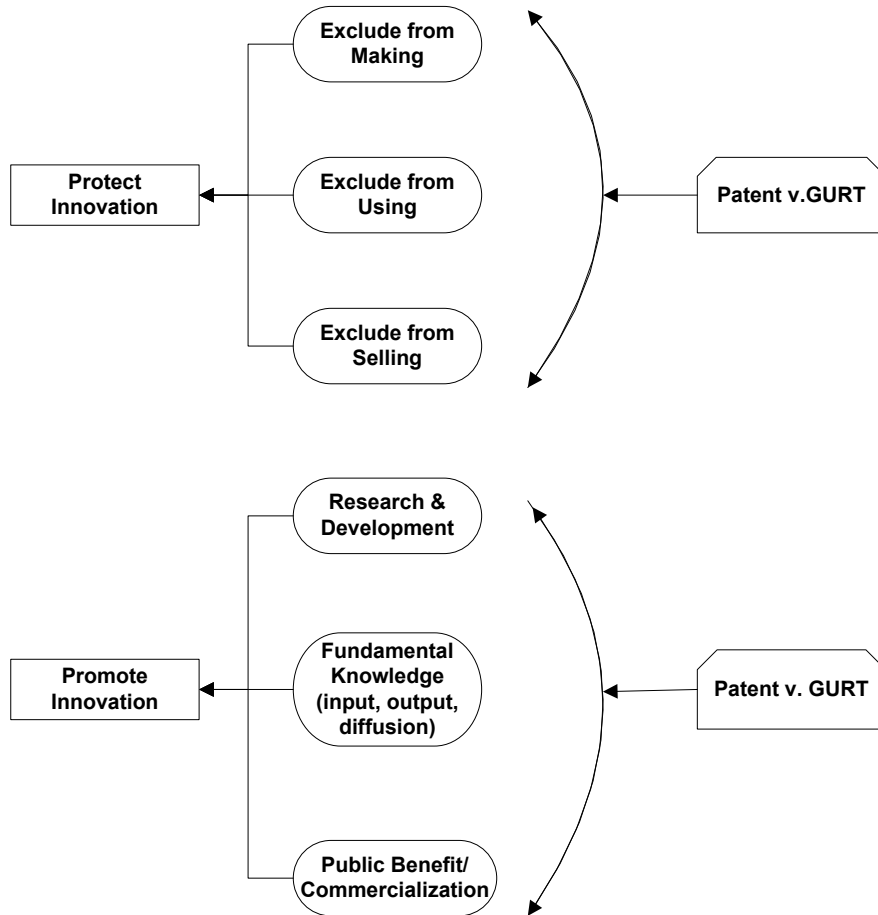
Appendix F: Innovation Enhancement Alternatives



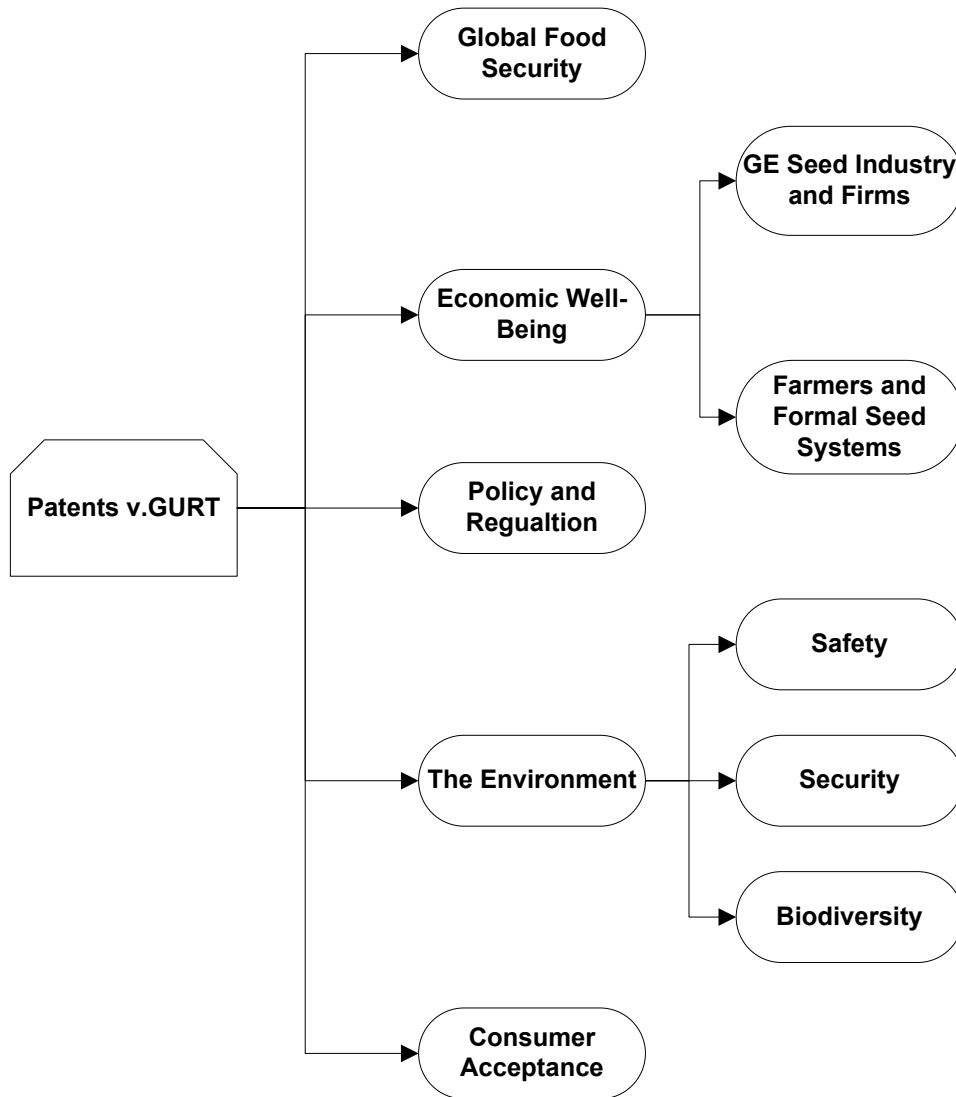
Appendix G: Foundation of the Research Design



Appendix H: Innovation Protection and Promotion Criteria



Appendix I: Viability Criteria



Appendix J: Data Source Specifics

Data Source Specifics

Initially, given the disparate nature of the stakeholders involved in this industry and their varied interests, a wide but specifically designed net is cast to gather quantitative and qualitative data. Although broad at the outset, the data sources narrow as the quality and quantity of information available from researching them begin to weed out those, which are unsatisfactory or superfluous.

Potential data sources include:

International/Regional/National U.N. or Governmental Organizations

a) Food and Agriculture Organization of the United Nations (FAO)

This organization is one of the primary sources of data for this thesis because its mandate emphasizes many of the criteria on which the analysis of alternatives is based. The most important are: achieving food security; improving agricultural productivity; and contributing to the growth of the world economy. (FAO, 2013 website: <http://www.fao.org/about/en/>) The FAO web site allows for access to numerous databases and information systems many of which are directly applicable to assessing the various criteria previously described. Examples of valuable databases and information systems that will be searched:

- AGRIS – The International Information System for the Agricultural Sciences and Technology
- CARIS – The Current Agricultural Research Information System
- FAOSTAT – FAO Statistical Database
- FAO Document Repository
- SIS – The Seed Information System Database
- WIEWS – The World Information and Early Warning System on Plant Genetic Resources

b) Organization for Economic Co-operation and Development (OECD)

This voluntary organization with 34 member countries was formally established in 1960 to identify, analyze and solve problems faced by its members. This organization

provides publically available information on agriculture, IP and innovation and their relationship to national economies and international economics. (OECD, 2013 website: <http://www.oecd.org/about/history/>) Examples of valuable OECD information that will be examined:

- Science and Technology Policy
- Biotechnology Policies
- Research Program on Biological Resources in Agriculture
- Various OECD-FAO Agricultural Publications
- OECD Patent Databases
- Agriculture, Innovation and GE crops
- OECD Library: Statistics
- OECD Library: Measuring Innovation

c) World Intellectual Property Organization (WIPO)

This United Nations agency promotes the international IP system as a means to enhance innovation for economic, social and cultural development. (WIPO, 2013 website: <http://www.wipo.int/about-wipo/en/>) There are numerous studies and articles commissioned for the OECD that specifically address IP issues related to the genetic engineering of crops, biotechnology in general and the interrelationship between WIPO and other relevant organizations (e.g. UNCTAD, OECD, UPOV, European Commission, IFPRI, etc.)

(<http://www.wipo.int/patent-law/en/developments/biotechnology.html>)

d) European Commission Directorate General for Agriculture and Rural Development

This EU organization deals with, “all aspects of the Common Agricultural Policy (CAP) including farm support, market measures, rural development policy, quality policy, financial and legal matters, analysis and evaluation as well as international relations relating to agriculture.” (web site:

http://ec.europa.eu/dgs/agriculture/index_en.htm) This organization has produced useful information related to genetically engineered crops in agriculture such as:

- Biotechnology: Genetically Modified Organisms (GMOs) in Agriculture
- Trade Implications of GMOs Unapproved in the EU
- Agriculture – Co-existence of Genetically modified, conventional and organic crops
Liability in Cases of Damage Resulting from the Presence of GMOs in Non-GM Crops

e) Eurostat

Source of European statistics from the European Commission

(<http://epp.eurostat.ec.europa.eu/portal/page/portal/eurostat/home>)

f) World Trade Organization (WTO)

This international organization centralizes trade negotiations for its members. This includes the implementation and monitoring of agreements and dispute resolution.

(WTO, 2013 website:

http://www.wto.org/english/thewto_e/whatis_e/what_we_do_e.htm)

For this thesis, the involvement of the WTO with IP is of particular importance as is the effects of genetically engineered seeds on trade.

g) United States Department of Agriculture (USDA)

(USDA Economics Research Service)

- USDA Economics Research Service – Biotechnology
- USDA Economics Research Service – Data Products
- USDA Economics Research Service – Publications (multiple international)
- USDA Economics Research Service – Economic Issues in Agricultural Biotechnology
- USDA Economics Research Service – Biotechnology

- USDA Economics Research Service - Rising Concentration in Agricultural Input Industries Influences New Farm Technologies
- USDA Economics Research Service – International Markets and Trade
 - Countries and regions
 - Food Safety and International Markets
 - Global Food Security
- USDA Economics Research Service – Countries and Regions

Primary Multinational Seed Firm Involved in Agricultural Biotechnology

a) Monsanto

As the largest GE seed company in the world, Monsanto will be the representative of the private firm stakeholder for this thesis. Other factors that make Monsanto the ideal selection to represent the multinational industry are:

- Significant vertical and horizontal integration
- Leader in innovation in the GE seed industry
- Subject to numerous lawsuits related to its enforcement of its IPRs
- Heavily involved in R&D
- Diversified into complementary farming products
- Publicly traded, which provides publically available company data
- Significant international interaction with farmers
- Significant interaction with international regulators and policymakers
 - A great deal of academic business and policy analysis available

b) Other Agricultural Biotechnology/Seed Firms

The value of potentially including other firms in this thesis lies in the various relationships that they may have with Monsanto. These relationships can be used to demonstrate innovation, IP and broader business strategies in which firm interaction is a fundamental requirement. Firms that may be of value here include rivals, suppliers and wholly owned subsidiaries within Monsanto's vertically and

horizontally integrated business structure.

Advocacy Groups

Three types of advocacy groups are examined for data, farm/farmer groups, NGOs, and consumer groups. The information from these groups are of a more qualitative nature and are subject to scrutiny because the very nature of advocacy suggests bias. However, these groups have a definite impact on the viability aspect of any alternative to patents and for this reason, their concerns are worth taking seriously. This is particularly the case with farmers in both developed and developing countries since they are most intimately connected with the implications of the thesis question.

Appendix K: Monsanto Technology / Stewardship Agreement ⁸⁴⁶

GLUE LINE

2014 MONSANTO TECHNOLOGY/STEWARDSHIP AGREEMENT (Limited Use License)

Form Number
140100000

PLEASE MAIL THE SIGNED 2014 MONSANTO TECHNOLOGY/STEWARDSHIP AGREEMENT TO: DRC Data Services, Attn: AgCelerate Agreements, 2009 Fourth Street, SW, Mason City, IA 50401

GROWER INFORMATION (please print)

Please complete this section with your business information. To sign this Monsanto Technology/Stewardship Agreement ("Agreement") you must be the **operator/grower** for all fields that will grow plants from Seed (as defined below). You represent that you have full authority to and do hereby bind to this Agreement yourself, all entities for which you obtain Seed, all individuals and entities having an ownership interest in any entities for which you obtain Seed, and that Monsanto

Company has not barred any of those individuals or entities from obtaining this limited-use license. Your name must be filled in and must match the signature below. This Agreement becomes effective if and when Monsanto issues the Grower a license number from Monsanto's headquarters in St. Louis, Missouri. Monsanto does not authorize seed dealers or seed retailers to issue a license of any kind for Monsanto Technologies.

Grower's Full Legal Name (First/Middle/Last) <input type="checkbox"/> Dr. <input type="checkbox"/> Mr. <input type="checkbox"/> Mrs. <input type="checkbox"/> Ms. <input type="checkbox"/> Suffix (Sr., Jr., II, III) <input type="checkbox"/>	Farm Business Name
Grower's Mailing Address (no P.O. Boxes)	Farm Physical Address (as listed with the FSA)
Grower's City <input type="text"/> State <input type="text"/> Zip <input type="text"/>	Farm City <input type="text"/> State <input type="text"/> Zip <input type="text"/>
Office Phone (include area code) <input type="text"/>	Last Four of Social Security # <input type="text"/>
Fax (include area code) <input type="text"/>	Role: <input type="checkbox"/> Operator <input type="checkbox"/> Owner/Operator <input type="checkbox"/> Farm Manager
Cell Phone (include area code) <input type="text"/>	<input type="checkbox"/> Other
Email <input type="text"/>	

If the above information changes, Grower agrees to promptly update this information via AgCelerate.com or by calling 1-800-768-6387, option 3.

SEED SUPPLIERS

Business Name <input type="text"/>	Area Code <input type="text"/>	Phone <input type="text"/>
City <input type="text"/> State <input type="text"/> Zip <input type="text"/>		
Business Name <input type="text"/>	Area Code <input type="text"/>	Phone <input type="text"/>
City <input type="text"/> State <input type="text"/> Zip <input type="text"/>		

This Monsanto Technology/Stewardship Agreement is entered into between you ("Grower") and Monsanto Company ("Monsanto") and consists of the terms on this page and on the reverse side of this page.

This Monsanto Technology/Stewardship Agreement grants Grower a limited license to use Genetically Modified ("GM") with Roundup Ready™ Flex cotton, Genetically Modified ("GM") Bollgard II™ cotton, Genetically Modified ("GM") Roundup Ready 2 Yield™ soybeans, Visive™ low linolenic soybeans with Genetically Modified ("GM") Roundup Ready 2 Yield™ technology, Genetically Modified ("GM") Roundup Ready™ Canola, Genetically Modified ("GM") Alfalfa, Roundup Ready™ Corn 2, Genetically Modified ("GM") DroughtGard™ Hybrids with Roundup Ready™ Corn 2, Roundup Ready™ Cotton, Genetically Modified ("GM") Roundup Ready™ Free cotton, Roundup Ready™ Soybeans, Visive™ low linolenic soybeans with Roundup Ready™ technology, Genetically Modified ("GM") Roundup Ready™ Sugarbeets, YieldGard™ Corn Borer corn, YieldGard™ Corn Borer with Roundup Ready™ Corn 2, Genetically Modified ("GM") VT Double PRO™ corn, Genetically Modified ("GM") DroughtGard™ Hybrids with VT Double PRO™ corn, Genetically Modified ("GM") VT Triple PRO™ RIB Complete™ corn blend, Genetically Modified ("GM") DroughtGard™ Hybrids with VT Double PRO™ RIB Complete™ corn blend, YieldGard VT Rootworm/R2™ corn, YieldGard VT Triple™ corn, Genetically Modified ("GM") VT Triple PRO™ corn, Genetically Modified ("GM") DroughtGard™ Hybrids with VT Triple PRO™ corn, Genetically Modified ("GM") VT Triple PRO™ RIB Complete™ corn blend, Genetically Modified ("GM") DroughtGard™ Hybrids with VT Triple PRO™ RIB Complete™ corn blend, Performance Series™ Sweet Corn, Genetically Modified ("GM") SmartStax™ RIB Complete™ corn blend, Monsanto patented germplasm and Monsanto Plant Variety Protection rights ("Monsanto Technologies"). Seed containing Monsanto Technologies are referred to herein as ("Seed"). This Agreement also contains Grower's stewardship responsibilities and requirements associated with the use of Seed and Monsanto Technologies.

- GOVERNING LAW:** This Agreement and the parties' relationship shall be governed by the laws of the State of Missouri and the United States (without regard to the choice of law rules).
- BINDING ARBITRATION FOR COTTON-RELATED CLAIMS MADE BY GROWER:** Any claim, action or dispute made or asserted by a Grower (or any other person or entity claiming an interest in Grower's cotton crop, hereafter "Grower") against Monsanto, or any person or entity involved in the production, development, distribution, and/or sale of the Seed containing Monsanto Technology ("Seed"), regarding the quality of Monsanto cotton Seed or the agronomic performance of Monsanto Technology in cotton Seed must be resolved by binding arbitration. The foregoing requirement to arbitrate specifically excludes any claim, action or dispute involving the infringement, validity, or enforceability of a patent or that otherwise arises under the U.S. patent laws. As a condition precedent to asserting any claim, action, or dispute regarding the quality of Monsanto cotton Seed or the agronomic performance of Monsanto Technology in cotton Seed, the Grower must provide notice to Monsanto pursuant to §10 of this Agreement. After Grower provides that notice, Grower may request in writing that the parties engage in good faith negotiations, which the parties will undertake within 30 days after Monsanto's receipt of the request. In the event that a claim is not resolved within the 30 days, or after 30 days following Grower's service of a claim notice if Grower does not request negotiations, any party may initiate arbitration. The parties pursuant to the provisions of the Federal Arbitration Act, 9 U.S.C. Sec. 1 et seq. and administered under the Commercial Dispute Resolution Procedures established by the American Arbitration Association ("AAA"). GROWER MAY ONLY BRING A CLAIM IN ARBITRATION IN GROWER'S INDIVIDUAL CAPACITY AND GROWER WAIVES ANY RIGHT TO DO SO AS A REPRESENTATIVE OR MEMBER OF ANY CLASS OR PUTATIVE CLASS. The arbitration hearing shall be conducted in the capital city of the state of Grower's residence or in any other place as the parties decide by mutual agreement. Grower and Monsanto/sellers shall each pay one-half of the AAA filing fee. Grower and Monsanto/sellers shall each pay one-half of AAA's administrative and arbitrator fees as those fees are incurred. The arbitrator(s) shall have the power to apportion the ultimate responsibility for all AAA fees in the final award. The arbitration proceedings and results are to remain confidential and are not to be disclosed without the written agreement of all parties, except to the extent necessary to effectuate the decision or award or as otherwise required by law.
- FORUM SELECTION FOR NON-COTTON-RELATED CLAIMS MADE BY GROWER AND ALL OTHER CLAIMS:** THE PARTIES CONSENT TO THE SOLE AND EXCLUSIVE JURISDICTION AND VENUE OF THE U.S. DISTRICT COURT FOR THE EASTERN DISTRICT OF MISSOURI, EASTERN DIVISION, AND THE CIRCUIT COURT OF THE COUNTY OF ST. LOUIS, MISSOURI, (ANY LAWSUIT MUST BE FILED IN ST. LOUIS, MO) FOR ALL CLAIMS AND DISPUTES ARISING OUT OF OR CONNECTED IN ANY WAY WITH THIS AGREEMENT AND/OR THE USE OF THE SEED OR THE MONSANTO TECHNOLOGIES, EXCEPT FOR COTTON-RELATED CLAIMS MADE BY GROWER. THE PARTIES WAIVE ANY OBJECTION TO VENUE IN THE EASTERN DIVISION OF THE U.S. DISTRICT COURT FOR THE EASTERN DISTRICT OF MISSOURI, INCLUDING THOSE BASED, IN WHOLE OR IN PART, ON THE DIVISIONAL VENUE LOCAL RULE(S) OF THE U.S. DISTRICT COURT FOR THE EASTERN DISTRICT OF MISSOURI. THIS AGREEMENT CONTAINS A BINDING ARBITRATION PROVISION FOR COTTON RELATED CLAIMS PURSUANT TO THE PROVISIONS OF THE FEDERAL ARBITRATION ACT, 9 U.S.C. §1 ET SEQ., WHICH MAY BE ENFORCED BY THE PARTIES.

4. GROWER AGREES:

- To accept and continue the obligations of this Monsanto Technology/Stewardship Agreement on any new land purchased or leased by Grower that has Seed planted on it by a previous owner or possessor of the land; and to notify in writing purchasers or lessees of land owned by Grower that has Seed planted on it that the Monsanto Technology is subject to this Monsanto Technology/Stewardship Agreement and they must have or obtain their own Monsanto Technology/Stewardship Agreement.
- To read before planting and to follow the applicable Technology Use Guide ("TUG") and the Insect Resistance Management Grower Guide ("IRM Grower Guide") as may be amended from time to time, which are incorporated into and are a part of this Agreement. Grower must comply with the requirements set forth in the TUG and the IRM Grower Guide and should follow the best management practices, recommendations and guidelines provided in those documents.
- To implement an Insect Resistance Management ("IRM") program, if applicable, in accordance with the most recent IRM Grower Guide and to cooperate and comply with these and any additional IRM programs Monsanto communicates to Grower.
- To acquire Seed containing these Monsanto Technologies only from a seed company with technology license(s) from Monsanto for the applicable Monsanto Technology(ies) or from a licensed company's dealer authorized to sell such licensed Seed.
- To acquire Seed only from authorized seed companies (or their authorized dealers) with the applicable license(s).
- To use Seed containing Monsanto Technologies solely for a single planting of a commercial crop, except in the case of Genetically Modified ("GM") Alfalfa where a single planting may be used for multiple cuttings.
- Not to save or clean any crop produced from Seed for planting, not to supply Seed produced from Seed to anyone for planting, not to plant Seed for production other than for Monsanto or a Monsanto licensed seed company under a seed production contract.
- Not to transfer any Seed containing patented Monsanto Technologies to any other person or entity for planting.
- To plant and/or clean Seed for Seed production, if and only if, Grower has entered into a valid, written Seed production agreement with a Seed company that is licensed by Monsanto to produce Seed. Grower must either physically deliver to that licensed Seed Company or must sell for non-seed purposes or use for non-seed purposes all of the Seed produced pursuant to a Seed production agreement.
- Grower may not plant and may not transfer to others for planting any Seed that the Grower has produced containing patented Monsanto Technologies for crop breeding, research, or generation of herbicide registration data. Grower may not conduct research on Grower's crop produced from Seed other than to make agronomic comparisons and conduct yield testing for Grower's own use. Monsanto makes available separate license agreements to academic institutions for research.
- To direct crops produced from Seed to appropriate markets. Any grain or material produced from Seed can only be exported to, or used, processed or sold in countries where all necessary regulatory approvals have been granted. It is a violation of national and international law to move material containing biotech traits across boundaries into nations where import is not permitted.
- Pending import approvals in China, Grower agrees not to export Genetically Modified ("GM") Alfalfa seed or crops (including hay and hay products) to China. In addition, due to the unique cropping practices Grower agrees not to plant Genetically Modified ("GM") Alfalfa in Imperial County, California, pending import approvals in China and until Monsanto grants express permission for such planting. Genetically Modified ("GM") Alfalfa seed may not be planted for the production of products.
- Grower agrees: 1) not to export Genetically Modified ("GM") Roundup Ready™ Flex Pima cotton seed, meal, linters, or gin trash to Korea pending import approval; 2) to deliver Genetically Modified ("GM") Roundup Ready™ Flex Pima cotton to an Arizona, California, New Mexico, or Texas gin that is on Monsanto's approved list (available at www.genmly.com under the Commodity Marketing section of the Stewardship tab); and 3) not to market cotton seed, meal, linters or gin trash from Genetically Modified ("GM") Roundup Ready™ Flex Pima to a third party who may send such products to countries where those products do not have all necessary regulatory approvals.

[The Agreement continues on the reverse side of this page.]

GROWER SIGNATURE
AND DATE REQUIRED

Name

Distribution: White to Monsanto, Yellow to Dealer, Pink to Grower

Date

846 Monsanto Technology Use Guides (2014) online:
Monsanto <<http://www.monsanto.com/products/pages/technology-use-guides.aspx>>.

Appendix L: Monsanto Technology / Stewardship Agreement (cont'd)

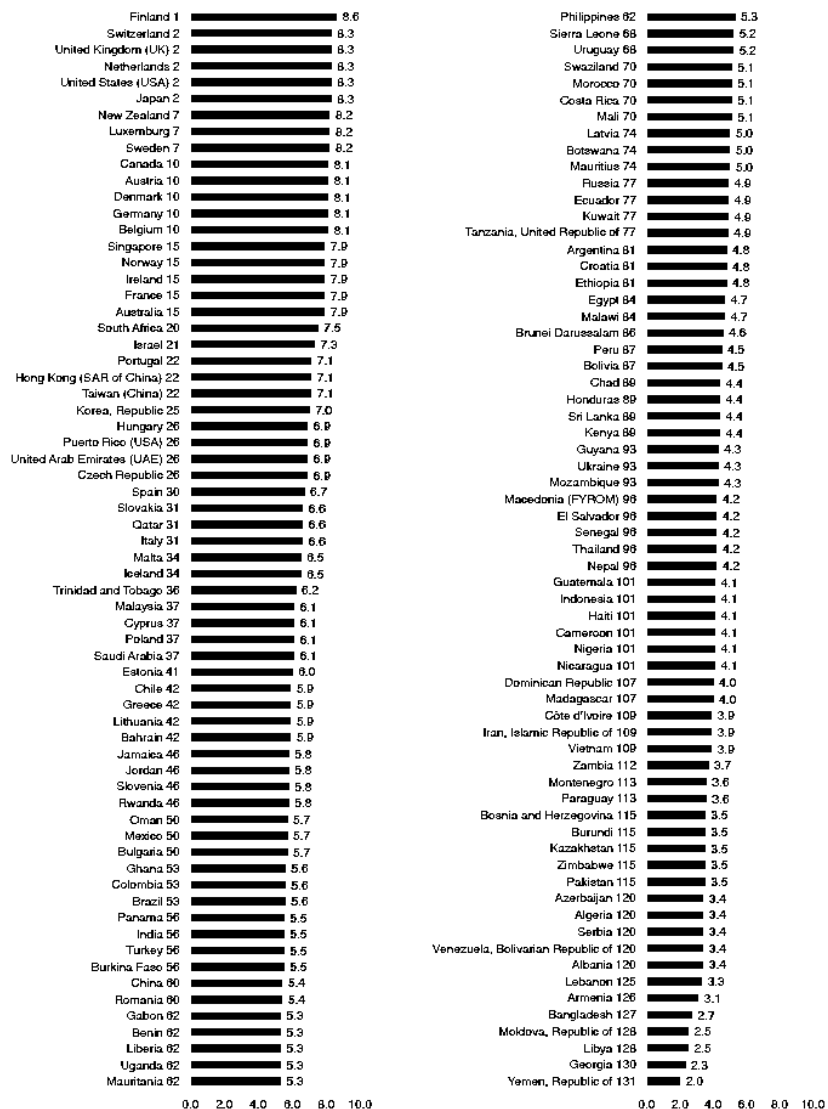
- To provide Monsanto copies of any records, receipts, or other documents that could be relevant to Grower's performance of this Agreement, including but not limited to, Summary Acreage History Report, Form 578 (Groucher ariett), Farm and Tract Detail Listing and corresponding aerial photographs, Risk Management Agency claim documentation, and dealer/retailer invoices for seed and chemical transactions. Such records shall be produced following Monsanto's actual (or attempted) oral communication with Grower and not later than seven (7) days after the date of a written request from Monsanto.
 - To identify and to allow Monsanto and its representatives access to land farmed by or at the direction of Grower (including wife areas) and bins, wagons, or seed storage containers used or under the control or direction of Grower, for purposes of examining and taking samples of crops, crop residue or seeds located therein. Such inspection, examination or sampling shall be available to Monsanto and its representatives only after Monsanto delivers or mails to the Grower a written notice at least seven (7) days in advance, and Monsanto also has reasonably attempted to discuss the visits with the Grower in advance of the visit.
 - To allow Monsanto to obtain Grower's internet service provider ("ISP") records to validate Grower's electronic signature, if applicable.
 - To pay all applicable fees due to Monsanto that are a part of, associated with or collected with the Seed purchase price or that are involved for the seed. If Grower fails to pay Monsanto for cotton related Monsanto Technologies, Grower agrees to pay Monsanto default charges at the rate of 14% per annum (or the maximum allowed by law whichever is less) plus Monsanto's reasonable attorneys' fees, court costs and all other costs of collection.
 - To use on crops containing Roundup Ready®, Roundup Ready® 2 Technology, or Roundup Ready® Flex only a labeled Roundup® agricultural herbicide or other authorized non-selective herbicide which could not be used in the absence of the Roundup Ready® gene (see TUG for details on authorized non-selective products). Use of any selective herbicide labeled for the same crop without the Roundup Ready® gene is not restricted by this Agreement. MONSANTO DOES NOT MAKE ANY REPRESENTATIONS, WARRANTIES OR RECOMMENDATIONS CONCERNING THE USE OF PRODUCTS MANUFACTURED OR MARKETED BY OTHER COMPANIES WHICH ARE LABELED FOR USE IN ROUNDUP READY® CROPS. MONSANTO SPECIFICALLY DISCLAIMS ALL RESPONSIBILITY FOR THE USE OF THESE PRODUCTS IN ROUNDUP READY® OR GENUITY® ROUNDUP READY 2 YIELD® CROPS. ALL QUESTIONS AND COMPLAINTS ARISING FROM THE USE OF PRODUCTS MANUFACTURED OR MARKETED BY OTHER COMPANIES SHOULD BE DIRECTED TO THOSE COMPANIES.
- Performance Series™ Sweet Corn**
- To read and follow the TUG and to abide by and implement Insect Resistance Management requirements on the product tag as may be amended from time to time, which are incorporated into and are a part of this Agreement. Grower must comply with the requirements set forth in the TUG and the tag, and should follow the best management practices, recommendations and guidelines provided in those documents.
 - To direct any fresh produce from Performance Series™ Sweet Corn for sale or use in the U.S., Canada and Mexico. It is a violation of national and international laws to move material containing biotech traits across boundaries into nations where import is not permitted. Grower must talk to Grower's buyer to confirm their uses of this product.
- 5. GROWER RECEIVES FROM MONSANTO COMPANY:**
- A limited use license to purchase and to plant Seed pursuant to the terms of this Agreement in the United States of America, comprised of the 50 states and the District of Columbia, except in any state or county where the products do not have all the necessary approvals and to apply Roundup® agricultural herbicides and other authorized non-selective herbicides over the top of Roundup Ready®, Genuity® Roundup Ready® or Performance Series™ Sweet Corn crops. Check with your local Monsanto representative if you have questions about the approval status in your state. Monsanto retains ownership of the Monsanto Technologies including the genes (for example, the Roundup Ready® gene) and the gene technologies. In purchasing seed containing the Monsanto Technologies, Grower solely receives the right to use the Monsanto Technologies subject to the conditions specified in this Agreement.
 - Monsanto Technologies are protected under U.S. patent law. Monsanto licenses the Grower under applicable U.S. patents (other than the Dow AgroSciences Patent Rights), to use Monsanto Technologies subject to the conditions listed in this Agreement. Dow AgroSciences LLC and Agrigenetics, Inc. (collectively "Dow AgroSciences") licenses the Grower under its applicable U.S. patents (the "Dow AgroScience Patent Rights") to use Dow AgroSciences' Event TC 1507 and Event DAS 591227 to the extent either is present in any SmartStax® Seed being obtained by Grower pursuant to this Agreement. Monsanto being authorized to act on Dow AgroSciences' behalf for this Agreement, subject to the conditions listed in this Agreement. These licenses do not authorize Grower to plant Seed in the United States that has been purchased in another country or plant Seed in another country that has been purchased in the United States. Grower is not authorized to transfer Seed to anyone outside of the U.S.
 - Enrollment for participation in Roundup Ready PLUS® Weed Management Solutions.
 - A limited use license to prepare and apply on glyphosate-tolerant soybean, cotton, alfalfa, or canola crops (or have others prepare and apply) tank mixes of, or sequentially apply (or have others sequentially apply), Roundup® agricultural herbicides or other glyphosate herbicides labeled for use on those crops with quizalofop, clethodim, sethoxydim, fluzilofop, and/or fenoxaprop to control volunteer Roundup Ready® Corn 2 corn in Grower's crops for the 2014 growing season. However, neither Grower nor a third party may utilize any type of co-pack or pre-mix of glyphosate plus one or more of the above-identified active ingredients in the preparation of a tank mix for use on glyphosate-tolerant soybean, cotton, alfalfa, or canola crops.
- 6. GROWER UNDERSTANDS:**
- Monsanto Company is a member of Excellence Through Stewardship® (ETS). Monsanto products are commercialized in accordance with ETS Product Launch Stewardship Guidance, and in compliance with Monsanto's Policy for Commercialization of Biotechnology-Derived Plant Products in Commodity Crops. Any crop or material produced from these products can only be exported to, or used, processed or sold in countries where all necessary regulatory approvals have been granted. It is a violation of national and international law to move material containing biotech traits across boundaries into nations where import is not permitted. Growers should talk to their grain handler or product purchaser to confirm their buying position for these products. Excellence Through Stewardship® is a registered trademark of Biotechnology Industry Organization.
 - Performance Series™ Sweet Corn, Genuity® Roundup Ready® Alfalfa and Genuity® Roundup Ready® Flex Pima cotton are subject to specific product export stewardship requirements.
 - Insect Resistance Management: When planting any YieldGard® brand corn products, Genuity® brand corn products or Genuity® Bollgard II® cotton products, Grower must implement an IRM program according to the size and distance guidelines specified in the IRM Grower Guide, including any supplemental amendments. Grower may lose Grower's limited use license to use these products if Grower fails to follow the IRM program required by this Agreement. When planting Performance Series™ Sweet Corn growers must implement the IRM program outlined on the product tag.
 - Crop Stewardship & Specialty Crops: Refer to the section on Coexistence and Identity Preservation in the TUG for applicable information on crop stewardship and considerations for production of identity preserved crops.

Thank you for choosing our advanced technologies. We look forward to working with you in the future. If you have any questions regarding the Monsanto Technologies or this license, please call 1-800-768-6387.

ALWAYS READ AND FOLLOW PESTICIDE LABEL DIRECTIONS. Roundup Ready® crops confer genes that confer tolerance to glyphosate, the active ingredient in Roundup® brand agricultural herbicides. Roundup® brand agricultural herbicides will kill crops that are not tolerant to glyphosate. Bollgard II®, DroughtGard™, Genuity®, Performance Series™, and YieldGard® are registered trademarks of Monsanto Technology LLC. Roundup Ready®, Roundup Ready 2 Yield®, Roundup Ready®, Roundup®, Genuity®, YieldGard®, DroughtGard™, DroughtGard™, YieldGard™, and YieldGard™ are trademarks of Monsanto Technology LLC. YieldGard™ and YieldGard™ are the Water Droplet Design™ are registered trademarks of Bayer. Herculex® is a registered trademark of Dow AgroSciences LLC. All other trademarks are the property of their respective owners. ©2013 Monsanto Company. 111-091202E(S) SA00138421

Distribution: White to Monsanto, Yellow to Dealer, Pink to Grower

Appendix M: 2015 Country Ranking by IPR Score⁸⁴⁷



⁸⁴⁷ *International Property Rights Index: 2013 Report* (2013) online: Property Rights Alliance <<http://internationalpropertyrightsindex.org>>.