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Openness and the Governance of Human Stem Cell Lines: A Conceptual Approach

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Declaration

This is to certify that the work contained within has been composed by me and is entirely my own work. No part of this thesis has been submitted for any other degree or professional qualification.

Signed:

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Abstract

My research examines the extent to which features of 'openness' might usefully contribute to mechanisms of governance of human stem cell lines, with a view to the production of therapeutic stem cell treatments for the provision of health benefits. The impetus for the project is the UK Stem Cell Bank, a national repository for stem cell lines and the focal point of a unique set of publicly supported, non-statutory arrangements for the informal (but mandatory) oversight of human embryonic stem cell lines (hESCs) in the UK. The sharing of stem cells through this mechanism promotes public confidence in embryo and stem cell research, and supports research by making (ethically-sourced and quality-controlled) human stem cell lines widely available to researchers, but the structure and functions of the Bank also impose constraints on the imminent commercial development and manufacture of stem cell therapies for human application. My thesis examines the role of 'openness' in systems of governance designed to facilitate not just research but the whole trajectory of stem cell technology, from research to production and delivery of clinical treatments. What is openness and what function does it have in purposive attempts to design mechanisms that will advance stem cell technology?

The bulk of my thesis maps out the conceptual foundations upon which systems of governance for the production of stem cell therapies may be grounded. It does not address the ethical and social debate surrounding embryo research and the embryonic derivation of stem cell lines, which are legally permissible in the UK. In Part I, I frame the problem of governance of ongoing use of stem cell lines as part of a larger policy endeavour related to the provision of public goods. Secondly, I propose a conception of reflexive governance that is capable of facilitation of technology in a multi-faceted heterogeneous environment. Part II explores traditional narratives of openness in science and technology, and how they might be reconceived in the context of modern scientific technology. In Part III, I apply my conception of facilitative governance to collective strategies or 'commons' approaches to facilitative governance. I then identify its applicability for the present UK system governing stem cell lines, and for the proposition of alternative structures and processes that might be better able to achieve the policy goal of provision of health benefits through delivery of therapeutic stem cell treatments.

Lay Summary

My thesis is about how human stem cell lines should be 'governed' in order to best facilitate the production of medical therapies. The UK Stem Cell Bank is an example of a type of governance mechanism in which the sharing of an asset with other researchers for the promotion of research ('openness') has an adverse effect on the potential for production of the goods that the research is intended to promote. It raises a wider set of issues about the tension between the need for disclosure ('openness') in the public system of science to enable the growth of knowledge, and the need for private companies to maintain control over knowledge and other resources ('exclusivity') in order to produce commercial products. The development of goods for the benefit of society ('public goods' such as stem cell therapies) requires the promotion of both scientific understanding and technological utility, and the task of governance is to work out how to promote them equally.

The first part of my thesis describes the current regulatory structure for stem cells in the UK, and sets out what I mean by 'public goods' and 'facilitative governance', which includes informal or social impacts on behaviour as well as government regulation. Most of my thesis is spent developing an accurate picture of 'scientific technology' in which there is increasing integration of science with technology, and overlap between the once separate systems of 'academic science' for production of pure knowledge, and 'private industrial technology' for production of practical knowledge and goods. My thesis suggests that in order to work out how to facilitate 'scientific technology' we ought to stop thinking of them as two separate systems, one of which is open and the other closed. I propose an integrated way of thinking about it to demonstrate how research, innovation and utilisation of resources for all purposes co-exist, and how 'openness' is achieved by exchange, through mutually negotiated terms of access to property, collective arrangements for sharing resources, and networks of interactive relationships.

In the last section of my thesis, I apply my concept of scientific technology to some collective strategies, and finally, I go back to the UK Stem Cell Bank to ask how my conceptualisation enables us to assess its functions.

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INTRODUCTION

Governance

The immense promise of human stem cells as a platform for development of therapeutic treatments that has been reported in recent years has raised much academic and policy debate related to the governance of their use. Chief among these is the debate over the use of human embryos in the cultivation of stable pluripotent cell lines, which provide the primary material for the generation of most types of tissue in the human body. The ethical, legal and social questions raised by this debate are fundamental and divisive and colour all aspects of policy-making related to research and development in the field of stem-cell based regenerative medicine. They persist, even though there are now technical means of inducing embryo-like pluripotency in cells of non-embryonic origin.

Important as the debate over embryo use is, the questions that it raises are not my questions. My thesis starts from the premise that – despite the above ethical concerns - the legal policy position taken in the United Kingdom is to permit the derivation of stem cell lines during the course of embryo research, which may be undertaken for the purpose of enabling development of treatments for serious disease. The aim of my thesis is to consider how the ongoing *use* of established stem cell lines, legitimately derived from embryos donated in accordance with statutory consent requirements, is to be governed in order to best *facilitate* the delivery of therapeutic products and concomitant benefits for individual and population health. This in itself is an important ethical and legal policy question, but not one which has received sufficient attention to date. I argue that, having taken the decision to permit embryo research for this purpose, it is incumbent upon policymakers to follow through with the support that is necessary to maximise the benefits of stem cell technology by fostering an environment conducive to the production of public goods. This is however only part of the focus of my work.

Openness

The focus of my consideration of facilitative governance is the concept of 'openness', which is the central element of a different type of ethical debate in relation to public support for science and the private production of technological goods. Questions associated with the notion of openness in the context of stem cell technology were brought to my attention by the existence of the UK Stem Cell Bank, a national repository for human stem cell lines, established as part of a system of informal oversight of cell lines of embryonic origin, instituted on primarily ethical grounds. The questions addressed by my thesis have come out of an examination of the unique features of the Bank as a vehicle for mandatory and voluntary sharing of stem cell lines among researchers, and the non-statutory power of its governing body to determine the ongoing uses to which stem cell lines disseminated by the Bank are put. These features were not problematic at the inception of the Bank, but now that the industrial production of the first clinical therapies involving embryonic stem cells appears imminent, they raise concerns about certain disincentives for private commercial activity in the field. This particular example is, moreover, simply one instantiation of a much wider set of questions about the nature of policies and laws that might facilitate the delivery of biotechnological products.

Cell developers, who are currently recipients of public funding, suggest the 'one-size-fits-all' banking requirement - by which they are required to relinquish their exclusive control over all of the cells derived from any one embryo and all cell lines generated under embryo licence - adversely affects their potential for involvement in the anticipated for-profit production of large quantities of stem cells as basic materials of manufacture. They argue that the potential for reputational damage to a particular cell line as a result of its widespread use by public sector researchers poses a barrier to its uptake by the large pharmaceutical corporations who are most likely to invest in the development of clinical products. Over time, the identity of the UKSCB has evolved to reflect, in addition to its primary ethical mandate, a predominant support for 'research', but although there has been express willingness and certain adaptations by the Bank to take into account commercial interests, there has been no movement on the exclusivity question. Any further impediment to

commercial activity is unwelcome in a field already encumbered by the huge upfront costs of cell line derivation and clinical trials, uncertainty as to the outcomes of developmental research, an absence of reliable precedents for risk assessment of cell-based products, and the improbability of patentability of cell lines, techniques and products in Europe. The example of the UKSCB therefore serves as an ideal platform upon which to begin an enquiry into a set of core and as yet unanswered research questions about how these multiple fields of influence on scientific and technological development can be managed. Although this thesis begins with the example of the Bank, its primary aim is to address the much broader set of questions that are in play.

Accordingly, my thesis does not provide an analysis of the UK Stem Cell Bank *per se*, but uses this case study as a way to address these broader questions. The Bank provides an example of a situation in which the proposition of the sharing of resources for the enhancement of research has the potential to inhibit the industrial development of the proprietary outcomes that the research aims to advance.

Questions

My questions are:

1. What is the relevance of appealing to openness for modes of governance that attempt to facilitate the production of public goods such as therapeutic stem cell treatments?

2. How might the concept and functions of 'openness' be reconceived in light of recent changes - the proprietisation of public science, the integration of science and technologies and organisational diversification - as a foundation for the construction of effective means of facilitation of 'scientific technologies'?

3. If the governance of scientific technologies is not dependent upon a concept of openness rooted in traditional distinctions between 'public' science and 'private' technology, what are the consequences of a reconceptualisation.

Method and approach

My thesis is largely based on desk-based research dealing with primary and secondary literature. Part I of the thesis addresses Governance: the UK regulatory framework for human stem cells, challenges and policy choices related to the provision of public goods, and my understanding of 'facilitative governance' as decentred, purposive and reflexive. In Part II, I examine the literatures pertaining to the 'traditional' models of open science and industrial technology, in an attempt to identify the functions of openness in those enterprises, independent of one another and the issues raised by the intensification of the relationship between them in recent history. My observations in regard to their origins, objectives and ethos shed light on the functions of openness, exclusivity and the interplay between them in each of these systems. These observations inform my analysis and conceptualisation in Chapter 6 of 'scientific technology' as we see it today. This is where the essence of the original contribution of this thesis lies. I consider that facilitation should be undertaken on the basis of an understanding of the whole, rather than a set of isolated components, necessitating an integrated conceptual framework that encompasses public and private sector involvement, scientific and technical research, commercial development and industrial production. In Part III, I use my integrated conception of scientific technology to assess collective strategies for governance that might have relevance for the facilitation of biotechnologies. Finally, I consider the implications of my perspective on scientific technology for stem cell technology and the UK Stem Cell Bank, thereby completing the circle of this thesis from concrete example through a reconceptualisation and a return to examine the consequences of my contribution.

Contribution

My main contribution is the proposition of an integrated conceptualisation of 'scientific technology' that does not reflect the dichotomy between the public system of open science and private industrial technology. The purpose of my conceptualisation is to provide an accurate representation of the modern environment that encompasses scientific and technological objectives and activities, as a basis for

devising effective means of facilitation of both research and productivity. I contend that the discourse around facilitation in governance of biotechnologies is inhibited by the perpetuation of oppositional value-laden caricatures of science and technology based on clear fault lines - between public and private, open and exclusive, communal and proprietary – that are not reflected in reality. These caricatures reinforce polarised perspectives that obscure the real problems and permit the prioritisation of science, openness and the public domain over technological utility, property and the market. Unfortunately, as a consequence, and in any policy environment they prevent the equal promotion and facilitation of all aspects of scientific technology that is necessary to ensure not only the advance of knowledge but its expression in tangible goods and products that provide highly sought after social benefits.

My integrated conceptualisation of scientific technology overcomes this polarisation. It is integrated by the synergy between science and technology, research and innovation resulting in new knowledge, the utilisation of resources, and a domain of interactivity and exchange across the public and private sectors. Resources are available and accessible in the domain of exchange, subject to the legal and social norms that shape them. Terms of access replace 'openness' and are negotiated between actors by all means, from commons arrangements to contracts, in complex networks of exchange of knowledge or technology. The ethos of this system is determined by the attitudes, policies and negotiations of the institutions, formal or informal, that govern the activities of actors in the system. By construing scientific technology in this way, the interests of all actors in the production of public goods may receive equal consideration, value and encouragement.

I submit that my conception of scientific technology and the public domain of exchange is preferable to the current appeals to a concept of openness that is of limited use outside of a narrowly defined traditional conception of open science, and advocate its adoption in order to instigate a move away from polarised and political posturing around openness.

PART I: GOVERNANCE

Introduction to Part I

In this Part, I define the scope and nature of the governance enterprise. Chapter 1 describes the existing regulatory framework for the production of stem cell lines and therapeutic stem cell-based products in the United Kingdom, as well as the informal system established for additional oversight of the ongoing use of human embryonic stem cell lines. Although the main features of the Stem Cell Steering Committee and the UK Stem Cell Bank are set out in some detail, I do not provide a comprehensive analysis of the oversight mechanism, or make any specific recommendations for improvement of the governance of the banking of embryonic stem cells. The UK Stem Cell Bank nevertheless plays an important role in my thesis. By providing me with an opportunity for examination of its structure and functions, it enabled me to identify the practical and conceptual tensions within it, which gave rise to my key questions about openness and exclusivity in the governance of biotechnologies. I found it necessary to formulate these questions broadly - in relation to the production of *public goods such as* stem cell therapies*,* a reconception of 'openness' in light of changes in the proprietisation and integration *of science and technologies,* and the consequences of such a reconceptualisation for *'scientific technologies'* – in order to address the underlying relationship between open science and proprietary technology.

An understanding of openness and exclusivity in science and technology was intended to be a preliminary step toward the development of a specific model or conceptual framework for the assessment or design of governance structures in order to facilitate stem cell technology. Instead it became the main contribution of my thesis: the formulation of an *integrated conceptualisation of 'scientific technology'*, which is foundational to such models or frameworks. which may be devised for use with respect to a wider range of technologies than just stem cell technology. It will serve, outside the scope of this thesis, as a platform for the evaluation and development of the USKCB, but also provides a conceptual basis for designing and

devising structures and functions for the facilitative governance of other emerging technologies.

In Chapter 2, I define the problem of governance as the provision of public goods. As the overarching policy goal is the delivery of the health benefits associated with clinical stem cell therapies, I construe the enterprise of governance as not simply the governance of the use of stem cell lines, but the facilitation of the public good of health. Health is not only a complex public good, but a *global* public good, comprising other goods and services and involving multiple social actors, public and private, with national and international implications. Provision of such public benefits requires the ability to deal with the innate resistance of public goods to commercial production and the complex coordination problems that arise at many levels.

In Chapter 3, I conceptualise the type of 'governance' equipped to facilitate the provision of health benefits as decentred, purposive, and reflexive. It contemplates purposive attempts to shape social behaviour, but recognises that such initiatives do not originate solely with the state and that informal arrangements can be an effective means of tailoring solutions to problems that government alone would have difficulty addressing. Decentred governance also enhances reflexivity: the capacity for continual reassessment and adaptation of its own means and methods, an attribute that is highly relevant in the context of rapidly changing technologies. I adopt this conceptual foundation as appropriate for the design of innovative arrangements to solve certain problems of emerging technologies, including the need to facilitate disclosure and exchange of information, data and materials among researchers in conjunction with the private production of commercially viable products.

By the end of this Part of the thesis, the reader will have an appreciation of the complex legislative and informal regulatory environment governing the use of stem cell lines in the UK, the overarching enterprise of governance for the facilitation of public goods, and my conceptualisation of the type of governance that is sought for the purposes of facilitation of emerging technologies such as stem cell therapies. This prepares the reader for Part II, in which I analyse the concept of openness, and

how it relates to facilitative governance, in the context of scientific technologies in the modern context.

Chapter 1. STEM CELLS IN THE UK

1.1 Introduction

The governance of embryonic stem cell lines in the UK is undertaken through formal legislative frameworks which address quality, safety and production of goods, as well as the informal oversight mechanism implemented by the Stem Cell Steering Committee through the UK Stem Cell Bank. The political legitimacy of the non-statutory authority adopted by the Steering Committee is not addressed as such in this thesis, but the objectives and functions of the UKSCB, and their evolution over time, raise questions regarding the efficacy of this particular form of governance, which is implemented by both state and non-state actors.

There is, in particular, a demonstrable imbalance in the public interests promoted through the Bank: the assurance of public confidence in the use of the products of embryos, and support for basic medical research, are prioritised in relation to the promotion of a commercial environment suited to sustainable product development. The value judgments that subordinate commercial activity to that which is scientific or social are problematic for my conception of 'scientific technology', which I describe in Chapter 6 as a synergistic undertaking that is reliant upon the complementary strengths of science, social perceptions and the marketplace. To understand the nature of this tension within the Bank, I first set out the properties of stem cells, and the prospects and problems that they offer.

Stem cell technology

Stem cells, which reside within many adult tissues, have unique properties: they are unspecialised as to tissue type, they have the capacity to proliferate in this state for long periods, and they are able to generate specialised cells and tissues through a process of differentiation. The value of this technology lies in the characteristic *pluripotency* evidenced by stem cells in the earliest stages of human embryonic development, by which they are able to differentiate into all of the various tissues of the human body. Techniques that enable scientists to isolate and manipulate

pluripotent cells of embryonic origin, and more recently to induce a state of embryo-like pluripotency in cells obtained from adult tissue, creates the potential for cultivation of most cell types in the human body and treatment of a wide range of diseases and conditions including Alzheimer's, Duchenne's muscular dystrophy, stroke, heart disease, diabetes, and arthritis. Given the capacity of human embryonic stem cells (hESCs) to replicate indefinitely,[1] and current developments resulting in increasingly reliable methods for directing cell differentiation, there is potential for scalable manufacturing of therapies for repair or replacement of tissues impaired by damage or disease.[2]

The fact that the embryo does not survive the disaggregation of the blastocyst is a source of irresolvable social debate,[3] despite the fact that embryos used in UK research are donated with informed consent, are surplus to the needs of the donor in relation to the fertility treatment for which they were created, and would otherwise have been permitted to perish. The induction of pluripotency in adult or 'somatic' cells does not entirely address the ethical problem for, although they instil greater social confidence than their embryonic counterparts, induced pluripotent stem (iPS) cells are capable of generating germ cells that can produce new embryos which could serve as a further source of stem cells.

Pluripotent stem cells are capable of significant contribution in three main areas of work: cell differentiation, the testing of new drugs, and the creation of cell-based

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[1] For a useful stem cell science primer, see US National Institutes of Health and US Department of Health and Human Services, 'Stem Cell Basics' in *Stem Cell Information*, available at http://stemcells.nih.gov/info/basics/, accessed 8 August 2012.

[2] *Ibid.*

[3] Hall ZW (2009) 'Stem Cell Research in California: The Intersection of Science, Politics, Culture and Law' 10 *Minnesota Journal of Law, Science and Technology* 1; Bruce A and Harmon SHE (2009) 'Discursive Typologies and Moral Values in Stem Cell Politics, Regulation and Commercialisation: Some Preliminary Observations' 6:2 *Journal of International Biotechnology Law* 61; De Lacey S (2006) 'Embryo Research: Is Disclosing Commercial Intent Enough?' 21:7 *Human Reproduction* 1662; Devolder K (2005) 'Human Embryonic Stem Cell Research: Why the Discarded-Created Distinction Cannot be Founded on the Potentiality Argument' 19:2 *Bioethics* 1467; Caulfield T and Brownsword R (2005) 'Human dignity: a guide to policy making in the biotechnology era?' 7:1 *Nature Reviews Genetics* 72; 'Jones D (2005) 'Dunstan, The Embryo and Christian Tradition' *Triple Helix* 10; Brownsword R (2003) 'Bioethics Today, Bioethics Tomorrow: Stem Cell Research and the Dignitarian Alliance' 17 *Notre Dame Journal of Law, Ethics and Public Policy* 15; Muscati SA (2002) 'Defining a New Ethical Standard for Human In Vitro Embryos in the Context of Stem Cell Research' 26 *Duke Law and Technology Review* 1; Holm S (2002) 'Going to the Roots of the Stem Cell Controversy' 16:6 *Bioethics* 493;

therapies. First, an understanding of *cell differentiation* is fundamental to advanced knowledge of human development and the invention of techniques for direction of the process; more research in this area is needed to provide information about how diseases arise[4] and to suggest new strategies for therapy. At present, scientists know that cell division and specialisation are controlled by molecular and genetic signals, and have identified some of the specific growth factors, such as the cytokines of hematopoietic (blood) stem cells,[5] which give rise to these signals. Current research seeks to identify more of these factors, to understand precisely *how* signalling directs cell development, and to devise appropriate techniques for safe introduction of the factors into the cells in order to facilitate predictable control of cell proliferation and differentiation. Significant advances have been made in the control of stem cell differentiation into specialised cells including cardiomyocytes (heart cells),[6] hepatocytes (liver cells),[7] neural (nerve) cells[8] and pancreatic cells.[9]

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[4] Lengerke C and Daley GQ (2009) 'Disease Models from Pluripotent Stem Cells' 1176 *Annals of the New York Academy of Sciences* 191.

[5] Ogawa M (1993) 'Differentiation and proliferation of hematopoietic stem cells' 81 *Blood* 2844.

[6] Lian X, Zhang J, Azarin SM, Zhu K, Hazeltine LB, Bao X, Hsiao C, Kamp TJ and Palecek SP (2013) 'Directed cardiomyocyte differentiation from human pluripotent stem cells by modulating Wnt/β-catenin signaling under fully defined conditions' 8 *Nature Protocols* 162; Ou D-B, Zeng D, Jin Y, Liu X-T, Teng J-W et al (2013) 'The Long-Term Differentiation of Embryonic Stem Cells into Cardiomyocytes: An Indirect Co-Culture Model' 8:1 *PLoS ONE*, available at http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0055233, accessed 7 May 2013; Kumar D, Kamp TJ, LeWinter MM (2005) 'Embryonic stem cells: differentiation into cardiomyocytes and potential for heart repair and regeneration' 16:2 *Coronary Artery Disease,* 111.

[7] Zhou W, Hannoun Z, Jaffray E, Medine CN, Black JR, Greenhough S, Ross JA, Forbes SJ, Wilmut I, Iredale JP, Hay RT, Hay DC (2012) 'SUMOylation of HNF4α Regulates Protein Stability and Hepatocyte Function' 145 *Journal of Cell Science* 3630; Pernagallo S, Tura O, Wu M, Samuel K, Diaz-Mochon JJ, Hansen A, Zhang R, Jackson M, Padfield GJ, Hadote PWF, Mills NL, Turner ML, Iredale JP, Hay DC, Bradley M (2012) 'Identification of a pro-angiogenic and anti-thrombotic synthetic biopolymer able to accelerate endothelialisation of intra-vascular devices' 1:5 *Advanced Healthcare Materials* 646.

[8] Shimomura A and Hashino E (2013) 'Epigenetic Regulation of Neural Differentiation from Embryonic Stem Cells' in Wislet-Gendebien S (ed) (2013) *Trends in Cell Signaling Pathways in Neuronal Fate Decision*, InTech, available at http://www.intechopen.com/books/trends-in-cell-signaling-pathways-in-neuronal-fate-decision/epigenetic-regulation-of-neural-differentiation-from-embryonic-stem-cells, accessed 7 May 2013; Zou Y, Chiu H, Zinovyeva A, Ambros V, Chuang D-F and Chang C (2013) 'Developmental decline in neuronal regeneration by the progressive change of two intrinsic timers' 340 *Science* 372, available at http://www.stembook.org/node/879, accessed 7 May 2013; Shi Y, Kirwan P and Livesey FJ (2012) 'Directed differentiation of human pluripotent stem cells to cerebral cortex neurons and neural networks' *7 Nature Protocols* 1836; Baharvand H, Mehrjardi N-Z, Hatami M, Kiani S, Rao M and Haghighi M-M (2007) 'Neural differentiation from human embryonic stem cells in a defined adherent culture condition' 51 *International Journal of Developmental Biology*, 371.

[9] Cho CH-H, Hannan NR-F, Docherty FM, Docherty HM, Joao Lima M, Trotter MWB, Docherty K, Vallier L (2012) 'Inhibition of activin/nodal signalling is necessary for pancreatic differentiation of human

Secondly, the ability to direct the differentiation of stem cells into specialised tissues, and to cultivate stable populations of terminally differentiated cells, provides a reliable basis for the toxicity and efficacy studies involved in the *discovery and development of new drugs.*[10] The use of stem cells in the cultivation of tissues not only complements, reduces or replaces animal testing, but ensures that a nuanced range of human tissue can be produced. The differentiation of stem cells into a variety of bodily tissues expands the number of tissue types available for testing, but further diversification occurs as a result of advances in the generation of iPS cells, which enable scientists to derive the stem cells from normal or diseased tissue recruited from an array of patient or disease cohorts that exhibit specific genetic or phenotypic characteristics. The result is the performance of drug screening on a broad spectrum of tissue types, which permits the development of pharmaceuticals that are targeted to specific diseases and patient cohorts, thus enhancing drug efficacy and the potential for delivery of personalised medicine.[11] Support for such diversity and the availability of iPS cells to facilitate research is reflected in the recent EU call for proposals[12] for establishment of a European Bank for Induced pluripotent Stem Cells (EBiSC), which will be funded by joint undertaking of the EU Innovative Medicines Initiative (IMI) and the European Federation of Pharmaceutical Industries and Associations (EFPIA). The call requires that the winning consortium is to create a financially sustainable vehicle for delivery of a diverse collection of iPS cells, and bespoke cell services, through one centralised facility, to meet the needs of the iPS community in Europe and beyond.[13]

Thirdly, stem cells can be used as basic materials in *cell-based therapies for human application* that may alleviate the demand for donation of transplantable organs and tissues and expand the arena of treatable conditions. To achieve these ends,

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pluripotent stem cells' 55:12 *Diabetologia* 3284.

[10] Kitambi SS, Chandrasekar G (2011) 'Stem cells: a model for screening, discovery and development of drugs' 4 *Stem Cells and Cloning: Advances and Applications* 51, available at http://www.dovepress.com/stem-cells-a-model-for-screening-discovery-and-development-of-drugs-peer-reviewed-article-SCCAA-MVP, accessed 7 May 2013.

[11] Kitambi SS et al (2011) Stem cells: a model for screening, discovery and development of drugs.

[12] See IMI 8th Call for Proposals 2012 Topics Text, IMI-GB-DEC-2012-25-Annex 1, available at http://www.imi.europa.eu/sites/default/files/uploads/documents/8th_Call/IMI_8thCallText_FINAL.pdf, accessed 7 May 2013. b

[13] *Ibid.*

scientists must be able to manipulate cells to ensure that they differentiate into the desired cell type, survive transplantation without rejection, integrate into surrounding tissue, and function appropriately without harming the recipient. The use of stem cells as materials in the development of therapies is fundamental to the practice of regenerative medicine (RM) as I discuss in the next section.

Regenerative medicine

Stem cell research is closely aligned with the field of regenerative medicine, which emphasises the use of whole human cells, as distinct from small chemicals, larger biological molecules or medical devices. The therapeutic use of cells began over 50 years ago with transplantation of bone marrow and haematopoietic (blood) stem cells, but its scope has expanded dramatically with advances in 'classic tissue engineering' of skin, bone and cartilage[14] and tools for cultivation of hESCs. The objective of RM is the replacement, regeneration[15] and possibly repair[16] of human cells, tissues and organs by provision of cells - particularly cells that can stimulate wider regeneration - to restore or establish normal function.[17] Pluripotent cells can be used as 'pure' therapies, but RM generally delivers cells in conjunction with other technologies, including stem and progenitor cell therapy, tissue engineering, materials science and genetics. It may also use non-cellular materials such as soluble molecules and gene therapy as vehicles for transference of therapeutic material to patients.[18] It is the combination of technical approaches, often stimulating and

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[14] Martin P, Hawksley R and Turner A (2009) *The Commercial Development of Cell Therapy – Lessons for the Future, Survey of the Cell Therapy Industry and the Main Products in Use and Development, Part 1: Summary of findings*, EPSRC Grand Challenge, remedi, Institute for Science and Society, University of Nottingham, 8.

[15] Daar AS and Greenwood HL (2007) 'A proposed definition of regenerative medicine', 1 *Journal of Tissue Engineering and Regenerative Medicine* 179, 181; the authors define RM on the basis of points of consensus identified by comparison of a number of definitions.

[16] Mason C and Dunnill P (2008) 'A brief definition of regenerative medicine', 3:1 *Regenerative Medicine* 1, 4, the authors exclude 'repair', as it is classically considered to involve synthesis of scar tissue instead of regeneration of normal tissue and restoration of normal structure and function, whereas Daar and Greenwood consider that cell regeneration may be the vehicle for repair.

[17] *Ibid.*

[18] Daar AS and Greenwood HL (2007), 181.

supporting the self-healing capacity of the body, that takes it beyond traditional transplantation and replacement therapies.[19]

At present, two therapies incorporating embryonic stem cells for human application have reached Phase 1 clinical trials. Geron began trials in 2010 in relation to a hESC-based treatment containing oligodendrocyte (nerve) progenitor cells (OPC), which was injected into four patients with complete thoracic spinal cord injuries. Although no serious adverse events were indicated in the Phase 1 (safety) trial,[20] Geron decided in 2011 not to proceed with Phase 2 (efficacy) testing, citing 'capital scarcity and uncertain economic conditions' as the reason for its move to sell the embryonic stem cell aspect of its business, and focus on other work.[21] The Geron work has not been completely abandoned however; in Jan 2013, BioTime Acquisitions Corp (BAC) reportedly entered into formal arrangements with Geron to acquire the embryonic stem cell program, including more than 400 patents and Geron's Phase 1 clinical trials for treatment of acute spinal cord injury.[22]

The second embryonic stem cell therapy to reach Phase 1 trials is a therapy developed by Advanced Cell Technology Inc (ACT) for the treatment of two types of macular eye disease - the leading cause of blindness in the developed world.[23] Based in Massachusetts USA, ACT has initiated three Phase 1/2 clinical trials (two in the U.S. and one European trial), to test the *safety and tolerability* of transplantation of hESC-derived retinal pigment epithelial (RPE) cells. The first two trials were commenced at the University of California in Los Angeles (UCLA) in November 2010 and January 2011, respectively, each involving the treatment of a single patient

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[19] *Ibid.*

[20] Presentation of Geron to the Pre-Conference Symposia of the joint 2011 American Congress of Rehabilitation Medicine and American Society of Neuro-Rehabilitation Annual Meeting.

[21] Flatow I, 18 November 2011 'Geron to End Embryonic Stem Cell Research' *NPR, Talk of the Nation,* available at http://www.npr.org/2011/11/18/142512098/geron-to-end-embryonic-stem-cell-research accessed 8 May 2013; Walsh F, 15 November 2011 'Stem Cell Trial Halted' *BBC News*, available at http://www.bbc.co.uk/news/health-15740133, accessed 8 May 2013.

[22] Fitzhugh M, 11 January 2013, 'Biotime Picks Up Geron's Stem Cell Assets' *The Burrill Report,* available at http://www.burrillreport.com/article-biotime_picks_up_geron's_stem_cell_assets.html, accessed 8 May 2013.

[23] Schwartz SD, Hubschman J-P, Heilwell G, Franco-Cardenas V, Pan CK, Ostrick RM, Mickunas E, Gay R, Klimanskaya I, Lanza R (Jan 2012) 'Embryonic stem cell trials for macular degeneration: a preliminary report', *The Lancet* 713.

in a single cohort (or group), the first with Stargardt's disease or macular dystrophy, and the second with age-related macular degeneration. In January 2012, preliminary results of the U.S. trials indicated that cells had attached and continued to persist without hyperproliferation or abnormal growth.[24] Further patients have since been added to these trials to make up a complement of four cohorts of three patients, each receiving increasing dosages of cells: the first cohort received 50,000 cells, the second 100,000 cells, the third 150,000 cells and the final group/cohort will receive 200,000 cells. The third ACT trial, involving 12 Stargardt patients, starting in March of 2012, and based at Moorfields Eye Hospital in London, follows a similar regime. The seventh patient (first in the third cohort) in this European trial has now received treatment, and NHS Lothian in Scotland has been approved as a further clinical site for the ACT European trial. The U.S. trials have also been expanded to include a new cohort (2a) for patients with better vision, established at Wills Eye Institute in Philadelphia.[25]

Cell therapy industry

Stem cell technology and RM have not developed in a commercial vacuum, but in conjunction with the cell therapy or 'CT-RM' industry that began in the 1990s with the establishment of firms developing blood therapies, diabetes treatments and first generation tissue engineering. After initial disappointment,[26] there was a shift in 2002-2006[27] toward second generation stem cell-based RM, new disease targets and a new focus on translation, resulting in growth in sales, numbers of patients treated, products in development and staff employed.[28] The industry is now capable of

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[24] *Ibid.*

[25] ClinicalTrials.gov provides information about the ACT Stargardt disease study and concurrent studies in the U.S. and Europe for dry AMD and Stargardt disease, with the following Identifiers: NCT01345006 (U.S. Stargardt disease), NCT01344993 (U.S. dry AMD), and NCT01469832 (European Stargardt disease). See also the Visionaware website: http://www.visionaware.org/blog.aspx?BlogEntryID=695, accessed 8 May 2013.

[26] Lysaght MJ and Hazlehurst AL (2004) 'Tissue engineering the end of the beginning' 10:1/2 *Tissue Engineering* 309.

[27] Martin P, Hawksley R and Turner A (2009), 9.

[28] *Ibid*, 10.

producing a wide variety of cell-based applications[29] including permanent cell-replacement therapies, immuno-modulation cell therapies, transient cell therapies that disrupt the natural progression of diseases, 'organoids' and 'primordia'. Despite advances, however the industry is still encountering challenges to commercial viability and corporate investment.[30] The difficulty in establishing an evidence base for clinical utility, lack of clinical uptake and poor sales creates a significant risk of market failure for most stem cell-based therapies. Effective therapeutic production requires closer collaboration with clinical end-users, funding for clinical studies, more regulatory certainty, clearer reimbursement policies and reduction of costs through development of 'enabling' technologies.[31]

1.2 Regulatory context

The highly complex UK regulatory system governing stem cell research and manufacture[32] has developed organically, in response to technical advances and social debates, and is aimed primarily at ensuring quality and safety at every stage, from basic research to product development, manufacture and marketing. It is based on three main legislative regimes, each administered by a statutory authority. The use of reproductive tissue in fertility treatment and embryo research is governed by the *Human Fertilisation and Embryology Authority* (HFEA);[33] quality and safety in the handling of 'other' human tissue, including stem cell lines intended for human application[34] is regulated by the *Human Tissue Authority* (HTA);[35] and pre-market authorisation of medicines and healthcare products is governed by the Medicines and Healthcare products Regulatory Agency (MHRA). Together the HFEA, HTA and MHRA administer UK legislation that implements European Directives in relation to

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[29] Mason C and Manzotti E (2009) 'Regen: the industry responsible for cell-based therapies' 4:6 *Regenerative Medicine* 783.
[30] *Ibid.*
[31] *Ibid.*
[32] As illustrated by the *Interim UK Regulatory Route Map for Stem Cell Research & Manufacture* published on the MRC website in March of 2009; available at http://www.mhra.gov.uk/Howweregulate/Medicines/Medicinesregulatorynews/CON041337, accessed 13 August 2012.
[33] *The Human Fertilisation and Embryology Act 1990* c. *37*, as amended by *Human Fertilisation and Embrylogy Act 2008* c. 22.
[34] *The Human Tissue (Quality and Safety for Human Application) Regulations 2007* No 1523.
[35] *The Human Tissue Act 2004* c. 30.

tissues and cells[36] and medicinal products for human use.[37] Although a restructuring of the tri-partite system was on the political agenda[38] at the point of submission of this thesis, the government has since decided, following a public consultation during 2012,[39] that the HFEA and the HTA will not be dissolved, nor their functions transferred to the Care Quality Commission (CQC) or the new Health Research Authority (HRA), as originally proposed in its review of public bodies. Instead, the HFEA and HTA will be subject to further assessment with a view to the feasibility of a merger, the streamlining of their activities, or the sharing of membership or leadership functions.[40] In the meantime, these three regimes converge when the cultivation of human stem cell lines results in development of a therapeutic product with potential for human application.

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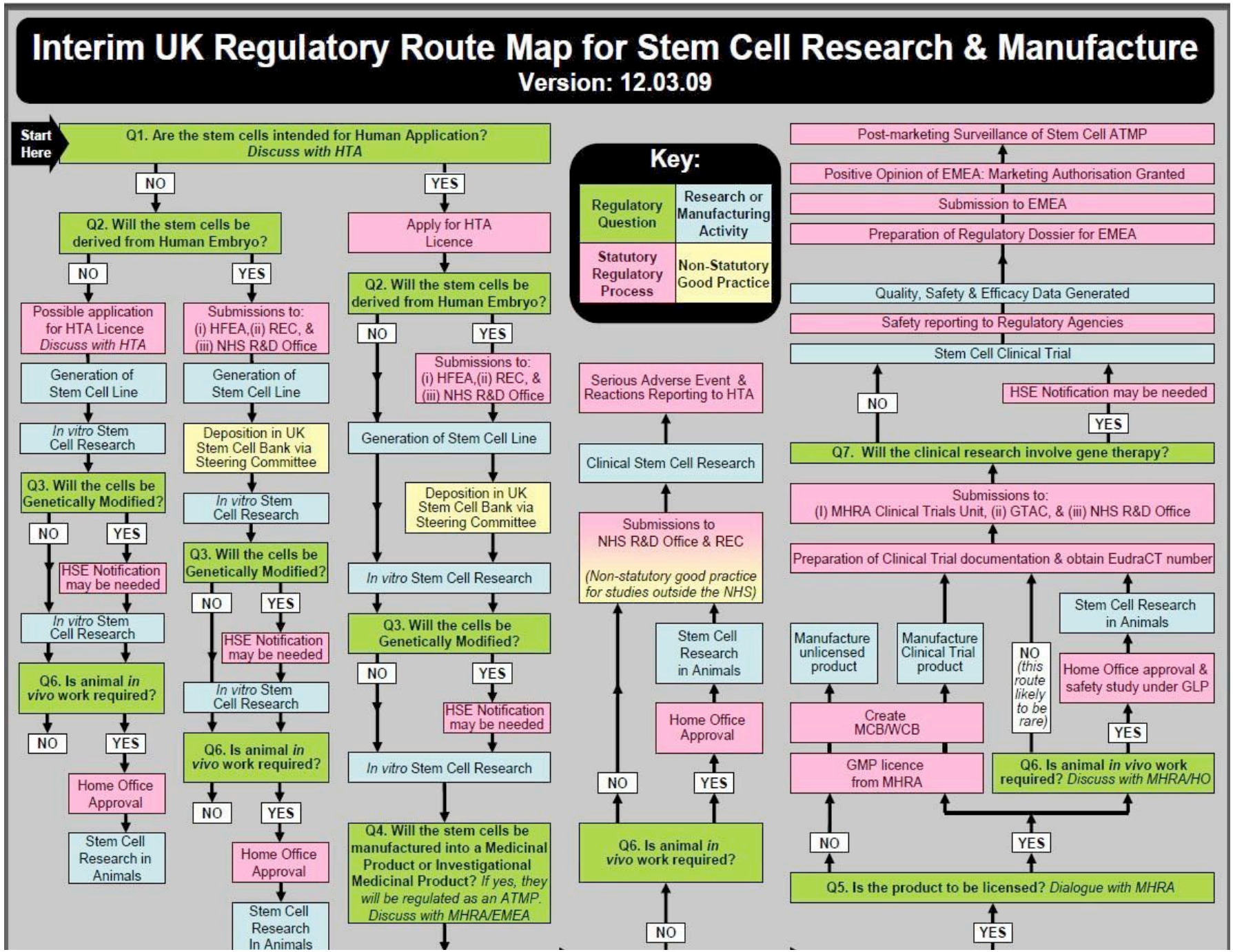
[36] *Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004* on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells.

[37] *Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001* on the Community code relating to medicinal products for human use.

[38] UK Department of Health (2010) *Liberating the NHS: Report of the arm's-length bodies review,* available at https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/152016/dh_118053.pdf.pdf, accessed 8 May 2013; Purvis B, 30 March 2011 'How the HFEA and HTA will be reorganised is still under debate', *Association of Medical Research Charities* available at http://policyblog.amrc.org.uk/2011/03/30/how-the-hfea-and-hta-will-be-reorganised-still-under-debate/, accessed 8 May 2013.

[39] *Department of Health,* Decision on the outcome of the consultation on the transfer of HFEA and HTA functions, 25 Jan 2013, available at http://www.infertilitynetworkuk.com/news/10/Decision%20on%20the%20outcome%20of%20the%20consultation%20on%20the%20transfer%20of%20HFEA%20and%, accessed 8 May 2013; Turner M, 29 January 2013, 'HFEA and HTA to remain separate for now' *Association of Medical Research Charities,* available at http://policyblog.amrc.org.uk/2013/01/29/hfea-and-hta-to-remain-separate-for-now/, accessed 8 May 2013*; BMA: News Views and Analysis*, 28 January 2013 'Regulators Spared from Quango Cull' available at http://bma.org.uk/news-views-analysis/news/2013/january/regulators-spared-from-quango-cull, accessed 8 May 2013.

[40] *Ibid,* BMA: News Views and Analysis, 28 January 2013 'Regulators Spared from Quango Cull'.


Interim UK Regulatory Route Map for Stem Cell Research & Manufacture
Version: 12.03.09
Start Here
Q1. Are the stem cells intended for Human Application? Discuss with HTA
NO
YES
Q2. Will the stem cells be derived from Human Embryo?
NO
YES
Possible application for HTA Licence Discuss with HTA
Generation of Stem Cell Line
In vitro Stem Cell Research
Q3. Will the cells be Genetically Modified?
NO
YES
HSE Notification may be needed
In vitro Stem Cell Research
Q6. Is animal in vivo work required?
NO
YES
Home Office Approval
Stem Cell Research in Animals
Submissions to: (i) HFEA,(ii) REC, & (iii) NHS R&D Office
Generation of Stem Cell Line
Deposition in UK Stem Cell Bank via Steering Committee
In vitro Stem Cell Research
Q3. Will the cells be Genetically Modified?
NO
YES
HSE Notification may be needed
In vitro Stem Cell Research
Q6. Is animal in vivo work required?
NO
YES
Home Office Approval
Stem Cell Research In Animals
Apply for HTA Licence
Q2. Will the stem cells be derived from Human Embryo?
NO
YES
Submissions to: (i) HFEA,(ii) REC, & (iii) NHS R&D Office
Generation of Stem Cell Line
Deposition in UK Stem Cell Bank via Steering Committee
In vitro Stem Cell Research
Q3. Will the cells be Genetically Modified?
NO
YES
HSE Notification may be needed
In vitro Stem Cell Research
Q4. Will the stem cells be manufactured into a Medicinal Product or Investigational Medicinal Product? If yes, they will be regulated as an ATMP. Discuss with MHRA/EMEA
Key:
Regulatory Question
Research or Manufacturing Activity
Statutory Regulatory Process
Non-Statutory Good Practice
Serious Adverse Event & Reactions Reporting to HTA
Clinical Stem Cell Research
Submissions to NHS R&D Office & REC
(Non-statutory good practice for studies outside the NHS)
Stem Cell Research in Animals
Home Office Approval
NO
YES
Q6. Is animal in vivo work required?
NO
Post-marketing Surveillance of Stem Cell ATMP
Positive Opinion of EMEA: Marketing Authorisation Granted
Submission to EMEA
Preparation of Regulatory Dossier for EMEA
Quality, Safety & Efficacy Data Generated
Safety reporting to Regulatory Agencies
Stem Cell Clinical Trial
NO
HSE Notification may be needed
YES
Q7. Will the clinical research involve gene therapy?
Submissions to: (I) MHRA Clinical Trials Unit, (ii) GTAC, & (iii) NHS R&D Office
Preparation of Clinical Trial documentation & obtain EudraCT number
Manufacture unlicensed product
Manufacture Clinical Trial product
NO (this route likely to be rare)
Stem Cell Research in Animals
Home Office approval & safety study under GLP
YES
Create MCB/WCB
GMP licence from MHRA
Q6. Is animal in vivo work required? Discuss with MHRA/HO
NO
YES
Q5. Is the product to be licensed? Dialogue with MHRA
YES

HFEA

All activities related to research involving human embryos[41] in the UK are licensed and monitored by the Human Fertilisation and Embryology Authority. Authorisation for derivation of human stem cell lines from embryos can only be obtained in conjunction with embryo research, under the terms of an embryo research licence.[42] As a result of the plurality of approaches to the status of the embryo within the European Union, rules on embryo research are left to the discretion of individual Member States: some countries prohibit or restrict it, while others such as the UK permit it on the basis of carefully constructed criteria. The EU does not *prohibit* the destruction of embryos in the course of research, but the lack of consensus prevents it from *financing* the derivation process because it causes the demise of the embryo. It will however finance the 'subsequent steps' of research and development in order to make use of the cells, a decision that might have been vetoed by the eight Member States opposed to embryo research, but which passed by reason of the concession of Germany, Italy and Slovenia.[43]

HTA

Embryos donated or created for stem cell research remain under the remit of the HFEA until the point at which the blastocyst is disaggregated and stem cells harvested. Thereafter, the process of cell line purification and tissue differentiation is governed by the Human Tissue Authority. Research grade cell lines remain under

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[41] Activities include the creation, procurement, keeping, using, processing, storage, distribution and traceability of embryos.

[42] *HFE Act 1990*, Schedule 2, Sections 3A(1) and (2)(a) and (b). There is no provision for the licensing of cell production on an industrial or commercial basis, as would be necessary should therapies become available in routine clinical practice.

[43] Council of the European Union, Press Release 11554/06 (Presse 215), *2747th Council Meeting, Competitiveness (Internal Market, Industry and Research)* Brussels, 24 July 2006, available at http://www.consilium.europa.eu/ueDocs/cms_Data/docs/pressData/en/intm/90654.pdf, accessed 8 May 2013; European Commission, *Community Research and Development Information Service* (CORDIS) Seventh Framework Programme (FP7), 25 July 2006 'Stem cell compromise allows approval of FP7 by Council', available at http://cordis.europa.eu/fetch?CALLER=FP7_NEWS&ACTION=D&QM_EN_RCN_A=26062; see also *BBC News* available at http://news.bbc.co.uk/1/hi/world/europe/5209106.stm, accessed 17 September 2012; *Financial Times* available at http://www.ft.com/cms/s/0/1d419f90-1b47-11db-b164-0000779e2340.html#axzz2SjJWH925, accessed 8 May 2013; *The Independent*, available at http://www.independent.co.uk/news/world/europe/eu-agrees-to-fund-stemcell-research-409162.html, accessed 8 May 2013.

the auspices of the HTA, whereas those cultivated with an intention for human application are governed by the HTA only until there is a reasonable expectation of clinical utility in a medicinal product.

MHRA/EMA

At that point, clinical grade cells may be classified by the MHRA either as an Investigational Medicinal Product (IMP or 'medicinal product'),[44] which must comply with MHRA pre-market criteria for manufacture, clinical trials and approval, or an Advanced Therapy Medicinal Product (ATMP)[45] which is subject to a centralised procedure for marketing authorisation conducted by the European Medicines Agency (EMA).[46] The ATMP classification is a recent development that accommodates innovative therapies, including cells that have been substantially manipulated by a manufacturing process, that typically fall somewhere between UK medicinal products and devices. The MHRA, as the Competent Authority for medicinal products in the UK, discharges national responsibilities for ATMPs, but if the regulatory status of a product is unclear, determination of classification will be jointly made by the EMA and MHRA. Absence of the requisite degree of manipulation implies that applications such as cell or tissue grafts are not 'products' and remain within the scope of the *Human Tissue (Quality and Safety for Human Application) Regulations* 2007.

1.3 Non-legislative oversight

In the midst of this tri-partite regulatory regime, the Steering Committee for the Stem Cell Bank and for the Use of Stem Cell Lines ('Steering Committee') and the UK Stem Cell Bank (UKSCB) provide a further level of non-statutory oversight.

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[44] EU Directive 2001/83/EC, Article 1, as amended.

[45] See http://www.ema.europa.eu/ema/index.jsp?curl=/pages/home/Home_Page.jsp&jsenabled=true, accessed 22 February 2012. See definition of ATMP in Article 2 of EC Regulation No 1394/2007 of the European Parliament and of the Council on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004.

[46] The EMEA was established by Regulation (EC) 726/2004 of the European Parliament and of the Council of 31 March 2004. The European authorisation procedure involves a single scientific evaluation of quality, safety and efficacy that will be conducted by a specialised Committee for Advanced Therapies, reporting to the Agency's Committee for Medicinal Products for Human Use.

Rationale

The primary objective in the establishment of the Bank was and is to promote social confidence in the regulatory regime[47] for embryo (rather than stem cell) research by ensuring ethical conduct in the ongoing use of the products of embryo research - human embryonic stem cell lines (hESCs). Although the Bank is capable of accommodating stem cell lines that vary as to cellular origin, geographical origin and intended use, and the widest participation is encouraged by the Steering Committee, there is no formal obligation on those handling non-embryonic stem cell lines in the UK to deposit them in the Bank or to comply with the Code of Practice.

The system was established specifically to address concerns about the regulation and use of embryonic stem cell lines. In 2001 there was a need to determine how human embryonic stem cell lines should be maintained, and to what degree they should be regulated, if at all.[48] There was an absence of any legislation governing the use of any human tissue created outside of the human body, the stem cell lines in question were of embryonic origin of debatable status, and the public was of divided opinion about embryo research.

Legislative Gap

The immediate problem confronting policymakers in 2001 was a legislative gap in the UK regarding the status of embryonic stem cell lines as human tissue. The *Human Fertilisation and Embryology Act 1990* had authorised the Authority to grant licences for fertility treatment, storage and research,[49] and set out in Schedule 2 to the *Act* activities for which such licences could be issued.[50] Embryos could be created *in vitro,* and kept and used, under licence for treatment services[51] or for purposes of a project of research[52] specified in the licence. Under the 1990 *HFEA Act*, licences could only authorise research involving the use of embryos if the

[47] HL Select Committee Report on Stem Cell Research 2002, Conclusions, sections 11 and 14.
[48] Report of the HL Select Committee on Stem Cell Research, 2002, paragraph 8.22.
[49] *Human Fertilisation and Embryology Act 1990,* s.11, and Schedule 2, para 1(1).
[50] *Ibid*, Schedule 2.
[51] *Human Fertilisation and Embryology Act 1990,* Schedule 2, paras 1(1)(a), (b) and (c).
[52] *Ibid*, paras 3(1)(a) and 3(1)(b).

Authority found such research necessary and desirable[53] for promotion of the treatment of infertility,[54] increasing knowledge about the causes of congenital diseases[55] or miscarriages,[56] the development of more effective techniques of contraception[57] or detection of genetic or chromosomal abnormalities in embryos prior to implantation.[58] The invention, in 1998, of the technique to isolate stem cells from human embryos prompted new *HFEA Regulations* in 2001[59] to expand the scope of research involving embryos. In addition to activities for the reproductive purposes contemplated by the *HFEA Act 1990*, the *Regulations 2001* enabled the Authority to authorise research that would:

- increase knowledge about serious disease or other serious medical conditions;[60]
- use such knowledge to permit development of treatments for serious disease;[61] and
- increase knowledge about the development of embryos.[62]

The authority of the HFEA in 2001 did not, however, extend to the stem cells isolated *from* the disaggregated embryo, and no rules had been promulgated in relation to the use of established embryonic stem cell lines. The Human Tissue Authority did not exist, let alone govern stem cell lines, prior to the enactment of the *Human Tissue Act 2004*. In 2001, legislation governing human tissue was fragmented and limited in scope, addressing for example the removal and use of body parts from deceased persons,[63] post-mortem examinations,[64] transplantation of organs,[65] corneal tissue[66] and anatomy.[67] Even when the *Human Tissue Act 2004* did

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[53] *Human Fertilisation and Embryology Act 1990,* Schedule 2, para 3(2).
[54] *Ibid*, para 3(2)(a).
[55] *Ibid*, para 3(2)(b).
[56] *Ibid*, para 3(2)(c).
[57] *Ibid*, para 3(2)(d).
[58] *Ibid*, para 3(2)(e).
[59] *Human Fertilisation (Research Purposes) Regulations 2001,* which were repealed by amendment of the *HFE Act 1990* by which they were incorporated into the *HFE Act 2008*.
[60] *Human Fertilisation and Embryology Act 2008,* Schedule 2, para 3A(2)(a).
[61] *Ibid*, para 3A(2)(b).
[62] *Ibid*, para 3A(2)(h).
[63] *Human Tissue Act* 1961 c. 54.
[64] *Ibid.*
[65] *Human Organ Transplants Act* 1989 c. 31.

come into effect, consolidating existing legislation and establishing the Human Tissue Authority, it did not apply to human stem cell lines as they are 'created outside the human body',[68] but only to material taken 'from a human body'.[69] The governance of quality and safety of cells cultivated *in vitro* was not addressed until 2007, when Section 14 of the *Human Tissue Act 2004* was amended by the *Human Tissue (Quality and Safety for Human Application) Regulations 2007* to include within the remit of the Human Tissue Authority activities ('procurement, testing, processing, distribution, import or export) related to tissue and cells intended for human application'.[70]

Embryonic Origins

The problem of the legislative vacuum was exacerbated by the *embryonic* origin of human stem cell lines and outstanding questions related to their moral and legal identity which, unlike that of embryos, had not been subjected to parliamentary debate. It was not clear whether an embryonic stem cell line is to be irrevocably identified with the embryo from which its progenitor cells were extracted, or whether it is transformed by derivation, purification and cultivation into a different thing: a source of living human tissue comparable to a reservoir of blood. The potential for cultivation of stem cells in perpetuity raised questions about the nature of the consent that should be obtained from the donor of the embryo, and how far the terms of that consent might affect ongoing research activities.

Although a House of Lords Select Committee on Stem Cells[71] (HL Committee) later decided that hESCs are not embryos and do not therefore need special regulatory treatment, the concern at the time was to adopt a policy approach, whether or not it involved legislative measures, that would favourably inform public perception. As public awareness was heightened and opinions were divided over embryo research,

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[66] *Corneal Tissue Act* 1986 c. 18.
[67] *Anatomy Act* 1984 c. 14.
[68] *Human Tissue Act* 2004, s. 54(7).
[69] *Ibid.*
[70] *Human Tissue (Quality and Safety for Human Application) Regulations* 2007, s. 7(3).
[71] House of Lords Select Committee on Stem Cell Research, Session 2001-02, Report.

priority was given to the definition and communication of government policy on the further handling of the products of such research. The pressing task was to decide how these 'slightly worrying things'[72] should be dealt with, and to do it more quickly than could be done through the legislative process.

Steering Committee

The twenty-six member Steering Committee is appointed by and reports to the public Medical Research Council and works closely with the Department of Health (DH), HFEA and the MHRA. Its informal mandate is the governance of the use of cell lines in the UK generally, and of the activities of the UK Stem Cell Bank. To this end it produces a Code of Practice for the Use of Human Stem Cell Lines ('Code of Practice' or 'Code')[73] through which it provides guidance for best use of established stem cell lines in the UK. The Code is intended for a community of users of cell lines that extends beyond those who deposit cell lines in the Bank. Deposition and compliance with the Code are recommended to users of all types of human stem cell lines, but are mandatory for those who have derived embryonic cell lines under licence in the UK. The role of the Steering Committee is primarily to oversee the activities of the Bank and of its users with a view to ensuring compliance with rules of ethical conduct. The role of the Bank is in the custody and banking of cells and their technical qualification and standardisation for purposes of quality and safety.

HL Select Committee Report

The early discussions about governance of the use of hESC lines resulted in a proposal by the UK Department of Health (DH) that a stem cell bank be created and that the MRC be invited to lead its establishment. The proposal was endorsed by the HL Committee, which had been convened to address issues of human cloning and stem cell research arising from the *Human Fertilisation (Research Purposes) Regulations 2001*. In its 2002 Report on Stem Cell Research (Report)[74] it affirmed in

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[72] Comment of participant in Roundtable discussion, University of Edinburgh, 2010.
[73] HL Report, para 6.1.
[74] HL Report.

principle[75] a need to establish a stem cell bank governed by a steering committee that would act as a means of providing oversight for the use of hESC lines and facilitate ongoing research in the field. In addition, the Report made clear that the rationale for the oversight was not to impose on hESC lines a level of formal regulation beyond that which applied to other human tissue, but to strengthen public confidence in the conduct of embryo research and the use of its products.[76] This is an important point from the perspective of the type of governance that I advocate in Chapter 3, because it underscores that the recommended 'oversight' was not intended to address matters of quality and safety in the handling of hESC lines, and suggests that there is scope for variation in the means that might be used to achieve public confidence.

Status: Human Tissue

The status of hESC lines, according to the HL Committee, is that of ordinary human tissue. Embryonic stem cells, cultivated *in vitro* and established as a cell line, are no longer embryos, and do not require special regulation of the sort applied to embryo research under the HFEA.[77] The HL Committee did not address whether they have an innate 'special' status, the nature and extent of the respect that should be given them, or the point at which stem cell lines should be considered 'biomaterials'. It found that despite the particular sensitivities that attach to certain (embryonic) material, no special arrangements need to be made for embryonic cell lines beyond those, such as informed consent, that apply to the use of other human material.

Ethical 'Oversight'

Notwithstanding the status of hESC lines as human tissue, the HL Committee felt that some level of oversight of ongoing research was necessary to demonstrate the integrity of the public management and ethical conduct of stem cell research. It recommended that a bank be 'responsible for the custody of stem cell lines,[78] which

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[75] *Ibid,* 8.26, 8.29.
[76] HL Report, Summary of Conclusions and Recommendations, 11 and 14.
[77] HL Report, 8.25.
[78] HL Report, 8.29; Summary of Conclusions, no. 14.

would reduce the 'ethical impact' of such research in three ways. Secondarily it would provide support for research.

First, the availability of stem cell lines to researchers through a bank would *minimise the number of embryos destroyed in research* by preventing unnecessary creation of additional cell lines. Consolidation of existing cell lines in one physical location would also make it easy for researchers and the HFEA to ascertain whether there were any lines suitable for use in newly proposed projects. The HL Committee was 'especially concerned' throughout its deliberations 'to minimise the need to generate new embryonic stem cell lines, while not impeding scientific and medical progress'[79] and suggested that ensuring access to stem cell lines would over time 'reduce the need for research on early human embryos.'[80]

Secondly, a stem cell bank would facilitate *traceability and guarantees of provenance.* Provenance referred to both the ethical and technical history of the cell lines, and was aligned with purity in reference to guarantees in more than one place in the 2002 Report.[81] How mechanisms for cell line purification and guarantees of provenance would function in practice was not addressed; it was proposed however that it be left to a steering committee to establish rules governing deposits in and withdrawals from the bank to ensure the maintenance of records related to the source of the stem cells, donor consent, and a full history of their storage and handling under good laboratory conditions.[82]

Thirdly, custody by a bank was considered to enable the *monitoring* of ongoing use,[83] presumably by acting as gatekeeper with capacity to regulate access by potential users to the banked cell lines. The Report provides little insight into monitoring systems, or the types of use that it might seek to deter. The decision as to the status of hESCs as ordinary human tissue implies that the proposal for oversight was not based on any particular concern about the capacity of hESC lines to

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[79] HL Report, 8.24.
[80] HL Report, Summary of Conclusions, no. 14.
[81] HL Report, 8.29; Summary of Conclusions, no. 14.
[82] HL Report, 8.26.
[83] HL Report, 8.29; Summary of Conclusions, no. 14.

differentiate into germ cells and thus generate embryos, with the potential for prohibited reproductive cloning[84] or unauthorised *in vitro* fertilisation. On the contrary, the Stem Cell Steering Committee in its Code of Practice attributes the decision to the fact that '[u]nlike human embryos, embryonic stem cells *do not have the potential to become a human person* and do not therefore have the moral status of human embryos' (italics added).[85] It also points out that new legislation in regard to cell lines for human application[86] has since established that research involving stem cell lines will not be regulated to the same extent as embryo research under the HFEA. In any event, the 'oversight' contemplated by the HL Committee would reserve to the steering committee a means of monitoring activities of the bank and its users, with discretion to pre-empt and intervene on ethical – and indeed any - grounds it should see fit. The recommendation that the steering committee should establish codes of conduct for the use of hESC lines obtained from the bank or from elsewhere'[87] leaves room for development of a substantial regulatory role.

Support for Research

Finally, as a secondary matter, it was considered that together with these functions a bank would *support research* by providing cell lines that were not only ethically sourced but of guaranteed *technical* purity.[88] It was felt that by disseminating the purified cell lines widely to both British and overseas scientists,[89] thus providing them with ready access to quality-controlled embryonic stem cell lines,[90] such a bank

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[84] Reproductive cloning was initially prohibited by The *Human Reproductive Cloning Act 2001,* which deemed it a criminal offence punishable by up to 10 years in prison to place into a woman an embryo created by any means other than by fertilisation; the *HRC Act 2001* was effectively repealed by incorporation of its provisions into the *Human Fertilisation and Embryology Act* 2008. *HFEA 2008* s.3(2) mandates that only 'permitted' embryos, which essentially originate from female ovaries and male testes, without genetic modification may be used for fertility treatment.

[85] Code of Practice for the Use of Human Stem Cell Lines, Version 5, April 2010, para 5.

[86] *Human Tissue (Quality and Safety for Human Application) Regulations 2007*.

[87] HL Report, 8.27.

[88] HL Report, 8.26.

[89] *Ibid,* 8.28; Summary of Conclusions, no. 14.

[90] HL Report, 8.22-8.29.

should have the effect of *facilitating research* as well as the ability to minimise embryo use[91] (italics added).

Further, the emphasis of the discussion as to custody and regulation[92] was on cells for use in basic *research*, as distinguished from cells that might ultimately be used for *therapeutic* purposes. The *2001 HFEA Regulations* that the HL Select Committee had set out to critique were concerned only with research purposes for the use of embryos, and deliberations that extended to the use of stem cell lines in this context remained very much in the 'upstream' end of the research and development process.[93] Regulation of cell lines intended for the treatment of patients was left to one side, on grounds that therapeutic applications were still some way off[94] and that, when they did come about, they were likely to be subject to existing controls including those operated by the Medicines Control Agency.[95] This was clearly a prioritisation of issues, and not intended as a principled or permanent exclusion of oversight for cells with potential for clinical use.

It is not surprising therefore that the separate chapter of the Report devoted to *commercial* interests[96] simply notes that the Report concentrates largely on scientific and ethical issues arising from stem cell research, and that the HL Committee had had before it only a limited amount of evidence concerning commercial interests in the field. It was acknowledged that commercial interests could, and to some extent already did at that time, play an important part in the development of stem cell research. The HL Committee was, however, unable to do more than identify issues that had come to its attention, even while recognising that these would have considerable significance for the legal and regulatory control of stem cell research, in which certain companies would have an obvious interest. These issues related

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[91] *Ibid,* 8.27.
[92] *Ibid,* 8.22-8.33.
[93] Comment made by participant during SCRIPT Open Science Roundtable, 17 Sept 2010.
[94] HL Report, 8.23.
[95] *Ibid*, 8.23. The Committee noted that in relation to gene therapy, the DH had set up the Gene Therapy Advisory Committee (GTAC) to provide further oversight of clinical studies from scientific, medical, safety and ethical standpoints. It recommended that when necessary the DH should consider either extending the remit of GTAC to oversee clinical studies involving stem cells, or establishing a similar body to achieve this.
[96] HL Report, Chapter 6: Commercial Interests in Stem Cell Research.

entirely to the patenting of research findings and stem cell lines, on which the HL Committee was not in a position to make a firm recommendation, though it cautioned against the restriction of stem cell technologies by overly broad patents. Admitting that it had drawn only tentative conclusions from a sketchy picture, the HL Committee suggested that the industry was still at the basic industry stage, and that corporations trying to position themselves for future profits were still facing uncertain research prospects, let alone uncertain therapeutic possibilities.[97]

In summary, 'oversight' as first articulated, reflected a desire on the part of relevant authorities to build public confidence in the regime for regulation of embryo research. The emphasis was on public responsibility in the procurement of stem cell lines, facilitation of transparency related to their technical and ethical origins, delivery of quality and safety assurances, and maintenance of some sort of surveillance over their ongoing use. The stated objectives were to minimise the number of embryos used in research, to guarantee the ethical and technical provenance of embryonic stem cell lines, and to monitor their use through methods of record keeping and codes of conduct. As I note later, the oversight function of the Steering Committee remains but takes a lower profile in relation to the role of the Bank in the support of research.

1.4 UKSCB: functions

Research support

The UK Stem Cell Bank was established to provide a repository of human embryonic, foetal and adult stem cell lines as part of the UK governance for the use of human embryos for research. Its role is to provide quality controlled stocks of these cells that researchers worldwide can rely on to facilitate high quality and standardised research. It is also ready to prepare stocks of 'clinical grade' cell lines as seed stocks for the development of therapies.[98]

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[97] HL Report, 6.9.
[98] UKSCB website http://www.ukstemcellbank.org.uk/about_us.aspx, accessed 10 October 2012.

Under the Steering Committee and its Code of Practice, the motivations for 'oversight' of hESCs as products of embryo research remain largely as envisioned by the HL Committee, but the whole endeavour is framed much more clearly in terms of support for research. The Code aims to provide 'confidence and reassurance to professionals and the public alike that stem cell research in the UK is performed to best practice and is conducted within a transparent and ethical framework'.[99] To this end, it provides guidance for those working with stem cell lines, specifies oversight mechanisms for research involving human embryonic stem cell lines, and governs the activities of the UK Stem Cell Bank.[100] The primary aim of the Bank is to act as a research resource centre: to enable researchers to access stem cell lines derived from adult, foetal and embryonic sources for the study of stem cell biology and related research and development.[101] These functions together *support research* that will help improve understanding of human development and disease and aid the generation of strategies and therapeutic interventions[102] for the treatment of serious disease.[103]

A comparison of the various versions of the Code of Practice indicates that ideas and models for oversight developed and evolved as plans for their implementation were worked out. The use of stem cell lines had not been debated at any length in the HL Committee and the scope of authority of the proposed steering committee for regulation of such use had not been defined. Whether the responsibilities ultimately assumed by the Steering Committee reflect 'mission creep' or the conscious or unconscious adoption of an expanded policy approach, such development is in keeping with the nature of the Code, which is regarded as an evolving document to

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[99] Code of Practice 2010, s. 1.
[100] Code of Practice 2010, s. 1.
[101] Healy L, Hunt C, Young L, Stacey G (2005) 'The UK Stem Cell Bank: its role as a public research resource centre providing access to well-characterised seed stocks of human stem cell lines' 57:13 *Advanced Drug Delivery Reviews* 1981, 1982. See also Stern S (2004) *Biological Resource Centers, Knowledge Hubs for the Life Sciences*, The Brookings Institution.
[102] Code of Practice 2010, s. 1.
[103] Code of Practice 2010, Foreword.

be revised and updated in line with practice and relevant legislation[104] and has undergone several revisions since its inception.

The shift in emphasis from ethical oversight to support for research is evident in a number of subtle changes from HL Committee Report to the Code of Practice. The objective of confidence building is extended by reference to practitioners as well as the public. The language of 'ethical monitoring' is replaced by the elaboration of specific systems for record keeping, quality management and audit. The Code contemplates support for both basic and clinical research, anticipating a wider role in the banking of clinical grade cells suitable for development of therapeutic products. It also envisions custody of human stem cell lines from all tissue sources (adult, fetal and embryonic) and geographical origins including those outside of the UK on a single site. Most significantly, quality control through characterisation and purification of stem cell lines to a consistent standard has become a significant feature of the Bank. For this purpose, the National Institute for Biological Standards and Control (NIBSC) was given responsibility for all aspects of the day to day operation of the Bank and for any breaches in operating standards, procedures or quality control arrangements. The Bank was established at the NIBSC premises in North London in January 2003 with public funding from the MRC and the Biotechnology and Biological Sciences Research Council (BBSRC).

A connection between the support for research and facilitation of sharing of stem cell lines is drawn only loosely. The Code asserts that by *facilitating sharing* of quality controlled stem cell lines by the clinical and research communities[105] it *supports research,* but the main benefit of sharing is perceived as a reduction in the need for individual research teams to generate their own stem cell lines and thus a minimisation of the use of human tissues (embryos) in research.[106] Although it is mentioned, there is no elaboration of the idea that sharing of cell lines may enable

[104] Code of Practice 2010, Foreword.
[105] *Ibid*, s. 4.
[106] *Ibid.*

different researchers to work on identical material so that direct comparisons may be made between studies.[107]

Whatever the effect of the sharing of cell lines through the Bank may be, the system was clearly not constructed with the view to streamlining the translation of scientific and technical understanding into commercial products. The objective of the Steering Committee was to negotiate social confidence in embryo research and its products, and to provide practical support for research. As I explain in later chapters, these objectives play a role in my assessment of the functions of the Bank as a governance mechanism and its failure to promote equally of all aspects of the stem cell technology endeavour.

Custody

The custodial role of the Bank ensures that a single body is responsible for the banked stem cell lines.[108] That it should function as a physical repository, rather than a directory, has several implications. First, the taking of physical custody sends a positive message of capability and control to the public. Secondly, it permits the repository host - the NIBSC - to manipulate the cell lines in its own laboratory facilities and so ensure their characterisation as to technical quality and safety, in accordance with national and international standards. Thirdly, centralised custody by a single body provides the Steering Committee with a one-stop shop for determining whether there are suitable cell lines available for proposed research projects, prior to granting its approval. The approvals mechanism derives from Steering Committee adoption of the HFEA legislative approach to authorisation of research involving embryos,[109] which requires that such activities appear to be 'necessary and desirable' and in accordance with specified purposes, as I discuss below.

Although not all cell lines in the UK will necessarily be deposited, the aspiration was that the Bank should become a national and international resource for researchers as well as a primary resource for the HFEA. Most importantly, physical custody

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[107] *Ibid.*
[108] HL Report, Summary of Conclusions, no. 14.
[109] *HFEA 1990*, as amended by the *HFEA 2008,* Schedule 2.

affords the Bank control over terms of deposit and access by others to the stem cell lines. It enables the Bank to control its relations with depositors and their rights in the deposited cell lines through imposition of standard MTAs, and to screen potential users and impose terms of ongoing use.

Monitoring

The somewhat misleading language of 'monitoring' used in HL Committee Report translates, in the Code of Practice, to the assurance of an *ethical framework* for research that is *transparent* to the public and is in keeping with *HFEA regulations*.[110] These objectives are realised by the Steering Committee through systems for tracing the ethical (and technical) provenance of stem cell lines, the adoption of criteria for withdrawal and use of stem cell lines from the Bank, and the reservation of a right to audit ongoing research where necessary. The Steering Committee also reserves to itself a power of veto by requiring application and prior approval of, among other things, deposition, withdrawal, ongoing research, and commercial use agreements.

Traceability: Ethical Provenance

The requisite 'ethical provenance' of a hESC line is that it is derived from an embryo that was donated with the informed consent of the donor, in accordance with rules on consent to the use of embryos in research, detailed in Schedule 3 of the *HFE Act 2008*. A consent to the use of any embryo *must* specify the purpose (or purposes) of the use[111] as relating to: provision of fertility treatment services (either to the consenting person[112] or another person[113]); technical training in embryological techniques;[114] or a project of research.[115] A consent to the use of any embryo *may* also specify conditions, subject to which the embryo may be so used.[116]

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[110] Code of Practice 2010, Foreword and s. 5.
[111] *HFE Act 2008*, Schedule 3, para 2(1).
[112] *HFE Act 2008*, Schedule 3, para 2(1)(a).
[113] *Ibid*, para 2(1)(b).
[114] *Ibid*, para 2(1)(ba).
[115] *Ibid*, para 2(1)(c).
[116] *Ibid*, para 2(1).

The gametes or other cells of a person must not be used to create an embryo *in vitro* unless he or she consents to the use of an embryo so created for one of the stated purposes.[117] An embryo created *in vitro* must not be *received* by any person[118] unless an effective consent is given by each 'relevant person' in relation to the embryo[119] for the use of the embryo for one of the stated purposes;[120] nor is it permissible for such embryo to be *used* for any purpose[121] unless the consent from each relevant person specifies that purpose, and the embryo is used in accordance with those consents.[122]

Before a person gives consent[123] he or she must be given an opportunity to receive proper counselling about the implications of taking the proposed steps,[124] be provided with relevant information[125] and be informed of the right, if any, to withdraw the consent.[126] The terms of the consent may be varied, or the consent withdrawn,[127] by notice given by the consentor to the person keeping the embryo to which the consent relates.[128] Subject to limited exceptions,[129] however, consent to the use of any embryo cannot be varied or withdrawn once the embryo has been used in provision of treatment services,[130] training[131] or for the purposes of any project of research.[132] Schedule 3 of *HFEA 2008* also specifies consent requirements, and criteria for exemption, in relation to the *storage* of gametes[133] and embryos.[134]

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[117] *HFE Act 2008,* Schedule 3, para 2(1)(a), (b), (ba) and (c).
[118] *Ibid*, para 6(2).
[119] A 'relevant person' is the donor of gametes or cells used to create either the received embryo (*HFEA Act*, Schedule 3, para 6(3A)(a)), or another embryo from which the received embryo is generated (para 6(3A)(b).
[120] *HFE Act 2008,* Schedule 3, para 2(1)(a), (b), (ba) and (c).
[121] *Ibid*, para 6(3)
[122] *Ibid.*
[123] *HFE Act 2008*, Schedule 3, para 3(1).
[124] *Ibid*, para 3(1)(a).
[125] *Ibid*, para 3(1)(b).
[126] *Ibid*, para 3(2).
[127] *HFE Act 2008*, Schedule 3, para 4(1)
[128] *Ibid*, para 4(2).
[129] *Ibid,* para 4(3).
[130] *Ibid*, para 4(2)(a).
[131] *Ibid*, para 4(2)(aa).
[132] *Ibid*, para 4(2)(b).
[133] *Ibid*, para 8(1).
[134] *Ibid*, para 8(2).

Under these rules it is technically permissible for donors to limit their consent by reference to particular types of research or development,[135] and thus impose conditions on use of the embryo that could affect future use of the stem cell line derived from it. In practice, this creates legal and administrative difficulties for present and future research, especially in light of the 'immortality' of the stem cell lines. The practice of the HFEA is therefore to permit derivation of hESC lines only from embryos donated under informed consent that places no specific constraint on their future use.[136] The policy is reflected in the HFEA standard terms of consent, which require a broad form of consent, and in the Code of Practice for stem cell use, which requires that the donor couple have given 'in principle' consent to the use of embryos in research.[137]

It is the responsibility of the Stem Cell Steering Committee to ensure that the necessary embryo donor consents, approvals, licences and authorisations are in place for all hESC lines deposited in the Bank, and for all projects receiving such cell lines from it.[138] To ensure traceability, copies of these are lodged with the Secretary of the Committee and maintained in strictest confidence.[139] Information regarding donor identity is revealed to neither the Steering Committee members nor Bank staff.

Criteria for Use: Embryo Purposes

A further means of oversight by the Steering Committee is its adoption of criteria, by reference to specific purposes for which stem cell lines may be used, to define the scope of permissible research. Despite recommendation by the HL Committee that they be regulated no differently than other human tissue, the Steering Committee applies to hESCs what are largely the requirements of the *Human Fertilisation and Embryology Act* for authorisation of embryo research, in which the activities

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[135] *Ibid*, para 2(1).
[136] HL Report, Conclusions, xxvii.
[137] Code of Practice 2010, s. 9.1.
[138] *Ibid*, s. 4.1.
[139] *Ibid,* s.4.
[139] *Ibid*, s. 9.1.

involved in 'keeping or using embryos'[140] must appear to the Authority to be 'necessary and desirable'[141] for one of the 'principal purposes' set out therein.[142]
The Steering Committee states that it 'expects that hESC lines are only used by *bona fide* research groups for justified and valuable purposes that reflect the requirements of the law in this area'[143] being:

'a. research which increases the knowledge about the development of embryos, or has the long term goal of helping to increase knowledge about serious diseases and their treatment (as set out in the 1990 *HFE Act*, as amended by the *HFE Act 2008*);
b. basic cell research which underpins these aims (as recommended in the House of Lords Report 2002); and
c. development of cell-based therapies for clinical trials in respect of serious human diseases.'[144]

With the addition of the specification of cell-based therapies as a means of treatment of serious disease, these are essentially the purposes identified in the '*HFEA* regulations'[145] as criteria for authorisation of *embryo* research.[146] The Code applies to approval of *hESC* research[147] virtually the same criteria as are applied by the HFEA in the licensing of *embryo* research.[148]

This application of the embryo regulations to hESC lines is defended by the Steering Committee on grounds that there was extensive parliamentary debate, during the passage of the *HFE Act* and its amendments in 1990, 2001 and 2008, over the use of embryonic stem cells in research. Even though no statutory change was brought about to extend the HFEA provisions to stem cell lines, the Committee holds to the view articulated by Parliament that hESC lines should not be used for *trivial* purposes.[149] The political legitimacy of the self-assumed regulatory role of the Steering Committee is not the focus of my thesis, but I raise its intervention in the research agenda here to indicate that there remains some scope for a change in the

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[140] *HFEA 2008*, Schedule 2, sub-paragraph 3(1)(b).
[141] *Ibid*, sub-paragraph 3A(1).
[142] *Ibid*, sub-paragraph 3A(2).
[143] Code of Practice 2010, s. 7.1.1.
[144] *Ibid.*
[145] Code of Practice 2010, Foreword and s. 5.
[146] *Ibid.*
[147] Code of Practice 2010, s. 7.1.1.
[148] Through the *HFEA 1990,* then the *HFEA (Research Purposes) Regulations 2001* (provisions of which were repealed, from October 2009, by incorporation into the *HFE Act* 2008) and the *HFE Act 2008*.
[149] *Code of Practice 2010*, s. 7.1.1.

perspective of the Steering Committee in favour of treatment of stem cell lines as 'ordinary' human tissue.

Criteria for Use: Commercial and Clinical Purposes

Restrictions on commercial activity in relation to hESCs are most evident in the early versions of the Code of Practice.[150] These expressly prohibited sales by requiring the agreement of depositors under the Materials Deposit Agreement (MDA) and users under the Materials Access Agreement (MAA) that cell lines would not be sold 'for financial gain'. In subsequent versions of the Code,[151] the Steering Committee began to address how the arrangements for deposit and access may be made more commercially friendly without relinquishing control over deposited stem cell lines. Although the prohibition has since been removed from the Code, the standard Research Use Licence still prohibits the use of hESC lines obtained from the Bank for any undefined 'commercial purpose' without the approval of the depositor, the Steering Committee and the Bank.[152] The distinction is preserved, not to prevent commercialisation *per se,* but to protect the intellectual property of the depositor of the banked cell lines in the event that the user should foresee a potential clinical application or other opportunity for commercial gain during the course of ongoing research. In such circumstances, the Steering Committee requires that the parties negotiate terms for allocation of potential intellectual property directly between themselves in the form of a commercial use licence. The main problem is that prior approval must always be obtained from the Steering Committee, giving it a veto over any proposed research activity, and increasing the administrative burden on the applicant.

The categorisation of research *purposes* as commercial or non-commercial is also difficult to sustain. The more cogent distinction on which to base assessment of potential for commercial gain is the difference between clinical and non-clinical research. Cell lines intended for the clinic are usually directed toward commercial

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[150] Code of Practice, Version 3, August 2006.
[151] Code of Practice, Version 4, draft – July 2009.
[152] Research Use Licence, Jan 2012, s. 2.9.

product development and can be identified on the basis of technical grade: unlike research grade cells they must be cultivated to the higher technical specifications of good manufacturing practice (GMP). Nevertheless, this distinction too can be problematic, as the grade of the cell line is not determinative of its commercial prospects. Laboratory grade cell lines can in some circumstances can be upgraded or converted to meet GMP standards, clinical grade lines may be used in basic research without expectation of any clinical product development, and occasionally medicinal products are developed and approved for clinical use without entering the commercial market.[153] For the purposes of devising models of collaborative governance, which I address in Chapter 7, a main objective is to minimise barriers in order to encourage the conduct of all types of research, thus facilitating tangible innovations as well as the advance of knowledge.

Compliance: Audit

Also related to ethical oversight is the fact that the Code of Practice contemplates the possibility of a minimal policing function for checking up on the conduct of research by users of stem cell lines withdrawn from the Bank. The Steering Committee reserves the right to seek 'periodic independent audit' of the research carried out by UK and overseas researchers 'in order to assure compliance with relevant regulations and permissions'.[154] Such regulations and permissions refer to specifically prohibited activities such as reproductive cloning, and activity outside of the terms of the research licence, if any. Enforceability is limited. Evidence of non-compliance with or deviation from appropriate licences, authorisations and formal procedures will result in 'immediate action' such as withdrawal of the cell line from the Bank, exclusion of the offending researcher from future use of the Bank, and notification of the non-compliance to the host institution, funder or national regulator of the researcher.[155] No other structure is established for this function.

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[153] Comment of participant in SCRIPT Roundtable Workshop, September 2011.
[154] Code of Practice 2010, s. 5.3.
[155] *Ibid.*

Quality assurance

Stem Cell Steering Committee oversight extends to governance of quality and safety through the establishment of systems for traceability of *technical* provenance that are separate to those for donor consent. The establishment of the Steering Committee and the institution of its informal oversight regime were not necessary merely for quality and safety purposes, as technical standards are already established by European Directives and UK legislation, as set out above in section 1.2. Nevertheless, the expertise of NIBSC is an undoubted asset for their implementation in the day to day operations of the Bank.

Traceability of Technical Provenance

Guarantees of technical provenance, and assurances of quality and safety are achieved in two ways: firstly through careful recording and documentation of all technical processes carried out in the Bank, in compliance with the UKSCB Quality Management System (QMS)[156]; and secondly through cultivation and standard characterisation of the cell lines, in accordance with international standards, in the NIBSC laboratory at the Bank.

Cell Characterisation

The standardisation[157] of quality and safety of stem cell lines is crucial for the ultimate recipient of a cell therapy, but is also important for the conduct of effective scientific research. The job of ensuring that cell lines available for research are of 'guaranteed purity and provenance'[158] is undertaken by the National Institute for Biological Standards and Control[159] whose mission is to provide quality assurance related to biological medicines. The NIBSC asserts that stem cells are 'potentially

[156] Code of Practice 2012, s. 4.2.1.
[157] Cobo F, Stacey GN, Hunt C, Cabrera C, Nieto A, Montes R, Cortés JL, Catalina P, Barnie A and Concha A (2005) 'Microbiological control in stem cell banks: approaches to standardisation' 68 *Applied Microbiology and Biotechnology* 456.
[158] HL Report 2002, 8.28; Summary of Conclusions, no. 14.
[159] NIBSC is a centre of the UK Health Protection Agency (HPA).

one of the most important emerging biotherapeutic medicines'[160] and that provision of 'consistent, quality-assured and defined cell lines'[161] to accredited researchers through the UK Stem Cell Bank is the key to the success of this new technology.

The technical role of the NIBSC is to guarantee consistent 'characterisation' of the deposited cell lines in accordance with international standards in order to facilitate the controlled differentiation of a pluripotent cell line into the desired tissue. 'Characterisation' involves reliable identification of stem cells, their isolation from heterogeneous populations, and their safe expansion *in vitro* to produce genetically stable colonies of cells without altering their potential for differentiation.

NIBSC is well suited to the task, being the world leader in the supply of (95% of) the World Health Organisation International Standard biological reference materials. These are used as benchmarks for measurement of biological activity or potency in vaccines, most biotechnology products in therapy and many other biologicals worldwide.[162] NIBSC scientists work to optimise culture conditions, culture media and assays, technologies and platforms for cell characterisation. Only after cell lines are characterised to NIBSC standards are they made available for release to qualified users approved by the Steering Committee.

Quality Management System

The system for documentation of technical provenance of banked cell lines is governed by the Human Tissue Authority, and implemented through the UKSCB Quality Management System. The QMS covers all licensable activities identified in the *HTA Directions*,[163] in compliance with the *Human Tissues (Quality and Safety for Human Applications) Regulations 2007*, implementing the *EU Tissues and Cells Directive*.[164] The QMS is a document management system established for the proper control and archiving of all relevant records regarding policies, procedures,

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[160] NIBSC website http://www.nibsc.ac.uk/spotlight/uk_stem_cell_bank.aspx
[161] *Ibid*, NIBSC website http://www.nibsc.ac.uk/spotlight/uk_stem_cell_bank.aspx
[162] *Ibid.*
[163] Code of Practice 2010, 4.2.1.
[164] *2004/23/EC*, 2006/17/EC and *2006/86/EC*

samples/users, quality control and training etc relating to the processes conducted in the Bank.

Records are maintained for each cell line, providing evidence of procurement, processing, testing, storage and release in accordance with the procedures described in the QMS.[165] This information is held in a Cell Line Master File, along with the original application form, the Materials Deposit Agreement and any information on the cell line provided by the depositor.[166] Each cell line is identified by a unique identifier traceable to the accession number given it upon deposit in the Bank.[167] This is linked to the unique application number held by the Steering Committee,[168] which means that donor anonymity can be maintained while permitting the possibility of tracing the line from donor to recipient or vice-versa in the event of medical necessity.[169] All of these systems go to the quality control functions of the Bank, rather than any particular aim to stimulate accessibility to the stem cell resources. As I suggest in the last Part of the thesis, one of the adaptations that would have to be made, if the Bank was to consider conversion into a global stem cell research commons, would be to identify some sort of biological marker, rather than a paper trace, to ensure traceability of stem cells through differentiation into tissues, and facilitate wider dissemination.

International facility

Another aspiration for the role of the Bank was that it might act not only as a national asset but as an international hub for stem cell research. The HL Committee asserted that the bank would 'undoubtedly become the preferred source of embryonic stem cells for British scientists',[170] would make stem cell lines available to the widest possible range of reputable researchers,[171] and should 'use its best endeavours' to import hESC lines generated overseas and facilitate distribution of UK lines to

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[165] Code of Practice 2010, 4.2.1.
[166] *Ibid*, 4.2.1.
[167] *Ibid.*
[168] *Ibid.*
[169] *Ibid.*
[170] *Ibid*, 8.27.
[171] *Ibid*, 8.28.

overseas scientists. Clearly stem cell research is not a purely domestic issue; scientific research and its commercial exploitation operate on a global basis, both of which are 'sensitive to differences in the regulatory environment'.[172] Further, international instruments and declarations govern some aspects of stem cell research.[173] The Bank presently has a strong international leadership role in the provision of guidance regarding harmonisation of standards and practices in the banking and qualification of stem cell lines. Glyn Stacey, director of the UKSCB, coordinates the International Stem Cell Banking Initiative, involving 106 collaborators, which in 2009 published consensus guidance for banking and supply of hESC lines for research purposes.[174]

The international character of the field has implications for governance mechanisms such as the construction of a global research commons, as I discuss in the last Part of the thesis, to facilitate communication and cooperation among scientists, standardisation of procedures, and exchanges of materials, information and data. Although it is outside the scope of this thesis, a further study might undertake an analysis of the host of legal and practical issues associated with opening access to human cell lines across national borders. This project would require an examination of international trade law related to living biological materials, issues in international intellectual property, and questions of international development, including access to medicines and the international human right to access the benefits of science and new biotechnologies.

1.5 UKSCB: organisation

The organisational structure of an initiative affects the type of governance that it delivers. In Chapter 3, I set out my conceptualisation of the type of governance that is appropriate to encourage facilitation of stem cell technology: it will be decentred

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[172] HL Report, 7.1.
[173] *Ibid*, 7.2.
[174] International Stem Cell Banking Initiative (2009) 'Consensus guidance for banking and supply of human embryonic stem cell lines for research purposes' 5:4 *Stem Cell Review* 301.

(involving state or non-state actors), purposive and reflexive. With this approach in mind I look to the organisational features of the UKSCB.

The organisation of the Bank is unusual in that it is a public initiative without being a statutory creature. Participation is voluntary for some and not for others. Voluntariness of participation is important in the discourse related to the design of collaborative or commons approaches to the promotion of innovation. Governance is neither legislative nor determined by the actions of the participants. The organisation of the Bank is determined by the Steering Committee through the use of the Code of Practice and material transfer agreements (MTAs) which are in part standardised and in part open to negotiation between depositor and user.

Deposition

The UKSCB is loosely connected to the UK legislative framework governing the use of embryos by the standard condition imposed by the HFEA on all embryo research licences issued in the UK. The licence is conditional upon deposition of a sample of each stem cell line derived thereunder in the Bank, and compliance with the terms of its Code of Practice. Once the stem cell line is fully cultured to ensure uniform characteristics, a sample of it must be deposited in the Bank.[175] Deposition is therefore mandatory in relation to lines derived under UK licence, even though the mandate is non-statutory. Deposition is also strongly recommended by the Steering Committee for stem cell lines of other cellular or geographical origins, but participation is purely voluntary and in the absence of a legal enforcement mechanism the Code of Practice is not binding upon them unless they opt into the banking system.[176] Funding may however have a determining role, as public sources will normally require compliance with the UKSCB banking regime. The significance of the licensing condition is that it brings all users of the Bank, whether

[175] Code of Practice, 3.3. Originally the conditional requirement was to deposit to *a* cell bank; see for example the licence issued to Roslin Cells: HFEA Licence R0136-3-B Platform Technologies Underpinning Human Embryonic Stem Cell Derivation.
[176] *Ibid*, Foreword.

mandatory or voluntary participants, under the Code and the legal obligations it mandates through the standard material transfer agreements.

Contractual construction

In addition to good practice, the Steering Committee, through the Code of Practice, defines the legal infrastructure of the Bank. There is no indication that the HL Committee considered the appropriate *legal and institutional infrastructure* or design of the Bank: contractual arrangements, the nature of property rights, permissible transactions in banked cell lines, or the allocation of intellectual property rights in the event of patentable inventions from the use of banked cell lines. The Steering Committee defines the terms of deposit and withdrawal for ongoing research use that frame the legal rights of depositors, users and the Bank in relation to the banked materials.

The MTAs[177] impose contractual obligations that shape the organisation of the Bank.[178] The Steering Committee defines two main banking routes: one for laboratory or research grade stem cell lines, and one for clinical grade hESC lines that meet the requirements of the *EU Tissues and Cells Directives* (EUCTD), as implemented by the HTA, for human application.

Laboratory Grade Cell Lines

The laboratory or research grade route, which applies to cells derived in the UK or overseas, requires a standard research grade Materials Deposit Agreement (MDA) between depositor and Bank and, upon dissemination, a standard Research Use Licence (RUL) between depositor, Bank and potential user. The RUL restricts the user to research uses of the banked material, but - in the event of an unanticipated opportunity for commercial use - the user may, with the approval of the Steering

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[177] Current versions of the standard MTAs are available on the UKSCB website: http://www.ukstemcellbank.org.uk/ accessed on 27 August 2012.

[178] For specific issues raised by MTAs see: Bennett AB, Streitz WD & Gacel RA (2007) 'Specific Issues With Material Transfer Agreements' in Krattiger A, Mahoney RT, Nelsen L et al (eds) (2007) *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* 697, MIHR: Oxford UK, and PIPRA: Davis U.S.A. Available at www.ipHandbook.org.

Committee enter into a private Commercial Use Licence (CUL) with the depositor. The RUL constitutes the grant from depositor to user of a non-exclusive royalty-free licence to use the banked material[179] in 'laboratory-based, *non-commercial in vitro* preclinical' research pre-approved by the Steering Committee.[180] It does not define 'commercial' or 'non-commercial' use, but the user agrees that it provides no right or licence to sell or make other commercial use of the banked materials or any derivative materials or products made from them.[181] In later chapters I raise the fact that the creation of a distinction between commercial and non-commercial use in a field such as stem cell technology is both undesirable and fraught with difficulties, and that the UKSCB would be advised to avoid this.

The depositor retains intellectual property rights in the banked material;[182] the user owns any intellectual property arising from use of the cells obtained from the Bank, but agrees to grant a non-exclusive royalty-free licence (without right to sublicence) back to the depositor and NIBSC to use any intellectual property or results or discoveries or inventions or derivative materials, whether patentable or not.[183] The user also agrees to obtain the prior permission of the depositor regarding any publication reporting on the research, such permission not to be unreasonably withheld or delayed.[184]

EUTCD (Clinical) Grade Cell Lines

The clinical grade route applies to hESCs derived within the UK, and is more complex, as it entails a UKSCB due diligence process that is not currently spelled out in the Code of Practice. Upon application to deposit, along with a standard clinical grade Materials Deposit and Distribution Agreement (EUCTA-MDDA) between it and the Bank, the depositor must supply a Quality Agreement (QuA) assuring that the cell line meets EUTCD requirements as implemented by the HTA, as well as a

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[179] UKSCB Research Use Licence s. 2.5.
[180] *Ibid*, s. 1.1(o).
[181] *Ibid*, s. 2.10.
[182] *Ibid,* s. 3.2.
[183] *Ibid,* s. 3.3.
[184] *Ibid*, s. 4.4.

Due Diligence Initial Assessment Form (DDIAF) upon which the UKSCB carries out a panel review of EUTCD compliance prior to recommendation of acceptance of the cell line as EUTCD grade. Upon dissemination of the cell line the potential user will enter into a standard clinical grade Material Access Agreement (EUTCD-MAA) with the Bank as well as a separate private Materials Use Licence (MUL) or CUL with the depositor, for research, clinical or commercial use, depending on the type of use anticipated for the cell line.

The EUTCD-MAA specifies that clinical grade cells obtained from the Bank are to be used strictly for a project or 'programme of work' approved by the Steering Committee, with express prohibition of attempts to identify the donor (of the embryonic source) of the hESC cells,[185] and of reproductive cloning.[186] If the banked material is intended to be used in a clinical trial or work leading to a therapy, the user must ensure its traceability, and instigate procedures for potential notification to NIBSC of any serious adverse event or any reaction during clinical application that may be linked to the quality or safety of tissues or cells. The EUTCD-MAA prohibits the transfer of banked materials to third parties without Steering Committee approval, and grants no right or licence to make clinical or commercial use of the banked materials. Any such licence, to be negotiated directly between depositor and user, should define intellectual property rights, and is to be annexed to the EUTCD-MAA. The Bank disclaims any liability for the merchantability or fitness of the banked material for any particular purpose of the user, declines to warrant that it is free from contaminants, and cautions the user to satisfy itself that it the cell lines are not hazardous or infectious.

Property

Under these arrangements, personal and intellectual property in a cell line in the custody of the Bank ostensibly remains with the depositor, even though a hESC line deposited under the mandatory HFEA licensing condition cannot be withdrawn

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[185] UKSCB Materials Access Agreement for Human Embryonic EUTCD Stem Cell Lines (EUTCD-MAA) s. 2.6.
[186] *Ibid*, s. 2.3.

thereafter. It is arguable that because the derivation of stem cell lines is at present in the UK almost solely funded from public sources, that property in all of the banked material ought to transfer to the MRC or the Health Protection Agency or some other relevant body to constitute a publicly-owned resource, but this is not the case. Legal property in the material obtained from the Bank and any progeny that it generates passes directly from the depositor to the authorised user. The sample can then be used by the recipient to cultivate a master stock of undifferentiated cells to ensure a perpetual supply. Neither the Code nor the MTAs address personal property rights in the tangible materials, but focus on allocation of intellectual property created by the user during the course of downstream research involving the banked material and its derivatives.

So, the Bank has custody of banked cell lines on something like terms of bailment, in which it acts as a trustee or intermediary for their qualification and dissemination to third parties. No common property among depositors or 'owners' of the banked cell lines is created as might constitute a 'common pool resource' or 'controlled commons'[187] established by and for the benefit of a community of users. Although presently public 'derivation centres' do not heavily contest the requirement to deposit a sample of each of their hESC lines in order to create a common resource for research, they anticipate the need in future for private investment in both cell derivation and development of products and the need for delivery of cells in scalable quantities for the sustainable manufacture and production of stem cell therapies. In that scenario they argue, private investors will be deterred by an inability to obtain and maintain the exclusive control of the genetic cell line that is necessary to avoid potential reputational damage due to unreliable practices or results arising from the work of other researchers. The deposition of any portion of a particular line (defined by its genome), thus making it available to others, is a permanent relinquishment of exclusivity. These developers would prefer something other than a 'one-size fits all' system in the Bank, to permit them to retain exclusive control over certain lines of their choice, and to deposit others. There is now provision for a limited (two year)

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[187] Ostrom E (1990) *Governing the Commons: The Evolution of Institutions for Collective Action*, Cambridge University Press, Cambridge, xi.

embargo on the release of a cell line from the Bank, giving the depositor a small window of exclusive control.

1.6 Conclusions

The system of informal oversight of the use of human stem cell lines in the UK sits at the centre of a complex regulatory framework governing the conduct of embryo research, quality and safety in the handling of human tissue, and the manufacture of clinical products. Despite clear guidance from the House of Lords denying that hESC lines require regulation of the sort applied to embryos, the effect of the system is to treat hESC lines more restrictively than other types of human tissue for human application. The broad non-statutory powers of the Stem Cell Steering Committee permit it to act as a gatekeeper to the use of banked hESC lines, through the specification of permissible research purposes and standard terms of deposit and access.

The primary objective of the Steering Committee in the oversight system is to demonstrate that research involving the stem cell products of destructive embryo research is being conducted within a transparent and ethical framework, for the support of research that will ultimately generate therapeutic treatments for serious disease. The primary role of the Bank is to provide a practical resource to support this research, which it does by ensuring the traceability of technical and ethical provenance of cell lines, and the provision of outstanding facilities for quality control and international leadership in stem cell banking and cell characterisation. All of these functions are intended to build social confidence in the process of embryo and stem cell research and to provide public resources for research.

While many of the features of the UKSCB are valuable and useful for the promotion of stem cell research, there remain real questions about the relevance of the original rationale for establishment of the Bank, and its limitations as a vehicle for the equal promotion of all aspects of 'scientific technology', as I describe it in Chapter 6, including encouragement of industrial development of stem cell products through the institution of appropriate incentive structures. Although I cannot provide a full analysis of the Bank within the scope of this thesis, nor identify specific

recommendations for optimising its facilitative capacity, I do in Chapter 8 make certain summary observations pointing to relevant considerations for development of the Bank.

Chapter 2. PUBLIC GOODS

2.1 Introduction

In the previous chapter I laid out the informal system of 'oversight' of human stem cell lines in the UK and the features of the UK Stem Cell Bank. In this chapter, I construe this system as governance of the use of human stem cells, which contributes to an overarching process for the production of public goods. It has a role to play in the process of research and development that generates stem cell treatments, which in themselves constitute a type of public good, and the therapies are antecedent goods in the wider social enterprise for the production of health benefits for individuals and the general population. I include this chapter first because the field of stem cell technology is invested in the pursuit of public goods; secondly to bring some clarity to a muddy area in which there are various grounds for designation of goods as public goods and different actors who produce them; and thirdly because the public goods raise various issues for governance, from the allocation of public support, to the design of environments conducive to the private production of public goods, to the complex coordination of multiple actors in the broader global playing field. The production of public goods such as stem cell therapies requires the promotion of scientific understanding, technological utility and the productivity of the commercial market, and the task of governance is to work out how to promote them all equally.

In Chapter 3, I set out my conceptualisation of the type of governance that is best suited to the achievement of the delivery of public goods such as stem cell treatments. If upstream research and downstream production and delivery are to interact with one another in a mutually supportive framework, models of governance will have to take into account the whole trajectory of the industry, starting with the procurement of human cells and ending with the sustainable delivery of treatments in the clinic.[188]

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[188] Polak J, Bravery C and Prescott C (2010) *Translation and commercialization of regenerative medicines,* 7 Journal of the Royal Society Interface, S675-S676, published on-line 6 October 2010.

2.2 Policy goal: health

The overarching policy goal of UK public support for stem cell technology is to facilitate public health benefits by delivering stem cell therapies to the clinic.[189] The UK Stem Cell Bank affirms that its objective is to facilitate improvements in public health'[190] and that this agenda is not limited to the UK national system of healthcare, but has global dimensions. The health goal is primary, despite secondary motives and agendas that take advantage of the policy support and public image of health. International leadership in stem cell research, for example, attracts foreign collaborators and investment and enhances economic growth; nevertheless in the absence of the drive for medical advances and public health, there would be no economic gain to promote, and no political benefit to be achieved. Multiple and diverse policy agendas, like opportunities to advance private interests, coalesce around health, and together make up the multi-dimensional mix of actors, interests and vehicles that characterise the production of global public goods.

A public good such as health is not a single good, but an *effect* with complex antecedents made up of a set of complementary goods (private and public) and different types of social actors.'[191] Health is a complex of goods that generates a social effect valued by the whole world, *and* arguably exhibits the intrinsic properties of an economic public good. In Chapter 6 I set out my conceptualisation of scientific technology, which enables the governance of the production of public goods through interactivity and mutual arrangements within a domain of exchange populated by all manner of public and private resources and actors across the public and private sectors. From the public perspective, what matters is that products get to the clinic. It does not matter *why* a particular arrangement or model is used, as long as everyone is happy with it. The tool that is used will have different benefits for different parties. This broadening of perspectives on the means that might be used to achieve public goods is central to the main contribution of my thesis.

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[189] Comment of participant, SCRIPT Roundtable Workshop, September 2011.
[190] UK Stem Cell Bank, Research Use Licence (January 2012), Annexed to the Code of Practice for the Use of Human Stem Cell Lines, section 3.4.
[191] Drahos P (2004) 'The Regulation of Public Goods' 7:2 *Journal of International Economic Law* 321, 323.

2.3 'Public goods'

In economic theory a pure 'public good' is one that is not capable of production in the market, on the basis of innate economic properties. These properties distinguish it from socially valuable 'public goods' that are in 'the public interest' or for 'the public good'. Most economic public goods are not however 'pure' public goods, providing wide scope for policy choice in the determination as to whether or to what extent public support will be provided for public goods, and to what extent there is a role for private involvement in production.

Economic public goods

Any good has certain intrinsic properties that determine its ability to be transformed into a marketable product for the purposes of commercial transactions. The properties that are critical to commercial activity - the sale of goods - are excludability and rivalness. A public good lacks these features, being intrinsically 'non-excludable' and 'non-rival' in its consumption, meaning that users cannot be prevented from accessing it, and multiple consumers can use it simultaneously. The following table sets out the conventional categorisation of goods according to their economic properties.

	Excludable (Appropriable)	**Non-excludable (Non-appropriable)**
Rival	*Private Goods* • food • clothing • personal belongings	*Common Goods* • fish stocks • timber • minerals
Non-rival	*Club Goods* • cinemas • parks (entry fee) • subscription television	*Public Goods* • clean air • national defence • free to air television

The classic example of a public good is a lighthouse, which emits light from which no passing ship can be excluded. Even if all shipowners were to jointly contribute to the building of the lighthouse, its operation is unsustainable as a commercial enterprise. As the provider has no means of excluding users from receiving the light it cannot collect payment in exchange for the good, and users will not pay for what they can obtain for free. Without revenues to cover the costs of operation the would-be provider cannot remain in business.

Excludability

A good is 'excludable' if it is possible to prevent someone from having access to it, thereby making it possible to collect payment for it. Exclusion occurs when potential users can be denied goods or services unless they meet the terms and conditions of the vendor.[192] No one would buy a cinema ticket, for example, if it is possible for anyone to walk into the cinema without paying. The economic idea of excludability is aligned with the legal concept of appropriability[193] or transferability of property rights. If a good is excludable, payment can be traded for 'access' which involves a transfer of legal rights. Capacity for transference of legal rights makes a good capable of being sold, exchanged, licensed or lent. Whereas commerce requires that a product be easily appropriable, a public good is non-appropriable or difficult to appropriate.

Rivalness

A rivalrous or 'rival' good is one for which consumers must compete. Its use by one consumer prevents anyone else from using it at the same time. A good that is non-rival can be enjoyed by an unlimited number of consumers, at the same time, without being depleted.[194] Its consumption by one consumer does not prevent simultaneous

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[192] Ostrom V and Ostrom E (1977) 'Public Goods and Public Choices', Workshop in Political Theory and Policy Analysis, Indiana University; first published in Savas ES (ed) (1977) *Alternatives for delivering public services: towards improved performance,* Westview Press, Boulder, 7.

[193] From Latin *appropriare* 'to make one's own'.

[194] Durability qualifies rivalry: a rival good can be consumed by multiple users, not simultaneously, but sequentially, over time. Durability reduces or dilutes rivalness, making it less susceptible to competition. A hammer for example is a *durable* rival good. It cannot be used by two people at the same time, but can be shared through time, as the first user does not 'use up' the hammer. A banana is a *nondurable* rivalrous

consumption by others. Most examples of non-rival goods are intangible. A public television broadcast, for example, can be viewed by one consumer without preventing the neighbour next door from watching the same television programme. The television itself is a rival good, because if you have that particular television set in your home I cannot have the same one in mine; the broadcasts themselves are non-rival, unless a subscription is required in order to access the broadcast in which case it will be considered a 'club' good because non-rivalry extends only to members of the club of subscribers. Other non-rival goods include a scenic view, clean air, street lights and public safety systems. Most intellectual property is non-rival. It may be 'anti-rival' if it becomes *more* valuable as more people use it.

Beyond jointness of use or consumption,[195] the implication for non-rival public goods is that their production *costs* are fixed. This does not mean that the total production costs are low, but that the *marginal* production costs are zero. Once the good is produced, the cost of an additional (marginal) individual accessing it is zero. After the initial investment, there is no cost involved in replicating it for delivery to more consumers. The engagement of a meteorologist and air time on the radio are necessary for delivery of a weather report, for example, but once the upfront costs are met any number of people can access it. My personal receipt of that piece of information, and its receipt by everyone else who turned on their radios today, adds no further cost to the production of the weather broadcast.

Market Failure

Together the features of public goods – non-excludability and non-rivalry – deter potential producers and prevent the production of public goods in a competitive market. In simplistic terms, a pure public good will not be produced by the market. The failure of the market is due to the fact that there is no incentive for consumers to pay for a public good. In markets driven by individual self-interest, people will not pay for what they can get without paying. In economic language 'competitive

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good: its consumption by one person prevents anyone else from consuming it; once it has been eaten by one person, it is depleted and can no longer be eaten by others.

[195] Ostrom V and Ostrom E (1977), Public Goods and Public Choices, 3.

markets provide poor incentives for the production of a public good, because potential producers cannot appropriate the benefits derived from use.'[196] Non-rivalry combined with non-excludability makes the complete transformation of a public good into a commodity impossible, and business in public goods unsustainable. As a result, a free market will under-provide these kinds of goods and if they are to be produced at all they must be provided by a non-market source.

Contingency

'Pure' examples of the various categories of goods are rare, because rivalness and excludability are not absolute characteristics, but are subject to contingencies. Goods normally exhibit these properties by degrees, along a continuum or spectrum of rivalry and excludability. *Non-rivalness* in consumption of a good can be affected by various circumstances. The air we breathe, for example, is not normally a rival good, but may be rival in a confined space. Rivalry in consumption can also emerge at different times with, for example, congestion on a road or the Internet: use is non-rival up to a certain capacity, after which the speed of everyone on the road (or Internet) reduces with each additional user. Knowledge assimilated to 'information' is conventionally considered the quintessential public good,[197] but becomes rival if publications are not easily accessible.

Non-excludability of a good is even more apparently contingent. The exclusion of people from access to certain goods may be difficult or costly in economic or social terms rather than entirely impossible. The degree of non-excludability of a good is affected by social norms and technologies, and determines where it sits at any point in time on the public goods continuum. Many classic public goods, such as the lighthouse example, could with some difficulty be made excludable by law. The UK authorities have for example collected payment for lighthouse services based on the routes followed by ocean-going vessels. Street lights too *could* be made excludable by technical means if light were to be broadcast only in infrared and special goggles issued to take advantage of it. A legal solution would be 'streetlight licences' for

[196] Stephan PE (1996) 'The Economics of Science' 34:3 *Journal of Economic Literature* 1199, 1201.
[197] Drahos P (2004) 'The Regulation of Public Goods' 7:2 *Journal of International Economic Law,* 321.

purchase only by those who go out after dark. In many cases the answer is an economic one: it may be *cheaper* to make a good such as light universally available than to make it excludable, either by technology or by law.

On the basis of its intrinsic properties it may therefore be difficult to determine whether or not a good is a public good incapable of market production. With the privatisation of scientific research for example, the view of science as a public good is becoming increasing untenable.[198] If science is a public good it does not need protection from market forces, but requires support because the market is not sufficiently interested in it. If it is not a public good then it should be marketable. If it is a 'quasi-public good' market failure is not absolute, but some support to cover transaction costs is required to ensure its stability in the marketplace.

Scholars are currently revisiting the textbook economic theory of public goods, with a view to adjustment of the concept of public goods to present political and economic realities.[199] It has been said that 'historically and by definition, it is very difficult to determine a stable range and extent of public goods.'[200] The properties of non-excludability and non-rivalry are, for example, considered poor predictors of publicness, of questionable suitability to provide critical benchmarks for modern decision makers[201] and inadequate to deal with the globalisation that many public goods have undergone: either as a result of the national reduction of barriers to international trade and cross-border policy harmonisation, or because national public domains have been exposed to cross-border externalities and policy choices made in

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198 Callon M and Bowker G (1994) 'Is Science a Public Good?' 19:4 *Science, Technology and Human Values* 395.

199 Kaul I (2012) 'Rethinking Public Goods and Global Public Goods' in Brousseau E, Dedeurwaerdere T and Siebenhuner B (eds) (2012) *Reflexive Governance for Global Public Goods*, MIT Press, Cambridge MA; Kaul I, Conceição P, Le Goulven K and Mendoza RU (2003) 'Why do Public Goods Matter Today? in Kaul I, Conceição P, Le Goulven K and Mendoza RU (eds) (2003) *Providing Global Public Goods: Managing Globalization,* United Nations Development Programme, Oxford University Press, Oxford and New York 2**;** Kaul I and Mendoza RU (2003) 'Advancing the Concept of Public Goods', in Kaul I et al (2003) *Providing Global Public Goods,* UNDP, OUP 78; also Desai (2003) 'Public Goods A Historical Perspective', in Kaul I et al (2003) *Providing Global Public Goods,* UNDP, OUP**.**

200 Doering OC III (2007) 'The Political Economy of Public Goods: Why Economists Should Care' 89:5 *American Journal of Agricultural Economics* 1125, 1128.

201 *Ibid*, 1128.

other countries or by global nonstate actors.[202] Further, the concept of publicness as availability of a good for all to enjoy is refuted by the suggestion that although some public goods may meet with wide public appreciation, preferences for public goods vary according to factors such as geography, socio-cultural context, and income level.[203] Given that democratic societies determine what goods and services the public should support or be involved in providing,[204] it has been suggested that economists should approach public goods from the perspective of political economy, declaring values rather than pretending complete independence from them and being aware of the objective implications of the values on which a policy rests.[205]

'Global public goods'

The economic focus on allocation of resources to public goods has expanded to include issues relating to the provision of 'global public goods', such as global public health and the protection of the environment, which have 'benefits that extend to all countries, people, and generations.'[206] The concept thus combines high social value and a multi-faceted economic 'good' with the added dimension of international public interest. 'Global public goods' are desirable to the world as a whole, encompass a wide range of physical commodities, services, technologies, and information, and are likely to demonstrate the attributes of economic public goods: once it is provided no one can readily be excluded from access to it, and consumption by one party does not prevent anyone else from consuming it.[207]

The concept of health in the literature of global public goods is focused largely on issues related to international development,[208] such as the prevention of pandemics through transmission of infectious disease. Emerging medical technologies should not however be excluded from the concept of health as a global public good on

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[202] Kaul I et al (2003) Advancing the Concept of Public Goods 81.
[203] *Ibid*,
[204] Doering OC III (2007) Political Economy of Public Goods 1128.
[205] *Ibid.*
[206] Kaul I et al (2003) Why Do Global Public Goods Matter Today? 3.
[207] *Ibid.*
[208] Kaul I et al (1999) 'Global Public Goods: International Cooperation in the 21st Century' United Nations Development Programme, Oxford University Press, Oxford and New York.

grounds that they are being pursued primarily in developed countries, or because it will be some time before they are transferred to less developed states. Issues of equitable access to the health benefits of medical treatment are part of the portfolio of policymakers involved in facilitation of provision, distribution and uptake of global public goods.

Like national public goods, these properties imply a lack of commercial incentive to produce the goods. The situation is exacerbated in the international context, as there is no global government to regulate or enforce production and limited harmonisation of normative regimes across transnational boundaries. The 'regulatory context'[209] in which public goods – and especially international public goods - are situated increasingly includes governance by global standards and non-state actors as well as states. While governments are still essential in providing public goods nationally and internationally, private actors including for-profit (firms) and not-for-profit (foundations, civil society organisations, households and individuals), also come into play.[210]

The central question is therefore how to ensure provision and the distribution and uptake of benefits, which in some cases happens automatically (for example clean air) and in others does not (technical knowledge).[211] My conception of facilitative governance set out in the next chapter affirms a 'decentred' approach to regulation, which encompasses a variety of state and non-state actors and legal and non-legal norms, as most likely to be capable of producing strategies for dealing with problems related to the supply and maintenance of public goods.

Criticism of conventional public goods theory also extends to an analysis of provision,[212] particularly the emphasis on market failure and provision by the state in the international context. The focus on government provision is challenged on

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[209] Drahos P (2004) The Regulation of Public Goods 321.
[210] Kaul et al (2003) Why Do Global Public Goods Matter Today? 9.
[211] Drahos P (2004) The Regulation of Public Goods 321.
[212] Kaul I (2012) 'Rethinking Public Economics: Recognizing Public Goods', draft paper 24/04/2012, available at http://www.ingekaul.net/pdf/2012/Rethinking_Economics_fin_Disc_Draft1.pdf accessed 15 October 2012.

grounds that the defining criterion of a public good is collectiveness in consumption, and that provision of public goods today tends to be a multi-actor process, both nationally and internationally.[213] The emphasis on *market failure* neglects the potential for *state failure* to provide public goods due to governmental limitations particularly in relation to delivery of goods outside of the national sphere.[214] Further, out-dated assumptions underpinning public goods theory arguably result in efficient but insufficient provision: public goods now result from public-private partnerships and that regional and global public goods may require national as well as international level interventions.[215] Lastly, the standard presentation of public goods says nothing about international cooperation, funding and institutional arrangements for the production of global public goods.[216] On the basis of this criticism, certain scholars[217] propose a new sub-discipline of 'global public economics'[218] which focuses on the public goods themselves, rather than on the role of the state, and addresses them in an integrated fashion, covering both national and international aspects of their provision.[219]

Social public goods

Even if health is not an economic good *per se*, there is no serious debate or challenge to the idea that health is in 'the public interest' and for 'the public good' despite the fact that these concepts are not yet well-defined in law or elsewhere. Of all social goals, the protection and promotion of health is arguably most fundamental to the welfare of human beings and remains a top priority for the public as well as for medics.

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213 *Ibid.*
214 *Ibid.*
215 *Ibid.*
216 *Ibid.*
217 *Ibid* Kaul I (2012) Rethinking Public Economics; also Sandmo (2006) 'Global Public Economics: Public Goods and Externalities', *Revue de l'Institut d'Économie Publique*, 18 to extend the analysis of public goods and externalities to an international setting.
218 'Global public economics' has been used elsewhere in relation to global taxes and subsidies: see Mirrless JA (2004) 'Global Public Economics', in Atkinson AB (ed) *New Sources of Development Finance,* UNU-WIDER Studies in Development Economics, Oxford University Press, Oxford, 200.
219 Kaul I (2012) Rethinking Public Economics: Recognizing Public Goods.

2.4 Public choice

The contingency and complexity of public goods creates possibilities for government authorities to makes choices about whether and to what extent they will be involved in the supply of public goods. Most public goods cannot be described as *pure* public goods, but are supported *as* public goods as a matter of policy choice.[220] Some choices are based on public interest grounds, as discussed earlier. It has been argued, for example, that science is not in economic terms a public good, but is rival and appropriable/excludable to a greater or lesser extent, depending on 'strategic configurations into which it enters'.[221] This is not a function of intrinsic properties but of choices. Society wants to view science as independent. The treatment of science as a public good to ensure its protection as a *sui generis* activity[222] is justified on strong public interest grounds.

With the recognition that most of the real economy operates 'in the messy world of impure public goods',[223] there is also room for extensive political debate over the resources to be devoted to the delivery of public goods and the extent to which markets and non-market systems should be involved in the process. Just because markets do not spontaneously generate a public good does not imply that states must do so. The focus of economic debate has therefore shifted from ensuring governmental provision of public goods and services, to determining who should provide them, and finding ways of organising the public economy to enable the market to play a greater role in provision.

2.5 Challenges

The complexity, contingency and increasingly global nature of public goods, and health in particular, creates serious problems for provision. The main challenge for public 'provision' is to find ways of addressing complex coordination problems, permitting production of public and private goods and services and the involvement

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[220] Kaul et al (2003), Advancing the Concept of Public Goods, 81.
[221] Callon M and Bowker G (1994) Is Science a Public Good?, 416.
[222] *Ibid.*
[223] Drahos P (2004) The Regulation of Public Goods, 321.

of a variety of social actors including public agencies and private suppliers. Government cannot simply 'provide' the final public good of 'health' - or stem cell therapies for clinical use - which requires production of a host of complementary public and private goods and services, including the generation of scientific and technical knowledge, stem cell lines, RM therapies and healthcare services.

Governance

Provision of public goods therefore requires some rules regarding consumption to ensure sustainability. These have typically been provided by state regulation through legislative structures and sanctions. These measures may not however be adequate to handle the coordination problems associated with the complex public good of health, as will be discussed in the next chapter.

The alternatives are not however limited to government regulation and completely unlimited use of public goods. If consumers can be organised to act as 'collective consumption units'[224] then alternatives may be available for the provision of public goods and services, including private suppliers and governmental agencies serving as suppliers. The difficulty is that consumers cannot be expected to organise themselves through the establishment of large voluntary organisations on the basis of consensual arrangements for the pursuit of public goods, unless there is a separate individual benefit of sufficient magnitude to make the effort worthwhile, or they can be coerced to pay a share of the costs of production.[225] It is difficult, but possible, for individuals to overcome the problem of collective inaction by a choice of constitutional rules to provide some organisational structure that will order future collective decision-making.[226] This type of organisation is the basis for the commons approaches to governance that I discuss in a later chapter.

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[224] Ostrom V and Ostrom E (1977) Public Goods and Public Choices, 1.
[225] Ostrom V and Ostrom E (1971) 'Public Choice: A Different Approach to the Study of Public Administration' 31:2 *Public Administration Review* 203, 207; Olson M (1965) *The Logic of Collective Action,* Cambridge U Press, Harvard University Press.
[226] Ostrom V and Ostrom E (1971) Public Choice: A Different Approach, 207.

Private Production of Public Goods

On the provision side, the difficulty for private suppliers is that private delivery of *public* goods is a different matter than the private delivery of *private* goods. The private producer of public goods must understand the public economy in order to successfully pursue opportunities within its constraints. Public goods are not like marketable commodities. Characteristically it is difficult to measure their quantity and quality; they are 'indivisible' into saleable units from which consumers can be excluded; they are consumed jointly and simultaneously, and supplied unilaterally without consumer choice as to either consumption or kind and quality of goods. Payment is not closely related to demand or consumption and allocation decisions are made primarily by political process.[227] Such problems of appropriation can deter private suppliers of public goods. [228]

Globalisation

Global public goods have their own problems, as outlined above, including the fact that standard public goods theory may fail to consider the international dimensions of global challenges. In science and technology there is increasing need for international collaboration and communication, standardisation of policies and procedures, exchanges of materials, information and data.[229] Organisational structures for governance should take into account the transnational nature of these networks.

2.6 Conclusions

My inclusion of this short description of public goods is intended primarily to raise the awareness of the reader in relation to the complexity and contingencies related to the definition and production of public goods, including health, and the fact that significant choices confront policymakers regarding their provision. 'Health' is, in

[227] Ostrom V and Ostrom E (1977) Public Goods and Public Choices, 7.
[228] Drahos P (2004) The Regulation of Public Goods, 325.
[229] Audretsch DB and Stephan PE (2002) 'The Economics of Science and Technology', 27:2 *The Journal of Technology Transfer* 155, 183-4.

public goods terms, a complex 'effect' that encompasses the production of antecedent public and private goods, and a multiplicity of social actors. It is a public good both in the sense that high social value is placed on it by individuals and governments, and by the public choices made to provide economic support for its provision. Public goods pose serious problems for provision, because the intrinsic economic properties that make them available for the benefit of everyone simultaneously makes them incapable of sustainable commercial production. These properties are however present in most goods to a greater or lesser degree and there is therefore room for public deliberation in regard to whether and to what extent governments will 'provide' the desired public good and how they might encourage private actors to become involved in aspects of the process. Such deliberations are an aspect of decentred governance in which public authorities are able to adopt policy choices to facilitate the production of stem cell lines and promote private investment in the development of stem cell technology.

In the next chapter I set out my conceptualisation of facilitative governance that is best suited to the type of challenges presented by the provision of public goods including stem cell products and their health benefits.

Chapter 3. FACILITATIVE GOVERNANCE

3.1 Introduction

In the previous chapter, I outlined the policy enterprise as one of provision of public goods, and health in particular. I also identified the distinctive features of public goods and the main problems that they pose for production. In Chapter 3, I place the discussion of public goods within a regulatory context by proposing a conceptualisation of 'facilitative governance' that is capable of fostering complex life sciences technologies and the provision of public goods for health. This view of facilitative governance accords with my conceptualisation in Chapter 6 of 'scientific technology' in a domain of interactivity and exchange that is conducive to design of strategies for facilitative governance in the life science technologies.

In Part II, I consider the concept of 'openness' in science and technology, and ask how and to what it extent it might enhance the objectives and functions of facilitative governance that I propose here.

My conception of governance is broad in scope. It is *de-centred:* not centred on state activity, but encompassing the actions of non-state entities as well as government in the shaping of social behaviour. It construes governance as *purposive,* contemplating positive attempts to achieve a broadly defined outcome. It encourages *reflexivity*, the continual reassessment and adaptation of methods by all actors in the system to avoid adverse impacts of their actions on one another. Inclusive of a diverse range of perspectives, reflexivity is considered the key to 'second order governance' that facilitates activity in environments potentially bogged down by complexity and heterogeneity. It is horizontal and participatory, rather than hierarchical; it is the collective negotiation of complementarity among actors, rather than an authoritative imposition of one perspective. Reflexivity is an 'open' process.

Finally, my abstract value-laden conceptualisation of facilitative governance provides a standard against which specific instruments or systems may be tested. It is not merely an observation of the world, but is intended to inspire practical discussions about governance and how it might be improved. In Part III, I propose

an analytical framework: preliminary steps toward strategies for the governance of stem cell technology, with potential application to other fields. I test that framework against the features of facilitative governance that I set out here as well as the UK arrangements for oversight of stem cell lines.

3.2 Terminology

I start with a note about terminology. The phenomenon that I refer to as 'governance' could equally be called 'regulation' and I use the terms interchangeably for self-explanatory purposes in certain contexts. The plethora of definitions and understandings of regulation and governance makes it impossible to adopt a name that does not have a pre-established definition or loaded connotation. In the field of medicinal products, for example, 'regulation' connotes a specific body of detailed legislative rules administered by the MHRA for the assurance of quality and safety through the conduct of phased clinical trials. 'Regulation' is associated with onerous hurdles en route to pre-market approval and delivery of a pharmaceutical product. The terms 'governance' and 'new governance' are equally problematic.[230] The recent appreciation of social activity as opposed to state measures in shaping behaviour is referred to by political scientists as a shift from 'government' to 'governance', and by regulatory theorists as a move to 'smart' or 'decentred' regulation. The absence of a common nomenclature is daunting to the reader[231] and requires scholars to continually reinvent the definitional wheel.

Concepts

Being led by a policy goal that prioritises facilitation of public goods for health, the significance of the conceptualisation of governance is not so much what it means[232] but what it can do, or what we can do with it.[233] There are strong connections between an understanding of governance, its functions and the normative principles

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[230] Karkkainen BC (2004) 'New Governance in Legal Thought and in the World: Some Splitting as Antidote to Overzealous Lumping' 89 *Minnesota Law Review* 471, 478.
[231] *Ibid.*
[232] Black J (2002) *Critical Reflections on Regulation*, ESRC Centre for Analysis of Risk and Regulation, London School of Economics and Political Science, 16, citing Rose N (1999) *Powers of Freedom: Reframing Political Thought*, Cambridge University Press, Cambridge, 9.
[233] Black J (2002) *Critical Reflections*, 19.

or values that are applied to it. With this in mind, I understand 'facilitative governance' to be inclusive of a wide range of actors and activity, purposive in direction and capable of reflexivity and adaptability. Its function is to negotiate solutions to problems that inhibit activity essential to the provision of public goods.

3.3 Decentredness

The foundation of my conception of facilitative governance is its broad scope, inclusive of a wide range of actors. I adopt the view that 'public goods problems are best understood within a concept of governance that political scientists, as well as regulatory and social theorists would refer to as 'decentred'.[234] 'Decentredness' describes a departure from traditional state-centred concepts of government, as distinct from 'non-centred' models of governance that admit very little if any role for the state. Both 'decentred' perspectives and non-centred 'network governance' theories of regulation are responses to an alleged 'failure' of state-centred regulation. They are different responses to the limitations of the traditional structures of liberal democracy, and the shortcomings of the two orthodoxies of 'regulation' and 'deregulation'. Decentred concepts of governance have become the dominant paradigm of regulatory scholars,[235] falling somewhere between restrictive concepts of government regulation and models of 'network governance' that admit only informal social activity.

Government

The conventional notion of 'regulation' is that of governmental 'command and control':[236] a body of legal rules backed by enforceable sanctions. Proponents of the inclusion of a wider range of institutions in concepts of governance describe regulation as 'hierarchical, state-centric, bureaucratic, top-down and expert-

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[234] Drahos P (2004) 'The Regulation of Public Goods', 322.
[235] *Ibid*, 323.
[236] Papaioannou T (2009) 'Governance and Justice: The Challenge of Genomics' in Lyall C, Papaioannou T and Smith J (eds) (2009) *The Limits to Governance: The Challenge of Policy-Making for the New Life Sciences* Ashgate, Farnham UK and Burlington USA, 21; Jordan A, Wurzel RKW and Zito A (2005) 'The Rise of "New" Policy Instruments in Comparative Perspective: Has Governance Eclipsed Government?' 53 *Political Studies* 477; Black J, (1997) *Rules and Regulators* Oxford University Press, Oxford; Black J (1999) 'Using Rules Effectively' in C McCrudden (ed) (1999) *Regulation and De-Regulation,* Oxford University Press, Oxford 95.

driven'.[237] It is exemplified by the US consumer protection and environmental regulation of the 1970s[238] and the British 'Westminster model'[239] of state-centred control; it is epitomised by attempts to micro-engineer solutions to societal problems through a series of fragmentary, piecemeal, and highly prescriptive regulatory interventions, producing an impossibly complex and tangled web of rigid, uniform one-size-fits-all rules.[240]

Quite apart from academic attempts to broaden the scope of 'regulation' to include non-state organisations, the political perspective on regulation is narrow and simplistic,[241] not solely because its methods are rigid, but because government treats it merely as part of economic management.[242] Regulation is considered a necessary but regrettable means of correcting market failures, and as a second best option for social organisation, as juxtaposed not against non-state means, but against the free market, which is considered preferable because it in principle provides economic freedom and consumer choice. This limited political view of regulation arises from the fact that quintessential regulatory bodies have been involved with public utility services such as water and energy, where problems of natural monopoly prevent markets from operating freely on their own.[243]

Networked governance

At the other end of the spectrum is what I refer to as 'networked governance' that denies any authoritative role for government. Rooted in the network theory of RAW Rhodes, it construes governance as informal, self-organising, inter-organisational networks that are supplementary to, and autonomous from, the formal authority of government.[244] On the basis of patterns of social order in policy-making, Rhodes

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[237] Karkkainen BC (2004) 'New Governance', 474.
[238] *Ibid.*
[239] Rhodes RAW (2007) 'Understanding Governance: Ten Years On', 28 *Organization Studies* 1243, 1246.
[240] Karkkainen BC (2004) 'New Governance', 474.
[241] Prosser T (2010) *The Regulatory Enterprise: Government, Regulation, and Legitimacy*, Oxford University Press, Oxford and New York, 1.
[242] *Ibid.*
[243] *Ibid.*
[244] Rhodes RAW (1996) 'The New Governance: Governing without Government', XLIV *Political Studies*, 652; Rhodes RAW (1997) *Understanding Governance: Policy networks, governance, reflexivity, and accountability*, Open University Press, Buckingham and Philadelphia; Rhodes RAW (2007) 'Governance: Ten Years On';

asserted that formal and informal institutional links between governmental and other actors, such as the professions, trade unions and big business, are structured around shared interests in public policymaking and implementation. These networks were described as characterised by interdependence and continual interaction among organisations, involving resource exchange, mutually beneficial negotiation, and a significant degree of autonomy from the powers of the state. They were also considered complementary to markets and hierarchies, and inclusive of government as one of the informal participants, without being accountable to the state.

The idea was that the growth of 'network governance' had 'hollowed out' the state by reducing the ability of the core executive to act effectively,[245] making it less reliant on a command operating code and more reliant on diplomacy.[246] In this 'private government of public policy by closed policy networks' the formal authority of government was considered at best *residual*. Initially, a small role was admitted for central government in (indirectly and imperfectly) 'steering' networks,[247] but it was later concluded that the use of central *steering* as a set of tools for managing governance was incompatible with a concept of governance as constructed through contingent and continuous networks.[248] Rhodes later revised his theory however in response to the academic criticism mentioned below.

'Decentred' governance

If the 'command and control' conception of governance pays too little attention to the 'complex causality of regulatory effects',[249] a decentred construction recognises the wide range of causality in the actions of state and non-state actors and legal and non-legal norms.[250] Between the models of 'government' and non-centred 'network

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Bevir M, Rhodes RAW and Weller P (2003) 'Traditions of Governance: Interpreting the Changing Role of the Public Sector in Comparative and Historical Perspective', 81 *Public Administration,* 1.

[245] Rhodes distinguishes intervention from control and suggests that although the British core executive often intervenes, its interventions do not have the intended effects, and so cannot be considered as control. Rhodes RAW, 'Understanding Governance: Ten Years On' (2007) 28 *Organization Studies* 1243, 1248.

[246] *Ibid,* 1248.

[247] *Ibid*, 1246.

[248] *Ibid,* 1257.

[249] Drahos P (2004) The Regulation of Public Goods, 322.

[250] Black J (2002) Critical Reflections.

governance', are many forms of 'decentred' governance perspective. What they have in common is that while they acknowledge that regulation can come from sources beyond the activity of the state, they do not deny government a role. They remain distinct from completely 'non-centred, privatised forms of civic action'[251] that would deny any effective role to government. What distinguishes the variants of decentredness is the degree to which they view non-state regulatory activities as *connected* to the state. In many theories of 'decentredness', non-government forces are simply innovative methods of public administration. 'New governance'[252] is described as a break from the old style of government to promote new and superior methods of public governance; scholars assert various public techniques[253] for harnessing non-state actors in order to create hybrid mechanisms for furthering policy objectives. These innovative methods of public administration are described as 'more collaborative, multi-party, multi-level, adaptive and problem-solving'.[254] They are 'open-textured, participatory, bottom-up, consensus-oriented, contextual, flexible, integrative and pragmatic'.[255] There are many variants on the 'new governance' type of decentredness theory: 'smart regulation' suggests multiple rather than single policy instruments and a broader range of regulatory actors;[256] the 'regulatory arrangements approach' would impose some constraints on the 'almost infinite' number of options for smart regulation by reference to national policy style, policy arrangements and the effects of adjoining policy arrangements;[257] a principles-based approach[258] favours replacement of detailed rules in legislation and codes of practice with principles, as a means of providing the target audience with expanded discretion in decision-making.

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[251] Lobel O (2004) 'Setting the Agenda for New Governance Research', 89 *Minnesota Law Review* 498, 508.
[252] Eberlein B and Kerwer D (2004) 'New Governance in the European Union: A Theoretical Perspective,' 42:1 *Journal of Common Market Studies*, 121. Available at http://onlinelibrary.wiley.com/doi/10.1111/j.0021-9886.2004.00479.x/pdf, accessed 22 May 2011.
[253] Lobel O (2004) Setting the Agenda, 509.
[254] Karkkainen BC (2004) New Governance, 473.
[255] *Ibid*, 474.
[256] Gunningham N and Sinclair D (1998) 'Designing Smart Regulation', available at www.oecd.org/dataoecd/18/39/33947759.pdf, accessed 23 March 2011. This is an abridged version of the concluding chapter of Gunningham N and Grabosky P (1998) *Smart Regulation: Designing Environmental Policy,* Oxford University Press, Oxford UK.
[257] Van Gossum P et al (2010) From 'smart regulation' to 'regulatory arrangements', 43 *Policy Science* 245.
[258] Black J (2008) 'Forms and paradoxes of principles-based regulation', 3:4 *Capital Markets Law Journal*, 425.

Other proponents of 'decentred'[259] theory do not presume that regulation is tied exclusively, or even predominantly, to the state but suggest that it is 'diffused throughout' society.[260] This sort of decentredness is not understood as innovative public administration *per se*, nor does it constitute a complete denial of an effective role of government, but it accepts that some patterns of order found in society may be 'regulatory activity' or 'governance', whether or not they are harnessed in any direct way by the state. This theory of decentredness does not abandon the concept of an role of an active state in a democracy,[261] nor try to replace conventional, sanctioned approaches in all contexts;[262] it promotes an alternative to entrenched or failed government structures without attacking the state as a whole.[263] This concept of governance or regulation suggests that to identify activities that are significant for systems of control being exercised in society it is necessary to think about non-governmental as well as state-centred activity. Without a broad analytical framework we might fail to recognise the acts of non-state entities as a significant regulatory force, or be ill-equipped to make sense of them. A 'decentred' analysis looks for patterns of social ordering or control in society that may or may not emanate from the state. [264]

Affirmation for this type of 'decentring' is found in the fact that Rhodes himself now claims to have adopted it, following substantial criticism[265] of his theory of network governance. The limits to networked governance[266] have been given specific consideration in the field of the new life sciences, where scholars have noted that 'the emphasis on networks in the governance literature tends to ignore the continued

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[259] Black J (2002) Critical Reflections, 1.
[260] *Ibid.*
[261] Lobel O (2004) Setting the Agenda, 502.
[262] *Ibid*, 506.
[263] *Ibid*, 502.
[264] Black J (2002) Critical Reflections, 1.
[265] Rhodes RAW (2007) Understanding Governance, 1259, citing Marinetto M (2003) 'Governing Beyond the Centre: A critique of the Anglo-Governance school' 51 *Political Studies* 592, 605. Rhodes concurs with his conclusion that the Anglo-Governance school has 'to undergo an intellectual crisis wrought by the growing weight of criticism'.
[266] Lyall C, Papaioannou T and Smith J (eds) (2009) *The Limits to Governance: The Challenge of Policy-making for the New Life Sciences*, Ashgate, Farnham UK and Burlington USA.

importance of hierarchy'.[267] They suggest that future governance of the life sciences should incorporate the most useful aspects of governance-based approaches and reconcile them with government initiatives in a way that does not exclude key stakeholders – including the pharmaceutical industry – from the policy debate.'[268] Rhodes now argues in favour of decentredness as an 'alternative way to conceptualise the institutions, actors and processes of change in government'. Without abandoning his foundations in network theory, he agrees that the state can act in a decisive way, and that the centre coordinates and implements policies as intended at least some of the time, even if too little importance is attached to unintended consequences that erode effectiveness.[269]

So, the broadening of the concept of regulation to one of decentred governance is a welcome[270] development, but it has its limitations. The shift from state versus market to the inclusion of non-state actors and non-economic rationales makes governance 'an all-pervasive phenomenon that cannot be isolated from broader social theory'.[271] 'Governance' could include virtually every system of social control, social norms and culture, in addition to the formal government functions of law and administration. The scope of the broadest conception of governance could be unwieldy and incoherent as a framework of analysis, or cause a loss of focus.[272] It is necessary therefore to define the activities understood as governance within limits or parameters, determined in accordance with the goals of governance.

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[267] Lyall C, Papaioannou T and Smith J (2009) 'The Challenge of Policy-making for the New Life Sciences', in Lyall C, Papaioannou T and Smith J (eds), *Limits to Governance,* 10.
[268] *Ibid.*
[269] Rhodes RAW (2007) Governance: Ten Years On, 1258.
[270] Prosser T (2010) *The Regulatory Enterprise*, Oxford University Press, Oxford, 2.
[271] Prosser T (2006) 'Regulation and Social Solidarity', 33:3 *Journal of Law and Society* 364, 375.
[272] Prosser T (2010) The Regulatory Enterprise, 19. Prosser overlays four competing classifications of regulatory activity on the broad scope of regulation in order to restore focus without forcing regulation into one narrow and restrictive single model.

A definition

My *definition* of governance is, therefore:

Governance is the sustained and focused attempt to alter social behaviour according to defined standards or purposes, with the intention of producing a broadly identified outcome.

This is an adaptation of the definition of 'decentred' regulation established by Black[273] and provides an appropriate lens through which to approach the regulation of the life sciences technologies. It is an *abstract* definition, independent of context, making it susceptible to application or adaptation to new circumstances. It refers to both the fundamental elements and the functions of governance.[274] Its *scope* is neither under- nor over-inclusive. It is not so narrow as to be rigid or exclude non-governmental controls and reflexive processes, but not so inclusive of non-state social ordering that it becomes incoherent. A 'sustained and focused *attempt*' is purposive or goal-oriented, can take many forms, and can be undertaken with the participation of a multidisciplinary contingent of actors in both national and international contexts. By focusing on *intentional* problem-solving, impersonal forces such as 'culture' and 'the market' are eliminated from the concept. No purposes are excluded *per se*, as long as they are defined, which permits commercial, social and even certain personal interactions, for the benefit of individuals, collectives or publics.

My conception of governance corresponds to the definition of regulation proposed by Julia Black, except that it omits the tasks she includes to exemplify what might be involved: standard-setting, information-gathering and behaviour-modification. These are drawn from the field of cybernetics[275] and provide specificity, as examples of important functions of regulatory systems, but I exclude them for two reasons.

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[273] Black J (2002) Critical Reflections, 20. The original definition is: 'Regulation is the sustained and focused attempt to alter the behaviour of others according to defined standards or purposes, with the intention of producing a broadly identified outcome or outcomes, which may involve mechanisms of standard-setting, information-gathering and behaviour-modification.'

[274] Black contrasts abstract 'essentialist' and 'functional' definitions with 'conventionalist' definitions that are applied in a particular context ('regulation' as used in x means…).

[275] The interdisciplinary study of the structure of regulatory systems.

First, two of them seem redundant. If regulation is conducted 'according to standards and purposes', it will presumably involve a mechanism for standard-setting. Likewise, if regulation is defined as an attempt to alter behaviour, the creation of a mechanism for behaviour-modification seems implicit in the definition. Perhaps these mechanisms have significance for the field of utility regulation, of which Black has experience, but it is not immediately apparent what they add, for my purposes, to the core definition. Secondly, the concern expressed by Black - that without mention of these exemplary tasks, 'regulation' could be construed too narrowly through the tendency of interpreters to focus heavily on one or the other of them[276] – is open to question. In any event, the articulation of possible mechanisms for expression does not change the core definition. I have therefore dropped all three, including information–gathering. The core definition proposed by Black nevertheless provides a strong foundation on which to build a regulatory approach to the use of stem cells.

3.4 Purposiveness

Governance, as I conceive of it, is action undertaken with a purpose and a goal. It involves intentional, systematic attempts at problem-solving. Policymakers and legal scholars differ from social scientists in the adoption of this positive approach. Lawyers cannot be content with the observation and analysis of social phenomena; our mandate is to find ways of addressing contemporary problems. We want to understand not only how regulatory forces function, but how they might work 'better' in order to achieve certain objectives. A conception of governance as 'purposive' recognises a degree of human 'intentionality' (whether or not linked to government) thus distinguishing it from other systems of social control and ordering.

A purposive approach will look to the subject (technology) for the goals of governance. There is a clear relationship between the goals of the enterprise and the goals for *governance* of the enterprise, in that they each address the same set of circumstances. Medicine and healthcare seek solutions to problems as a means of

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[276] Black J, *Critical Reflections on Regulation*, ESRC Centre for Analysis of Risk and Regulation, London School of Economics and Political Science 2002, 20.

promoting practical health benefits; the objectives of stem cell research and innovation are to develop therapeutic treatments that will eventually become routinely available in the clinic and so improve human life. The objective of governance is to facilitate, directly or indirectly, the achievement of these goals, which it does through *purposive* measures: the design, construction or coordination of mechanisms or arrangements. Purposiveness is not to be confused with the authoritative imposition of measures, or a static approach to problem-solving. The point of the purposive construction of innovative governance strategies, such as those I consider later in this thesis, is that they should have built into them capacities for second order reflexivity, which is an important tool of facilitation. Purposiveness in this sense differs from the purpose-oriented *substantive law* described by Teubner as programmes of action implemented through regulations, standards and principles, which he distinguished from both *formal* (rules-oriented) and *reflexive* (procedure-oriented) types of legal rationality.[277]

3.5 Reflexivity

Rational problem-solving

In the literature of governance,[278] conventional approaches to regulation are associated with systems of rational problem solving, and their failure to provide procedures for identifying and addressing the unintended consequences of their actions. The concept of reflexivity that I adopt as a component of facilitative governance differs from, but has been influenced by, Teubner's theory of reflexive *law,*[279] which draws upon ideas about 'responsiveness' that originated in mechanisms

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[277] Teubner G (1983) 'Substantive and Reflexive Elements in Modern Law' 17 *Law & Society Review* 239, 257.

[278] Voss J-P and Kemp R (2005) 'Reflexive Governance for Sustainable Development: Incorporating feedback in social problem problem-solving', Paper for ESEE Conference, special session on transition management, 14-17 June 2005, Lisbon.

[279] Teubner G (1983) 'Substantive and Reflexive Elements; Teubner G (1986) 'After Legal Instrumentalism: Strategic Models of Post-Regulatory Law' in Teubner G (ed) (1986) *Dilemmas of Law in the Welfare State,* Walter de Gruyter, Berlin and New York; Teubner G (1987) 'Juridification - Concepts, Aspects, Limits, Solutions' in Teubner G (ed) (1987) *Juridification of the Social Spheres,* Walter de Gruyter, Berlin.

of legal enforcement.[280] The enforcement-based concept of responsiveness was expanded to encompass broader notions of deliberative democracy and restorative justice[281] which informed the Teubner ideas on reflexive law,[282] as well as more recent formulations of 'really responsive' regulation.[283] Teubner suggests that reflexive law, instead of 'taking over responsibility for the outcomes of social processes', 'restricts itself to the allocation, correction and redefinition of democratic self-regulatory mechanisms.'[284] His 'reflexive law' a. is *justified* by the desirability of coordinating recursively determined forms of social cooperation;[285] b. facilitates decentralised integration of semi-autonomous *social systems* by structuring and restructuring their internal discourse and methods of social coordination; and c. has an *internal rationality* that is not based on precisely defined formal rules or substantive principles, but tends toward procedural norms that regulate processes and organisation and the distribution of rights and competencies.[286] In my thesis these aspects of reflexivity are features of a decentred conceptualisation of governance, rather than law, and function to remedy difficulties associated with problem-solving approaches to regulation, without necessarily involving the authority of state or government regulators.

Regimes of 'rational problem-solving' are systems of optimal rules for a specific environment that can be implemented through sophisticated methods of intervention and control. The aim is to eliminate uncertainty and uncontrolled influences by concentrating on a specific slice or dimension of a complex reality – selecting relevant elements, using linear constructions of cause and effect, placing goals in hierarchical order, and allocating responsibilities. This 'productive reduction of complexity'[287] is behind 'modern science', technological development, bureaucratic

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[280] Ayres I and Braithwaite J (1992) *Responsive Regulation* Oxford University Press, Oxford.
[281] Braithwaite J (2002) *Responsive Regulation and Restorative Justice* Oxford University Press, Oxford; Selznick P (1992) *The Moral Commonwealth* University of California Las Angeles Press, Berkely 463; Nonet P and Selznick P (1978) *Law and Society in Transition: Toward Responsive Law,* Harper/Colophon, New York.
[282] Theories of reflexivity are 'mostly on the same wavelength' as those of responsiveness: Braithwaite J (2006) 'Responsive Regulation and Developing Economies' 34:5 *World Development* 884, 885.
[283] Baldwin R and Black J (2008) 'Really Responsive Regulation' 71:1 *Modern Law Review* 59.
[284] *Ibid*, Teubner G (1983) Substantive and Reflexive Elements, 239.
[285] *Ibid*, 254-5.
[286] *Ibid*, 255.
[287] Voss J-P and Kemp R (2005) Reflexive Governance, 5.

organisation, policy making and other patterns of social organisation in a variety of fields.[288] Its power is said to lie in the fact that it constructs specialised world views that permit formulation of narrowly targeted objectives and the concentration of capacities for action and control over processes within the defined boundaries of the system.[289] The rationalist approach has achieved tremendous technological developments, sophisticated patterns of social regulation and a high economic efficiency of production.[290]

In spite of its strengths, however, rationalist problem-solving fails to address important dynamic features of complex systems. The more the process is focused on its specialist perspective and disengaged from the 'full messy intermingled natural reality',[291] the greater the failure to take account of embeddedness and interdependencies within the complex environment. The more effective it is in achieving its particular instrumental purposes, the greater the impacts of the unintended consequences of its actions. To third party recipients, these effects are referred to as 'externalities', and to the original problem solver they are the 'side effects' or 'repercussions' of its actions.

Second order reflexivity

Reflexivity is the capacity of a system to address the consequences of rationalist problem-solving: to continually reassess its own effects and methods in situations that exhibit multiplicity, complexity and uncertainty, where the unanticipated consequences of first order governance create 'second order' problems. Reflexive governance is not an attempt to foresee scientific advances,[292] nor anticipatory governance that predicts future developmental pathways as a means of enhancing public administration.[293] Theorists describe it as concerned with itself: it treats its

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[288] *Ibid.*
[289] *Ibid.*
[290] *Ibid.*
[291] *Ibid,* 6.
[292] Williams R (2006) 'Compressed foresight and narrative bias: pitfalls in assessing high technology futures', 15:4 *Science as Culture* 327.
[293] Laurie G (2011) 'Reflexive governance in biobanking: on the value of policy led approaches and the need to recognise the limits of law' 130:3 *Human Genetics* 347, 351, citing Karinen R and Guston DH (2010) 'Towards anticipatory governance: the experience of nanotechnology' 27:4 *Sociology of the Sciences*

own systems as part of the dynamics that need to be governed.[294] They suggest that reflexivity happens at two levels. 'First order' reflexivity addresses self-induced problems: it is the confrontation of the implications and side-effects of the 'instrumental rationalities'[295] through which governance mechanisms undertake problem-solving. This can be understood as a function of modernity or development: societies grow in cycles, producing problems and solutions to these problems, which produce new problems.[296]

Through 'second order' reflexivity, governance reflects on and reconstructs its own methods of 'rational problem-solving'. It addresses not only the problems that are self-induced, but also its own 'working, conditions and effects.'[297] Second order reflexivity is '*analysis*' or 'critical reassessment' rather than 'problem-solving', because reference to a 'solution' implies an unambiguous problem that may be isolated and 'solved' in a deliberative manner. Second order analysis is a procedural approach, which interrupts the routine problem-solving processes of first-order reflexivity, and may lead to new *methods and processes* of handling problems that are more 'open', experimental and oriented to learning.[298]

Second order reflexivity therefore adds a dimension to governance that enables more nuanced approaches to complex problem-solving than are possible through direct first order attempts alone. I construe it as the means of addressing problems of method or process that are 'interstitial' to first order issues. It facilitates an understanding of *specialisation* of methods, and the interdependencies and aggregate effects that arise through application of specialised concepts and strategies. Sophisticated understanding of a complex of relationships enables *integration*

Yearbook 217; Guston DH (2008) 'Innovation policy: not just jumbo shrimp' 454 *Nature* 940; Joly Y (2010) 'Clinical Translation of Stem Cell Therapies – Intellectual Property and Anticipatory Governance' 7:2 *SCRIPTed.*

[294] Voss J-P and Kemp R (2005) Reflexive Governance, 4.

[295] *Ibid,* 7.

[296] Voss J-P and Kemp R (2005) Reflexive Governance, 2, citing Beck U (1994) 'The Reinvention of Politics: Towards a Theory of Reflexive Modernization' in Beck U, Giddens A and Lash S (eds) (1994) *Reflexive Modernization*, Polity Press, Cambridge, 1.

[297] *Ibid,* 7.

[298] *Ibid,* 7.

through the establishment of connections, organisation of communications and promotion of interaction.[299]

Scholars understand the processes of reflexivity, and their implication for governance, in a variety of ways, and recognise that reflexivity is itself an aspect of governance properly subject to reflection. Some see it as a mode of 'steering' by which actors are encouraged to examine and adapt their assumptions, institutional arrangements and practices.'[300] Others construe it as 'partnership in governance', which is dependent upon a culture of trust, communication, deliberation and interaction, to which actors bring an attitude of receptivity to new ways of framing problems and potential solutions.[301] I consider it a process of negotiation of compatibility and complementarity among actors that resolves problems or reduces barriers to the respective undertakings contributed by individual actors to the production of complex public goods. It is the foundation of facilitation, which I discuss separately below.

Although reflexive strategies may take different forms in different contexts according to the objectives, problems and actors involved, a number of fundamental functions or capacities of reflexivity have been identified: integration, assessment, anticipation, coordination and adaptation. These capacities are all in essence designed to augment recursive feed-back dynamics between actors and the system of governance, in ways that address complexity, uncertainty and the 'path dependence' that first order governance can produce. At the root of each of these functions is wide participation, interaction, and communication.

Reflexive functions

Integration

The integration of different perspectives is a fundamental element of the facilitation

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[299] *Ibid*, 7.
[300] Rip A (1998) 'The Dancer and the Dance: Steering in/of science and technology' in Rip A (ed) (1998) *Steering and Effectiveness in a Developing Knowledge Society*, Uitgeverij Lemma BV, Utrecht, 27; Hendriks CM and Grin J (2007) 'Enacting reflexive governance: the politics of Dutch transitions to sustainability' 9:4 *Journal of Environmental Policy Planning* 333.
[301] Laurie G (2011) Reflexive governance in biobanking, 351.

of multidisciplinary activity. Integration occurs through joint problem solving in situations typified by heterogeneous origins or elements. Communication is the first step toward treatment of problems in a complex situations: it should expand the understanding and perspectives of the actors concerned, with implications for their actions. There is a growing literature dedicated to the conceptualisation of 'transdisciplinary knowledge production' or 'new knowledge production', across the disciplines of science and technology, with application to a number of fields including education, environmental science and organic agriculture.[302] Integration is a theme both in governance and (as I discuss in Part II) in new paradigms of scientific technology based on the erosion of the distinction between public and private.

Integration is not the institution of one perspective over others, but permits the full recognition of different perspectives in the system. It is argumentation among participants, and exchange of views as to the appropriate actions and processes of governance.[303] Theories of regulation apart from reflexivity converge on similar concepts of procedural openness as a means to integration. Called by a variety of names: 'proceduralisation', 'civic science', 'scientific proceduralism', or 'democratisation', they share in common the desire to open up the decision process, to deny any one voice authority in that process, and through the integration of views and perspectives to arrive at accepted solutions to intractable problems.

There are many metaphors for integration. It is a bridge that connects and unites, facilitating communication instead of isolation. It is also a doorway that permits movement in both directions and enables interaction between parties and activities in

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[302] See for example: Gibbons M and Nowotny H (2000) 'The Potential of Transdisciplinarity' 3 *Priority Programme Environment* 67; Nowotny H, Scott P and Gibbons M (2003) 'Mode 2 Revisited' 49:3 *Minerva* 179; Klein JT (2004) 'Prospects of Transdisciplinarity' 36:4 *Futures* 515; Hirsch Hadorn G, Bradley D, Pohl C, Rist S and Weismann U (2006) 'Implications of Transdisciplinarity for Sustainability Research' 60:1 *Ecological Economics* 119; Jäger J, Hirsch Hadorn G, Hoffmann-Riem H, S Biber-Klemm S, Grossenbacher-Mansuy W, Joye D, Pohl C, Wiesmann U, Zemp E (eds) (2008) *Handbook of Transdisciplinary Research*, Springer, Switzerland; Polk M and Knuttson P (2008) 'Participation, value rationality and mutual learning in transdisciplinary knowledge production for sustainable development' 14:6 *Environmental Education Research* 643.

[303] Black J (1998) 'Regulation as Facilitation: Negotiating the Genetic Revolution' 61:5 *Modern Law Review* 621.

different rooms of a house. Governance designs appropriate structures, institutions and systems to achieve integration: the architecture does not spring up automatically. It is built.

Anticipation

Anticipation is the exploration of possible outcomes and long-term systemic effects of actions, and can occur at many points in a reflexive system. The significance of anticipation is in its avoidance of 'path dependency'. If effects can be assessed in the *early stages* of technological development, adaptation of social and institutional structures can take place before they become entrenched within their contexts. Future developments and impacts may be unknown and not formally predictable at this stage, but scenario foresight methods can usually enable anticipation of alternative paths and possible impacts. [cite]

Assessment

Assessment is necessary to gain a prerequisite understanding of existing practices or production structures, their real as well as anticipated consequences, the possible alternatives to the *status quo* and strategies for their implementation. The key is the broad participation of all affected social actors in assessment and goal formulation. Articulation of the full range of values, and respective perceptions of the problems represented within the affected constituency constitutes a basic condition of reflexivity. *Participatory* assessment of present processes as well as aims and alternatives is therefore seen as fundamental to facilitation of change through coordination and adaptation.[304]

Coordination

Coordination addresses the problem created by the distribution of capacities for control among a heterogeneous group of actors. Restructuring of the relationships of actors to one another is not easily achieved within institutionalised hierarchies, but can take place through *interactive networks* for strategy development, which

[304] Voss J-P and Kemp R (2005) Reflexive Governance, 7.

facilitate the sharing of perceptions, interests and knowledge of the various stakeholders. Coordination of control through second order reflexivity may also contribute to first order system restructuring, depending on other exogenous factors and circumstances.

Adaptation

Mutual *adaptation* takes place through the participatory processes described, in which actors are forced to articulate and defend their analyses, goals and strategies for handling problems. Anticipatory interaction permits the development of strategies intended to preempt problems, rather than dealing with them in real time, through trial and error.[305] Due to inherent *uncertainty* about long-term dynamics and systemic effects, *strategies* as well as cognitive, institutional and technological *structures* need to be adaptive in order to allow for error and learning. This entails the need for capacities to respond to unexpected effects and developments. Strategies should feature *experimentation, monitoring and evaluation* in order to systematically work with new experiences, altered interpretations and changed circumstances. The result is more robust patterns of governance than individual steering approaches contrived by separate actors.[306]

Reflexive governance

'Reflexive governance' is shaped by the interplay[307] between first order governance and first and second order reflexivity on its effects and processes. 'Governance' includes the actions of individual actors that impact on others, and mutual actions to manage such actions. It incorporates first order solutions that address problems after

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[305] Voss J-P and Kemp R (2005) Reflexive Governance, 7; also Joly Y (2010) 'Clinical Translation of Stem Cell Therapies – Intellectual Property and Anticipatory Governance' 7:2 *SCRIPTed,* in which the author proposes that 'real-time monitoring' through use of empirical methods, should be used to calibrate and fine-tune an anticipatory strategy for governance of the technology transfer process, thus providing a 'longitudinal temporal framework of the impact of open models and technology transfer policies on the actual uptake of stem cell research by the private sector'. Joly admits that while both the anticipatory model of governance and real-time monitoring have been used to improve *public administration*, neither have been tested in relation to *private* actions affecting science and technology.

[306] Voss J-P and Kemp R (2005) Reflexive Governance, 7.

[307] *Ibid.*

the fact, and the second order ability to balance specialisation and integration in the ongoing modulation of developments. It benefits from rational problem-solving, but is limited by the constraints of the complex context in which it is embedded. It is characterised by continual learning, rather than an aim to attain complete knowledge or maximisation of control.[308]

Reflexive governance can therefore be expected to produce better results than conventional approaches. It offers platforms for deliberation that complement conventional political decision-making, enabling better definition of problems, mutual adaptation among stakeholders for rectification and prevention of unintended consequences, and ultimately a more effective means of achievement of societal aims.

Problems related to decentred and reflexive governance however include questions of *political legitimacy* regarding the assumption of roles of authority by non-state actors, as well as the absence of any *value* structure to guide it, or *criteria* by which to assess its effectiveness. Protagonists of reflexivity agree that the *dominance* of any one actor in the system is problematic and assert that the effectiveness of reflexive governance is dependent upon the engagement of a diverse range of perspectives in the interaction process, as well as the prevention of domination by any one actor or group of actors that would suppress challenges to its own perspectives and strategies.

The normative *values and principles* of governance at the level of second order reflexivity are those of the actors in the system. Some regulatory theorists regard the determination of principles for governance of social matters to be problematic, because they are either left to the 'whim' of politicians or to social norms.[309] This is regulation from a political perspective, in which 'good governance' is defined in procedural terms, economic matters are dealt with by principles that promote or mimic market forces, and there is no easy way to identify appropriate principles or

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[308] *Ibid.*
[309] Prosser T (2010) The Regulatory Enterprise, 3.

standards for regulation of social matters. From the perspective of decentred and reflexive governance, important public interest issues such as safety are properly addressed by government through first order legislative instruments; within those parameters, second order reflexivity negotiates the collective values of the interested actors. This is a beauty rather than a drawback of the system, as it facilitates the best representation of the values and interests of all involved rather than an approximation imposed by an external authority.

The need for evaluative criteria has been posited by both proponents[310] and critics[311] of reflexive governance. Reflexive processes are susceptible to misuse, as participatory mechanisms permit opportunistic behaviour and power struggles among stakeholders as well as constructive debate and cooperative interactive strategy development.[312] The pragmatic approach to what is 'working' is likely to be inadequate, given that in any complex social situation it will be difficult to determine what is relevant, let alone effective. Evaluation should therefore extend to the dynamics of reflexivity as well as its results, on the basis of criteria that amount to more than a checklist of predefined outcomes.[313]

As there is presently no empirical evidence of the effectiveness of reflexivity, it is difficult to discern when unreflexive first order instruments might be adequate to deal with challenges. The clue to the appropriate role of reflexivity is that where unreflexive approaches appear to be credible, the challenge that they address is a relatively straightforward one.[314] The contribution of reflexive instruments is their capacity to achieve outcomes in circumstances that are beyond the capacity of other approaches to engage.[315]

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310 Voss J-P and Kemp R (2005) Reflexive Governance, 19.
311 Prosser T (2010) The Regulatory Enterprise, 3.
312 Voss J-P and Kemp R (2005) Reflexive Governance, 19.
313 *Ibid.*
314 Gunningham N (2012) 'Regulatory Reform and Reflexive Regulation: Beyond Command and Control', in Brousseau E, Dedeurwaerdere T and Siebenhuner B (eds) (2012) *Reflexive Governance for Global Public Goods*, MIT Press, Cambridge MA USA, 101.
315 *Ibid.*

3.6 Facilitation

It is said that 'reflexivity ensures that regulation is not solely about control, but about facilitation.[316] The concept of facilitation is not however synonymous with reflexivity. I want to say that 'facilitation' comprises both the means and the outcome - that something has not been facilitated unless it is achieved - but that is not quite the case. To 'facilitate'[317] an action or process is to make it easy, or easier. The term shares its origins with the adjective 'facile',[318] meaning ignoring the true complexities of an issue, or (of a person) having a superficial or simplistic knowledge or approach. The object of facilitation is an action or process. It is directed toward a fixed goal, but it affects the dynamic process, whether or not the outcome is successfully achieved. To facilitate technological advance is to make it simpler and easier for players to undertake their individual tasks, thus easing the way to the mutual achievement of societal goals.

I construe the nature of this reflexive facilitation or easing process as one of negotiation rather than 'cooperation'. In later chapters I address the negotiation of degrees of openness through contractually constructed mechanisms of governance in relation to access to knowledge and materials. Actors are by definition receptive to cooperation in the negotiation of governance, or they would not be at the table, but the process is not a soft one: it requires them to engage, argue, agree and adapt in order to proceed with activity that might otherwise have been inhibited. Negotiation seeks mutual advantages by focusing on interests rather than positions, and sticking to objective criteria;[319] actors are not prepared to compromise their *essential* interests and values in the process.

For all these reasons, my conceptualisation of facilitative governance as decentred, purposive and reflexive is arguably well suited to facilitation of life sciences

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316 Black J (1998) Regulation as Facilitation, 621.
317 Also French *faciliter*, and Italian *facilitare:* Oxford Dictionaries on-line, available at http://oxforddictionaries.com/definition/english/facilitate?q=facilitate, accessed 23 October 2012.
318 From the Latin *facilis:* Oxford Dictionaries on-line, available at http://oxforddictionaries.com/definition/english/facilitate?q=facilitate, accessed 23 October 2012.
319 Fisher R, Ury W and Patton B (1991) *Getting to Yes: Negotiating Agreement without Giving In*, Houghton Mifflin Company, Boston, New York, London.

technologies. It is capable of addressing *complexity* among stakeholders and interested parties, *fragmentation* of knowledge and of power and control, *interdependencies* among social actors and government, *autonomy* and ungovernability of various actors, and the absence of a clear distinction between *public and private.*[320] Strategies in these circumstances are likely to be hybrid (involving both government and non-governmental actors), multi-faceted (employing a variety of strategies simultaneously) and indirect (reflexive).[321]

3.7 Conclusions

The role of facilitative governance in the provision of public goods is to enable multiple actors to more easily fulfil their individual roles in the process, within the most complex and dynamic systems. Decentredness and reflexivity are key features of a concept of governance that is suited to the task. A decentred perspective recognises as 'governance' the impact of actions by both state and non-state actors on one another. It permits reflexivity, or 'second order' governance by all actors, through continual reassessment of the effects of their actions, and their mutual adaptation, rather than an authoritative imposition of one perspective. Theories of reflexivity emphasise themes of actor participation, integration of interests, exchange of knowledge across disciplines, and the negotiation of optimal arrangements for coordination and adaptation.

The themes of inclusiveness, non-hierarchical participation and reflexivity in this concept of governance are indicative of 'openness'. All actors may have a voice. In this context, openness means access to the processes or procedures of governance, rather than access to substantive *resources* or property, which is the subject of the next chapters on science and technology. 'Access' is the invitation to participate in the interactive process: the engagement between the parties that generates innovative strategies for resolution of problems and avoidance of inhibitors of individual activity. Openness enhances interactivity and the potential for innovation, a theme

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[320] Black J (2002) *Critical Reflections*, 6.
[321] *Ibid.*

that reappears in relation to the sharing of resources in science and technology.

The paradox is that openness in reflexive governance facilitates closure. Collective deliberation enables individual actors to proceed with further decision-making and activity, in pursuit of their own contributions to the provision of public goods. Interaction, cooperation and coordination in governance facilitates the exclusive activity of actors in the system.[322] This juxtaposition of open and closed is another theme that reappears in the context of scientific technology, in which interactivity and innovation give birth to excludable and rival products.

These first three chapters have set the stage for the central analysis of the thesis. I suggest that the oversight and use of human stem cell lines is one element of a complex process culminating in the delivery of public goods, and that the achievement of the benefits of cell-based clinical therapies involves networks of scientific and technical innovation, commercialisation and exploitation, in a supportive social environment. I adopt a purposive, decentred and reflexive concept of governance as appropriate to the task of facilitating strategies for the provision of public goods. In Part II, I consider the concept of 'openness' in modern scientific technology, and ask how and to what it extent it might enhance the objectives and functions of facilitative governance that I propose here.

[322] Voss J-P and Kemp R (2005), 20-21.

PART II: OPENNESS

Introduction to Part II

In Part I, I described mechanisms for UK governance of human stem cell lines, and identified the provision of public goods as the policy objective behind the facilitation of production of human stem cell therapies. I concluded that decentred and reflexive governance, which is in theory the system most capable of coping with complexity, is a form of procedural openness, in that it provides access to reflexive governance processes that facilitate the undertakings of actors that contribute to the delivery of public goods. In this Part, I consider the extent to which 'openness' provides a means of access to *resources* for the facilitation of such undertakings.

'Resources' for the production of stem cell therapies are those essential to science and technology: intellectual resources - data, information, knowledge – as well as tangible, material resources. 'Access' to resources is not merely about control or consumption, but requires a level of engagement that facilitates the innovative as well as exploitative processes of scientific technology. Vehicles of access should permit the direction of resources toward private ends, but also maximise opportunity for resources to be engaged, manipulated and reconfigured: to generate novel outcomes that are themselves available for 'use and reuse'. My objective is to assess the extent to which 'openness' exhibits these features and might therefore be useful in regard to strategies for the facilitation of delivery of stem cell therapies.

I first look to the individual literatures of open science and industrial technology for characteristics of 'openness'. The conventional narratives construe science and technology as separate systems engaging in different modes of innovation that are oriented to the achievement of two different, but equally important, social goals: the production of knowledge, and the production of goods that deliver tangible social benefits. My examination of these literatures sheds light on the meaning and functions of openness in these individual contexts that inform my understanding of how science and technology relate to one another – and the significance of openness,

if any - in the current conduct of most research and development, which I construe as 'scientific technology'.

In Chapter 4, I find in the open model of science a public concept of openness in which results of scientific research are released into the public domain to facilitate rapid innovation in the generation of new knowledge. It features disclosure of intellectual resources, communisation of property, and accessibility through the public domain. Open science is supported as a public good, which permits the pursuit of new knowledge without regard for practical value, and the creation of a commonly held public resource. The practice of public disclosure is facilitated by and reinforces a cohesive social system, driven by collaboration and competition for recognition of original work, rather than economic results, bound together by moral and social norms. The 'sharing' of data and materials among scientists is not altruism, but a responsibility undertaken to fulfil specific functions, and adhered to out of a professional commitment to advance the interests of science.

In practice, open science does not achieve *unlimited* access to scientific results through the 'public domain': the release of certain types of content may be restricted to protect public interests, published material is only as public as its readership, and access may be limited by the capacity of potential users to obtain and use it.

In Chapter 5**,** I look for concepts of openness in the literature of industrial technology and find that while the 'public' concept of openness does not extend to technology, the common perception of technology as 'closed' is simplistic and misleading. It is true that technology is distinguished from open science on grounds that it by necessity obtains *exclusive* control over resources in order to facilitate the production of economic products in a competitive market. This exclusivity must however be read in the context of the whole enterprise of technical innovation and industrial production, which embodies two paradoxes of open and closed.

The first paradox is to be expected: that from the openness of technical innovation comes closure in stable products. Within an individual firm, the dynamic, chaotic processes of innovation are tempered throughout by exploitation, which produces

economic value and enables the concretisation of tangible products capable of commercialisation. The goal of an industrial firm involved in technical innovation is to generate products with practical and social utility: it draws resources from a wide variety of sources, but having obtained them, maintains control over them in order to facilitate their 'exploitation' as they are transformed into commercial products. The creative talents, energy and resources of the firm are funnelled into specific developmental pathways, from which all other interests are excluded pending the birth of the tangible product or invention. The technology only becomes accessible to external actors upon public disclosure during application for patent, or when products are released onto the commercial market. The limitations that this narrow focus imposes on the volume of innovative research and development of products is not in issue because the goal of a firm is not *maximisation* of technical innovation for the industry or society as a whole, but *sufficient* innovation to support production of *enough* intellectual property and tangible goods to meet the objectives and sustain the viability of the firm. Optimal and efficient production is not reliant upon *unlimited* access to resources, nor on the practice of public disclosure of its own resources for use by others.

The second paradox is less obvious: that exclusivity facilitates openness through the dissemination of products on the commercial market. In industry, the value of technical innovation is captured by property rights, which render intellectual and tangible products 'alienable' or 'transferable' - capable of dissemination –- through legal and commercial transactions. This means that technical resources, comprising intellectual and tangible property, can therefore be accessed through private commercial and non-commercial transactions.

The notion of private access to resources as 'open' appears at first to contradict the concept of public openness associated with circulation of commonly held resources to a public domain of users. The concept of openness as both public and private, is only problematic, however, if public and private correspond to open and closed, and open and closed are construed as absolute states. The divisible nature of property rights ensures that arrangements for the transfer of some part of the full package of legal rights can be devised as a means of 'sharing' of proprietary assets. Legal

instruments such as contracts and licensing regimes can therefore be used to create private 'modules' of openness, tailored to an appropriate domain of actors and defining the nature and extent of the rights of access and use being conveyed. The negotiation of such transactions is in effect participatory governance of resources as discussed in Chapter 3, with the effect that individual or cumulative networks of such arrangements can amount to significant volume of 'knowledge transfer' or 'technology transfer' conducive to further innovation.

Moreover, public and private modes of openness come together when private legal instruments are used to structure arrangements that create common property, or facilitate the sharing of resources. Some of the collective strategies lumped under the heading of 'commons approaches' that attempt to achieve degrees of access to common pool resources, do not create common property resources at all, but negotiate collective legal arrangements for the use of private resources that remain essentially under proprietary control. I discuss some of these in Chapter 7.

In Chapter 6, I consider how these public and private concepts of openness are situated in the reality of modern scientific technology, and to what extent they might be employed in facilitative governance. In Chapter 5, I purposely avoid mention of the relationship between science and technology, in order to focus on the features of technology and the essential processes of innovation and exploitation within a firm. In Chapter 6, I recognise that the construction of 'open' science and 'exclusive' technology as two discrete systems is an inaccurate depiction of the modern reality of scientific technology, adherence to which inhibits the facilitation discourse. In the absence of more integrated conceptions of science and technology, I propose one of my own. It forms a basis for consideration of integrated approaches to openness, access, and facilitative strategies for advancement of scientific technology: arrangements and structures that create optimal conditions for innovative use and exploitation of resources.

My conception of 'scientific technology' is based on increasingly strong technical synergy between science and technology, and a weakening of the institutional and social architecture that defines open science. The literature of life sciences

governance reflects concerns regarding the breakdown of open science indicated by institutional and practical changes that erode the culture of openness. The breakdown is attributed largely to progressive privatisation, patent problems, and the subversion of the scientific 'ethos' in favour of commmercial incentives and the lure of social benefits such as stem cell technologies and health. These changes, which are widely reported but impossible to quantify are, I suggest, symptoms of stress on what has always been an artificial distinction between open science and commercial technology.

The sociology of science literature recognises the open science model as a social construct, institutionalised following the Scientific Revolution to promote the rapid growth of reliable knowledge through the use of empirical methods and the circulation of results in a (non-market) ethos of collaborative competition. The social organisation of open science supports the production of scientific knowledge as a public good, thus creating an edifice of largely publicly funded science within the predominant market culture. Although the *institutional* structure of open science demarcated it from the surrounding environment, the *substantive* relationship between science and technology was not as well defined. Science and technology have always been to some extent interconnected, because their different orientations - toward understanding and utility - inspire and support one other. Given this natural relationship, and modern research methods, it is not surprising that closer and more reciprocal connections between them are evident in many fields of study. In medical research, science and technology are as two sides of a coin, the explanatory power of science practically inseparable from its potential for technical utilisation. Understanding and utility are not different questions, but facets of the same question.

This interdisciplinarity in fields such as medicine has gradually infiltrated the institutional, social and funding structures of open science. Public support for 'science' extends easily to technical research objectives in which science plays an integral or instrumental role in resolving practical problems. Academic scientists patent their discoveries on the back of the technical methods and processes that they invent to enable them to answer scientific questions. Similarly, it is an easy step for private industrial firms to employ scientists to provide direct and simultaneous input

to technical innovation, rather than waiting for scientific or policy agendas to generate answers to the relevant questions in their own time.

With the intensification of dynamics between science and technology, and reduction in the 'pure' scientific agenda, one cohesive organisation of 'open science' is increasingly untenable. As the ramparts start to crack, some 'pure' academic science is still generated as per the open science model, but actors inside and outside – including funders, policymakers, scientists and private firms - are able to mingle and engage in new and different forms of collaboration with one another. What emerges is a piebald landscape of public and private actors in many different types of organisation. The backdrop of the market environment is more easily visible, while the fortress of pure science is of smaller scope and has a less prominent profile.

My conception of modern 'scientific technology' is of a meta-system that encompasses both 'open science' and proprietary activity, in which actors, public and private, are all participants in the enterprise of production of public goods. Facilitation of the enterprise of scientific technology, then, must encompass the whole network of dynamic activity: innovative scientific and technical research, collective approaches for resolution of bottlenecks and other problems, and proprietary commercial activity.

In this landscape, I identify the concepts that integrate modern scientific technology, and reconsider the role of public and private modes of 'openness'. Outside of the institution of publicly funded pure academic science, the term 'openness' is of limited use in describing the types of social organisation that might govern the dynamic utilisation of resources. Between the extremes of open and closed there is potential for collaboration and integration in which research and industry, innovation and exploitation, public and private, enhance one another. Neither public access to nor exclusive control over resources can be taken for granted, but *controlled* access and use negotiated on mutually beneficial terms can achieve objectives that neither the public domain nor the market may be capable of. The 'domain of exchange' permits all means of conveyance for provision of access to, and definition of the terms of engagement of, resources. Different vehicles with different functions can

be mixed and matched in this domain of exchange, which integrates the concepts of the scientific domain of knowledge and the technological domain of commerce. Collective strategies can negotiate terms of shared use of pooled resources held in common, or establish private property regimes, such as non-exclusive licensing. An ordinary contract of purchase and sale can also be considered a 'module' of openness constituting 'knowledge transfer' or 'technology transfer' capable of use in ongoing innovation, according to the agreed terms of access. These vehicles for communication and transmission of resources create different 'spaces' - 'channels' and 'pools' - for exchange, tailored to collective or individual needs or problems.

Chapter 4. OPEN SCIENCE

4.1 Introduction

In Chapter 4, I examine the origins of modern science and the functions of openness in the model of open science that emerged in Europe following the Scientific Revolution. The narrative of 'open science', as it emerged from the 'Scientific Revolution' in the 17th century, reveals that ideas of openness in the pursuit of innovation are closely tied to concepts of 'publicness'. The literature describes a system, autonomous from technology, in which the practice of communication or disclosure of research findings[323] links science to the public domain. Openness is thus equated with *publication,* which fulfils several purposes in the advancement of scientific understanding. The result is the cumulation of a body of reliable knowledge, which constitutes common property and an enduring *public* resource. The whole enterprise of science is a *public good*, sustainable only through the application of external resources, including *public* funding of research and its infrastructures. 'Publicness' is a feature of the behaviours, institutions, funding, outcomes and recipients of science.

Openness in this public sense is not however an unqualified good, but is subject to various types of limitation. The lessons of history indicate that the function of publication may be dependent upon particular economic, social and cultural conditions. Public and private interests restrict the types of research outcomes that are appropriate for publication, and delimit the scope of the public domain in which they are circulated.

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[323] Merton RK (1938) 'Science and the Social Order', in Sztompka P (ed) (1996) *On Social Structure and Science,* University of Chicago Press, Chicago and London, 272.

4.2 Objectives

Science is the pursuit of reliable knowledge about the natural world. In conventional narratives, it attempts to understand the properties and functions of natural phenomena, which results in the 'discovery' or revelation of previously unknown truths. Despite connotations of passivity, 'discovery' as demonstrated in this chapter is a highly strategic pursuit that engages a specific methodology promoted through an organised social system that magnifies individual efforts through collective coordination. The formal enterprise of science is intent upon the generation of knowledge as an end in itself,[324] without regard for its immediate or potential utility,[325] but without implication that its outcomes are not useful. The ability of science to observe, explain and understand is a powerful tool for technology, as I discuss in the next two chapters.

4.3 Origins

Scientific revolution

Western science is rooted in a system of 'open science' that crystallised during a period of massive change that swept European society from the Middle Ages[326] into the Modern era. Although records of observations and experiments date back to classical antiquity, the dawn of modern science is thought to correspond to the 'Scientific Revolution' that took place between roughly 1550 and 1700,[327] toward the end of a wider cultural Renaissance that swept Europe between the 14th and 17th centuries. It was a time of great social, political and intellectual upheaval, as well as great achievement, as traditional ways of thinking about society and the natural

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[324] Rai AK (1999) 'Regulating Scientific Research: Intellectual Property Rights and the Norms of Science' 94:1 *Northwestern University Law Review* 92.
[325] Faulkner W (1994) 'Conceptualizing Knowledge Used in Innovation: A Second Look at the Science-Technology Distinction and Industrial Innovation' 19:4 *Science, Technology & Human Value*s, 425, 434.
[326] The Middle Ages is the period of Western history from the 5th to 15th centuries, situated midway between the Classical period and the Modern era. It is normally marked from the collapse of the Western Roman Empire (the end of Classical Antiquity) until the beginning of the Renaissance and the Age of Discovery, the periods which ushered in the Modern era.
[327] Godfrey-Smith P (2003) *Theory and Reality: an introduction to the philosophy of science,* University of Chicago Press, Chicago and London.

world were critiqued, challenged and reformed. The discovery of the Americas by Christopher Columbus in 1492 marked the beginning of European exploration and colonisation of the American continents, leading to new global exchange in commerce and trade.[328] In the following century, a Protestant revolt against the Catholic Church, followed by a Catholic counter-reformation, caused a split within Western Christianity. Challenges to orthodox thinking stressed intellectual hierarchies, creating an environment conducive to the questioning of scientific as well as religious doctrine, which fed into the Enlightenment movement of the 18th century.

Historians disagree as to whether this period should be referred to as a 'revolution', which implies a radical discontinuity between it and the rest of history,[329] and other processes of transformation have been postulated,[330] but there is little disagreement about the significance of the new knowledge and methods that it heralded.

Immense changes occurred across mathematics, physics, astronomy, biology, medicine and chemistry in the 15th and 16th centuries. The most symbolic of these was the displacement of the earth from the centre of the universe by astronomer Galileo Galilei (1564-1642). Nicolaus Copernicus (1473-1543) had produced the first detailed theory of the movement of the earth around the sun (instead of vice versa) which Galileo confirmed through mathematics, experiments and telescopic observation of the heavens, thus contradicting Aristotle and the scholastic worldview that had been inherited from the Middle Ages. Kepler (1571-1630) advanced this work by showing that the earth and other planets move in ellipses around the sun, rather than circles. A general theory about mechanism and matter in the mid-17th century culminated in the 1687 publication by Isaac Newton (1642-1727) of a unified mathematical treatment of motion on earth and in the heavens that

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328 Godfrey-Smith P (2003) *Theory and Reality*, 14.

329 Shapin S (1996) *The Scientific Revolution,* University of Chicago Press, Chicago USA and London UK; Grant E (1996) *The Foundation of Modern Science in the Middle Ages: Their Religious, Institutional and Intellectual Contexts*, Cambridge University Press, Cambridge. The continuity theory suggests that there was no 'revolution' or radical discontinuity between the intellectual development of the Middle Ages and the developments in the Renaissance and early modern period.

330 *Ibid.* Other views assert that the changes were the result of multicultural influences in Europe, or that they were not new but reasserted classical ideas.

demonstrated that elliptical orbits were the result of gravitational forces. Important advances were also made in medical anatomy. Andreas Vesalius from Padua used empirical methods to break away from the anatomical reports of Galen (129 – c 200 AD) that had dominated Western medical science for nearly two millennia. In 1543 he published his seminal work *De humani corporis fabrica* ('the fabric of the human body') containing descriptions and illustrations of human dissections contradicting aspects of Galen's work based on monkeys and pigs. In 1628, William Harvey published a description of the circulatory system pumped by the heart.

New methods

Changes in the investigatory methods and philosophy that accompanied these advances were as important as the discoveries themselves: they are so fundamental that earlier methods are considered by many to be *pre*-scientific. Formalisation of the methodology of experimental science that lays the foundation for modern 'open science' is attributed to British philosopher Sir Francis Bacon who published his ideas in his *Novum Organum Scientarium* or 'New Instrument of Science' as part of a larger work, in 1620. The 'Baconian' or 'scientific' method of acquiring natural knowledge is a system of inductive reasoning based on the testing of hypothetical explanations of observations, which contradicted the Aristotelian method of deductive reasoning, unsupported by empirical evidence, which was predominant at the time. The Baconian reformulation of natural philosophy is significant because it proposes a method of scientific *innovation*, or as Bacon described it the 'invention' of knowledge.[331] This he distinguished from the method of 'cultivation' of knowledge associated with the received philosophy of the time, making it very clear that his philosophy would not interfere with those that 'supplied matter for disputations or ornaments for discourse – the professor's lecture or the business of life'. He proposed (for the benefit of both) that there be 'two streams and two dispensations of knowledge', and similarly 'two tribes or kindreds of students in philosophy - tribes not hostile or alien to each other, but bound together by mutual

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[331] Sargent R-M (ed) (1999) *Francis Bacon: Selected Philosophical Works*, Hackett Publishing Co Ltd, Indianapolis USA, xiii.

services'. In addition to his description of an inductive method of experimental research, which in itself held potential for the increase of knowledge through the work of individual scientists, Bacon advocated a collective approach to the enterprise of science. He articulated an expectation that data and methodology should be documented, archived and made available for scrutiny, reproduction and verification by other scientists.[332] This is the practice of disclosure that I discuss below, which is at the heart of the modern system of 'open science'. Moreover, he construed the scientific process as a community endeavour that required financial and philosophical support from institutions such as governments and universities,[333] suggesting that knowledge should constitute a public good available to all, and an input into the generation of additional knowledge.[334]

Institutions

The new systematic methods gave rise in Europe to a community of experimental scientists envisioned as an autonomous 'Republic of Science' or body politic,[335] with its own intellectual and organisational structure for the pursuit or 'production' of reliable knowledge. Sociological and economic accounts of open science describe a cohesive and efficient system in which the advancement of science is predicated upon freedom of enquiry and the *communication or disclosure of acquired knowledge*, supported by socially enforced norms of behaviour that generate trust in the scientific endeavour.

Widespread support for this 'Republic' was reflected in institutions across Europe. The private provision of funds to support individual scientists within universities was crucial to the creation of *scientific research institutions* for the advancement of the new methods and philosophy of science. When Cambridge University was established in the 1200s, for example, its 'Masters' taught existing courses of

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[332] Dick HG (ed) (1955) *Selected Writings of Francis Bacon,* Modern Library, New York.
[333] *Ibid.*
[334] Maskus KE and Reichman JH (2004) 'The Globalization of Private Knowledge Goods and the Privatization of Global Public Goods' 7:2 *Journal of International Economic Law* 279, 283.
[335] Polanyi M (1962) 'The Republic of Science: Its Political and Economic Theory', in Mirowski P and Sent E (eds) (2002) *Science Bought and Sold: Essays in the Economics of Science*, University of Chicago Press, Chicago and London, 465.

study, but conducted no original research; it was only through the funding by *royal endowment* of several Cambridge and Oxford professorships in the 16th and 17th centuries that the recipients began to combine teaching with research, and the university became a place where new knowledge was generated.[336]

In contrast to the universities, *national scientific academies* and *professional societies* that grew up across Europe, some of which created or retained links to universities, had the sole objective of fostering scientific research. They played a critical role in promoting interactions between individuals across institutions through the organisation of meetings and the publication of peer-reviewed work. One of the earliest of these was the Royal Society of London, established in 1660, having begun as the Oxford 'experimental science club' following the methods of Bacon in 1648. Official scientific societies were also chartered by the state to provide technical advisory expertise,[337] offering the societies direct government contacts, state sponsorship entailing financial support and recognition, and the freedom to manage their publications, membership and administration. Today there are many more institutions, including universities, national laboratories, government agencies, and corporations that provide physical space and support for scientific research.

Defence of purity

The formalisation of the system of open science achieved three important objectives. First, it made an economic *public good* of science in general and scientific knowledge in particular. The support of government and private patrons facilitated the freedom of enquiry and accumulation of knowledge as a common resource in the public domain. Secondly, it created a social *organisation* capable of enhancing knowledge production, in which disclosure or 'openness' has specific central functions. Thirdly, it protected the *purity* of empirical science from pseudo-scientific medieval practices, antithetical philosophies, and more recently from the utilitarian

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[336] Porter R (ed) (2003) *The Cambridge History of Science,* Vol 4 Cambridge University Press, Cambridge, 91.
[337] *Ibid.*

objectives of technology. In total, the social construct creates a bastion of science, defended from the effect of the surrounding social, economic and technical environments. While the objective of creating this special regime is to support scientists and their new methods of enquiry in order to maximise the intensity of the production of knowledge within it, the notion of 'purity' that has become fixed in the culture of open science is arguably overstated, even for its original purposes. As I discuss later, the modern strain on the open model of science is in part because the institutional distinction between science and technology is not an accurate reflection of the relationship between science and technology.

Rejection of Secrecy

Historically, the revelation of discoveries provided fundamental protection for the enterprise of science conducted within a predominant culture of secrecy. Modern science is said to have coincided with a rejection of the culture of medieval secrecy[338] that prevailed in many areas of social and economic life during the Middle Ages. The technological know-how of the craft guilds as well as geographical discoveries, maps and trade routes were kept guarded and outside of the public domain. Political and religious views mandated that 'peculiar' or 'occult' knowledge should be withheld from 'the vulgar multitude' lest it impart powers over material things.[339] Knowledge so 'special' as to be withheld from the public would have included 'nature's secrets'[340] pursued through the practice of alchemy, which was influential through the 17th century.

Antithetical Philosophies

The rejection of secrecy by the 'new scientists' within this culture does not signify the evil of secrecy *per se*, but underscores the need for scientists to be able to see and scrutinise each others methods and results, and so distinguish and reject unreliable

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338 Bernal JD (1939) *The Social Function of Science*, MacMillan, New York, 150.
339 Eamon W (1994) *Science and the Secrets of Nature: Books of secrets in medieval and early modern science*, Princeton University Press, Princeton NJ.
340 David P (1998) 'Common Agency Contracting and the Emergence of Open Science Institutions' 88:2 *American Economic Review*, Papers and Proceedings of the Hundred and Tenth Annual Meeting of the American Economic Association, 15.

practices. This openness was important, because new scientists were in effect converted from among medieval natural philosophers and alchemists, and the transition to the new practices was not immediate. Although Western alchemy may now be recognised as a 'protoscience'[341] that contributed to the development of chemistry and medicine, unlike modern science it also included principles and practices related to mythology, religion and spirituality. Alchemists of the ancient philosophical tradition laid claim to profound magical powers, such as the ability to turn base metals into gold and silver, and to create the elixir of life conferring youth and beauty. Rocks were seen as growing in a quasi-biological sense, and chemical reactions were indicated in astrological relationships between planets. Alchemists had little incentive to disclose their secrets, and their practices persisted for centuries in parallel with those of disclosure and dissemination that were adopted by the new scientists.[342]

The formulation of 'new science' was also a defence against Aristotelian philosophies and humanist theories that preceded and surrounded it. Just prior to the Scientific Revolution, during the early part of the European Renaissance[343] (1300-1450) there was a period of scientific regression in which a reaffirmation of the worldview of ancient Greek philosopher Aristotle coincided with a reverence of Classical traditions and a new Italian ideology of humanism.[344] Neither Aristotle nor the humanist cultural and educational reforms were conducive to advances in science or the scientific method. The philosophy of Aristotle, carried over from about 350 BC, bore little resemblance to modern scientific methods.[345] Although his conception of formal logic and study of natural phenomena contributed much to

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341 Dobbs BJT (1975) *The Foundations of Newton's Alchemy,* Cambridge University Press, Cambridge, 1; Thorndike L (1923-1958) *A History of Magic and Experimental Science*, Columbia University Press, New York.

342 Eamon W (1994) Science and the Secrets of Nature.

343 The 'European Renaissance' was a rebirth (Italian 'rinascimento') of intellectual life following the stagnation of the 'Dark Ages'. 'Dark Ages' refers to the period of intellectual darkness between the extinguishing of the light of the Western Roman Empire and the dawn of the Italian Renaissance; originally including most of the Middle Ages between the 6th and 13th centuries, its use is now generally restricted to a tumultuous period during the 10th and 11th centuries.

344 Hall AR (1954) *The Scientific Revolution, 1500-1800: The Formation of the Modern Scientific Attitude* Longmans, Green and Company, London, New York, Toronto, 161.

345 *Ibid*, 162.

modern science, the Aristotelian method of study in fields that we would today regard as sciences - physics, biology and other natural sciences – was largely qualitative rather than quantitative.[346] He held that scientific truth could be reached by way of authoritative argument: if sufficiently intelligent men discussed a subject long enough, the truth would eventually be discovered. His results were deduced from unsupported observation and reason rather than measurement or mathematics, and as a result his work in the physical sciences became obsolete with the application of mathematics in the 16th century.[347]

New philosophies of science were also a contradiction of the cultural and educational reforms of the early Renaissance period. Inspired by the humanist movement of Florence and Naples, these reforms challenged the medieval system of scholastic education based on practical, pre-professional and 'scientific' studies.[348] Scholars, writers and politicians sought instead to advance civic life through education in the humanities: grammar, rhetoric, history, poetry and moral philosophy.[349] Citizens - male and female - were equipped with the ability to speak and write persuasively in order to facilitate community engagement and instigate action.[350] Nature was considered an animate spiritual creation that was not governed by laws or mathematics. As a result, physics and astronomy stagnated and natural philosophy declined, as logic and deduction were subordinated to intuition and emotion.[351]

Nevertheless, by the second half of the 15th century the economic and political conditions in Europe were improving, and Renaissance culture provided the tools for further social change. Peace and the decline of famine and the plague resulted in economic prosperity, as Europe began to recover from population losses to a Black Death pandemic of a hundred years earlier. The *printing press* that emerged about

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[346] *Ibid.*
[347] The failings of Aristotle were largely due to the absence of concepts like mass, velocity, force and temperature. He had a conception of speed and temperature, but no quantitative understanding of them, which was partly due to the absence of basic experimental devices, like clocks and thermometers.
[348] Grant E (1996) *The Foundation of Modern Science in the Middle Ages: Their Religious, Institutional and Intellectual Contexts*, Cambridge University Press, Cambridge.
[349] *Ibid.*
[350] *Ibid.*
[351] *Ibid.*

this time was a significant catalyst for intellectual exchange and expansion of Renaissance culture.[352] Invented by Johannes Gutenberg around 1440, it had a huge impact on European society and was a particular asset to science, technology and academia in general. The increased output and decreased cost of books made information available to a much larger segment of the population, stimulating lay literacy and democratising learning. Printed copy provided a superior basis for scholarship by preventing the corruption associated with hand copying and facilitating access to texts preserved in standardised form. Easy dissemination promoted faster propagation of new ideas and more reliable progress in critical studies and science. The 'information revolution' initiated by the printing press was on a par with the effect of the Internet today.[353]

Patronage

It is not clear how the open ethos of science first arose and then persisted within an antithetical culture, and although it is possible to appreciate the functions of openness in modern science without understanding its historical evolution, one theory raises points that are relevant to my thesis. Paul David argues that spontaneous emergence of openness is improbable, and that the new attitude is attributable not to its institution *ab initio* by some external agency[354] but to its practical functions in the social and institutional contexts in which the new scientists were working.[355] His research suggests that the social norms of disclosure grew out of the feudal system of aristocratic patronage prevalent throughout medieval Europe, under which political

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[352] *Ibid.* During the late fifteenth and the sixteenth centuries the Renaissance spread north from Italy and adapted to conditions in Germany, France, England, and Spain. In the monarchical states of England, France and Spain Renaissance culture was court-centered and anti-republican. A strong tradition of anti-clerical lay piety in Germany emphasised education and practical religion. Schools and colleges were established to provide a humanistic education imported from Italy to prepare the sons of gentlemen and nobles for church or civil service careers. Renaissance humanism did not have the effect of secularising society in the north, as it had in Italy. Northern humanists were devoted to classical learning, but were chiefly interested in what constituted original Christianity, with the aim of restoring the ancient apostolic purity of the church.

[353] *Ibid.*

[354] David P (2008) 'The Historical Origins of "Open Science": An Essay on Patronage, Reputation and Common Agency Contracting in the Scientific Revolution' 3:2 *Capitalism and Society,* Berkeley Electronic Press, Article 5.

[355] David P (1998) Common Agency Contracting, 16.

elites, kings, princes and nobles provided *conspicuous support* for the intellectual and creative talents of skilled individuals with whom they surrounded themselves.

If the theory is tenable, the collective benefits of intellectual exchange were discovered in circumstances of patronage, as might be expected, but that the support extended to a range of talents apart from those of scientists (including philosophers and mathematicians, artists, poets and musicians, engineers and architects) and was motivated by interests wholly unrelated to the advancement of the 'clients' that were supported. The services of such individuals were elicited not only to meet the mundane needs of the court, but to make a 'public display of magnificence',[356] through disclosure of their intellectual, creative and inventive skills and expertise, thus currying ostentation and prestige and enhancing the esteem of the patron. New utilitarian advances were often kept secret, but the 'ornamental'[357] function reflected upon the power and authority of the court, and was instrumental in securing a crucial public and political image. The publicisation of the 'marvellous achievements' of the savants met the need for self-aggrandisement of the patron and rewarded the client with reputational benefits and the security of employment and status in the court in what would have otherwise been precarious economic conditions.

David's account also gives a plausible description of the evolution of a peer review mechanism for the verification of credentials.[358] It suggests that with the advances in mathematical methods during the 16th century it became difficult for the patrons to evaluate the claims and reputations of their clients, giving rise to opportunities for fraud and the risk of embarrassment of the patrons. The task of screening individuals for sponsorship, including the new type of scientist, was therefore delegated to informal networks of correspondents which later devolved into institutionalised communities of fellow practitioners and experts.[359]

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[356] *Ibid,* 18 citing Strong R (1984) *Art and Power*, Boydell, Woodbridge Suffolk, UK.
[357] *Ibid.*
[358] David P (1998) Common Agency Contracting, citing Strong R (1984) *Art and Power*, Boydell, Woodbridge Suffolk, UK.
[359] *Ibid,* 18.

The patronage theory suggests that the practice of revelation of knowledge arose to perform a particular function in a particular set of socio-economic, political and cultural circumstances, and was sustainable through the provision of external support. That the disclosure of achievements advanced science was peripheral to the goal of pleasing the patron, suggesting that the capacity of openness to enhance intellectual exchange, and so advance knowledge, may be independent of the nature of the immediate incentive for the disclosure. Further, although 'clients' presumably competed with their colleagues for patronage and were engaged by the patron on the basis of their ability to generate astounding things, they were free within the confines and protection of the court to engage in their chosen pursuits. These features have parallels in the functions of disclosure in the organisation of open science, which I discuss below. A further observation is that although the benefits of patronage and openness within the courts extended to a range of 'clients' including artists and technical advisors, it was the enterprise of science, as distinct from art or technology, that culminated in the social construct of open science.

Utilitarianism

It is not until the 'Republic' of open science is established in the institutions of Europe that a clear demarcation occurs between 'pure' science and the utilitarian aims of technology and the economic incentives of the market. The emphasis of science on understanding motivated by intellectual curiosity[360] or satisfaction,[361] for the production of knowledge as an end in itself[362] is distinguished from the technological focus on utility.[363] Scientists were encouraged to 'ignore all considerations other than the advance of knowledge',[364] and to focus on the scientific significance of their work, to the exclusion of its potential uses or social

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[360] Motives are in reality complex and mixed: Mayr O (1982) 'The science-technology relationship', in Barnes B and Edge D (eds) (1982) *Science in Context: Readings in the Sociology of Science*, Open University Press, Milton Keynes, 155, 159.
[361] Rai AK (1999) 'Regulating Scientific Research: Intellectual Property Rights and the Norms of Science' 94:1 *Northwestern University Law Review* 77, 92.
[362] *Ibid.*
[363] Faulkner W (1994) 'Conceptualizing Knowledge Used in Innovation: A Second Look at the Science-Technology Distinction and Industrial Innovation' 19:4 *Science, Technology & Human Value*s 425, 434.
[364] *Ibid.*

repercussions more generally. Practical applications might at the outset of the work be unforeseeable, a point commonly illustrated by Einstein's theory of relativity, which had no apparent utility until the first atomic bomb exploded 40 or 50 years later.[365] The process of scientific 'discovery' as formalised in the system of open science sought to generate and validate previously unknown truths. There is a wide literature, which I cannot examine here, that considers the philosophical bases for determinations of 'truth', by which new findings or theories are accepted into the corpus of reliable knowledge.[366] Despite debate about whether it is possible to make a positive determination that results are 'valid' or true',[367] the characterisation of science as a quest for understanding is not heavily disputed.[368]

One of the themes of my thesis is that this institutionalised distinction between open science and proprietary technology does not accurately reflect the technical relationship between science and technology, and confuses the dialogue about facilitation. As I discuss in Chapter 6, the 'pure' pursuit of knowledge does not imply a lack of conversance between science and technology. Freely chosen fields of scientific enquiry may be inspired by technical advances; there is little debate about the explanatory value of science for technology; and the connection between the two in the eye of the public has a direct effect on public confidence in the enterprise of science. In that chapter, I suggest that not only does the intersection of science with utilitarian interests pursued through private means *not* undermine the value or purity of science, but it has positive benefits that are ignored to the detriment of science and society. The model of science as a public institution promotes the unfortunate perception that it operates within an impermeable bubble, susceptible to violation by forces that prevail in the surrounding market environment.

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365 Polanyi M (1960-61) 'Science: Academic and Industrial' 89 *Journal of the Institute of Metals* 401, 401. There is some evidence however for the fact that, upon derivation of the formula ($e=mc^2$) Einstein understood its practical significance for the production of the atomic bomb.

366 Popper K (1989) *The Logic of Scientific Discovery*, Basic Books, New York; Campbell D (1974) 'Evolutionary epistemology' in Schelpp PA, *The Philosophy of Karl Popper: Vol 14*, Open Court, LaSalle Illinois; Ziman J (1979) *Reliable Knowledge,* Cambridge University Press, Cambridge; Kitcher P (1993) *The Advancement of Science*, Oxford University Press, Oxford.

367 Popper K (1989) *The Logic of Scientific Discovery.*

368 Nelson RR (2003) 'The advance of technology and the scientific commons' 361 *Philosophical Transactions of the Royal Society A: Mathematical, Physical and Engineering Sciences* 1691, London, published online 4 July 2003, 1696-7.

Science for technology

History suggests therefore that the institution of open science serves to enhance production of knowledge by protecting the new methods from dilution, absorption or abolition by competing practices, philosophies and cultural systems. Modern scientists hold to the notion of purity as a means of repudiation[369] of non-scientific criteria for the acceptability or value of their work, and to defend the autonomy of science against control by other institutions – economy, state or religion - that might limit or threaten its continuance as a valued social activity.[370] In practice, however, this 'sentiment'[371] of purity may be too emphatic: it has been critiqued as being more rigid than is necessary or beneficial, given that science does not operate in a social vacuum, but impacts upon and interacts with other spheres of interest and value. Merton goes so far as to suggest that the 'pure science' tenet has helped to prepare its own epitaph.[372]

The desire that drove Bacon to produce his new methodology was that it might unlock scientific learning, rather than isolate scientists and scientific knowledge from society. His objective was not to protect science *from* technology, but to promote it *for* technology. Bacon saw the 'real and legitimate goal of the sciences'[373] to be 'the endowment of human life with new inventions and riches',[374] and he aspired to 'improve philosophy by bringing in industrious observations, grounded conclusions and profitable inventions and discoveries'.[375] Bacon admonished his readers to 'consider what are the true ends of knowledge',[376] and to 'seek it not either for pleasure of the mind, or for contention, or for superiority to others, or for profit, or fame, or power, or any of these inferior things, but *for the benefit and use of life*',[377]

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369 Merton RK (1938) Science and the Social Order, 282.
370 *Ibid.*
371 *Ibid.*
372 *Ibid.*
373 Sargent R-M (ed) (1999) *Francis Bacon:* xiii.
374 *Ibid.*
375 *Ibid.*
376 Bacon F (1620) *Novum Organum Scientarium - The New Organon of Science: Or True Directions Concerning the Interpretation of Nature,* from the translation by Wood, Devey and Spedding, in Spedding J, Ellis RL and Heath DD (eds) (1857–74) Vol 4, *The Collected Works of Francis Bacon,* 15 Vols, Longmans, London.
377 *Ibid.*

(italics added) and to 'perfect and govern it in charity'.[378] The change that he instigated was not a move away from the utility of technology, but away from the Aristotelian school of natural philosophy that had long dominated the curriculum of medieval universities.[379] He accused the schools of having 'usurped a kind of dictatorship over the sciences',[380] so that philosophy and intellectual sciences were 'fruitful of controversies, but barren of works'.[381] It was not Aristotle *per se* that Bacon disliked, but the 'unfruitfulness of the way, and the idleness of the speculations'[382] in the method of learning. Bacon desired a new productive type of knowledge and the methods that could be used to achieve the knowledge.[383] 'His recurrent theme was one of progress as the acquisition of *useful and beneficial* knowledge through organised research'.[384]

4.4 Ethos

Against this historical backdrop, I examine the functions of openness in the 'modern' organisation of open science as it came to be. What Bacon envisioned as methods and practices for the rapid increase of knowledge and ultimately technological advance are implemented through a complex social system, in which disclosure of findings among scientists has not only an intellectual role, but specific functions in the reinforcement of the social organisation itself. This system or 'ethos' comprises a communal enterprise of science based on exchange of resources, competition for recognition, reputational rather than economic incentives, and a moral commitment to the advance of knowledge. It is a public system embodying a public conception of openness. An understanding of the functions of disclosure in this system of science is fundamental to an analysis of change, and the promulgation of new strategies to facilitate 'science for technology' in different circumstances. Before addressing the specific functions of disclosure, I look to the sociology of science for a functionalist

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[378] *Ibid.*
[379] Sargent R-M (ed) (1999) *Francis Bacon,* xiii.
[380] *Ibid.*
[381] *Ibid.*
[382] *Ibid.*
[383] *Ibid.*
[384] *Ibid.*

perspective on the social structure and placement of science as a complex system.

Functionalist approach

Sociologists of science in the Mertonian tradition[385] have, since the mid-twentieth century, characterised the structure of science in similar ways, emphasising the freedom of enquiry, a public domain of knowledge and the growth of knowledge - norms that are shared with academe more generally.[386] Although some consider the 'old' sociology developed by Merton to have been superseded thirty years ago, his approach to science as a whole social structure, his framework of imperatives or 'norms' of science, and his description of the rewards and incentives that motivate individual scientists continue to provide a significant part of the foundation for contemporary work in the sociology and economics of science. Unlike more recent work in the sociology of knowledge, the functionalist approach of Merton and his followers does not seek to explain in sociological and philosophical terms how *particular* scientific beliefs are justified; nor does it focus on internal processes as to how and why scientists draw specific conclusions of fact from their enquiries about the natural world. It emphasises instead the organic unity of the elements or organs of a social system, each of which have functions necessary to its survival.[387]

I consider this perspective on science as an appropriate platform from which to think about the reflexive tools or models of governance to facilitate modern science. The functionalist approach is positivist and teleological in orientation. Science is construed positively as a social construct, with an objective reality that can be subjected to empirical methods of study in a 'disinterested' search for the social laws

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[385] See for example Barber and Hagstrom: Barber B (1990) *Social Studies of Science*, Transaction Publishers, New Brunswick, New Jersey; Barber B (1987) 'The Emergence and Maturation of the Sociology of Science', 5:3/4 *Science & Technology Studies*, 129; Barber B and Hirsch W (1978) *The Sociology of Science,* Greenwood Press; Hagstrom WO (1974) 'Competition in Science' 39:1 *American Sociological Review* 1; Hagstrom WO (1971) 'Inputs, Outputs and the Prestige of University Science Departments' 44:4 *Sociology of Education* 375; Hagstrom WO (1965) *The Scientific Community*, Basic Books, New York.

[386] Rai AK (1999) Regulating Scientific Research, 91.

[387] The analogy of the organism also flags up the homeostatic nature of social systems by which a social equilibrium is maintained among the organs or institutions, and reinstated if external shocks should disturb its balance. Such equilibrium is achieved through socialisation of members into the basic values and norms of the community, which is conducive to enforcement through social sanctions of reflexive governance.

that govern it.[388] The teleological perspective explains phenomena on the basis of their purposes or outcomes rather than postulated causes; theories, for example, are seen as 'networks of predictive generalisations'.[389] Although it may not always be appropriate, the teleological model is consistent in its own terms, and given my purposive conceptualisation of governance for the delivery of public goods, it is preferable to the alternative causal approach.[390]

Imperatives

The structure of social behaviour in scientific communities as described by Merton turns on four sets of 'institutional imperatives' that together comprise an open 'ethos' for the advancement of science. I refer to these norms of 'universalism', 'communism', 'disinterestedness' and 'organised scepticism'[391] individually below, as they pertain to the specific functions of disclosure. The 'ethos' of science for Merton, however, is not simply a list of behaviourial rules. It is the whole complex of institutional norms and social values that are internalised by scientists, shaping their conscience and forming a binding moral consensus regarding the 'scientific spirit'.[392]

Merton derives his imperatives or 'mores' of science from the *goal* and the *technical methods* (which he calls 'norms') of science. The goal of science he characterises as the 'extension of certified knowledge'.[393] The methods to achieve it are 'adequate and reliable empirical evidence' (a prerequisite for sustained true prediction) and 'logical consistency' (a prerequisite for systematic and valid prediction).[394] These

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[388] These ideas date back to Emile Durkheim (1858-1917), the French sociologist whose writings are the basis of functionalist theory. Durkheim was one of the first sociologists to make use of scientific and statistical techniques in sociological research.
[389] Godfrey-Smith P (2003) *Theory and Reality: an introduction to the philosophy of science*, University of Chicago Press, Chicago and London, 125.
[390] This point was made by David Bloor, himself a proponent of a causal approach put forward in the 1970s. See Bloor: *The Strong Programme in the Sociology of Knowledge*, available at http://www.andrew.cmu.edu/course/76-101AA/readings/Bloor.htm, accessed 9 November 2012.
[391] Merton RK (1938) Science and the Social Order. The norms are sometimes summarised under the mnemonic 'CUDOS': communalism, universalism, disinterestedness, originality, scepticism: Ziman J (1994) *Prometheus Bound: Science in a Dynamic Steady State,* Cambridge University Press, Cambridge, 177.
[392] Merton RK (1938) Science and the Social Order, 267.
[393] *Ibid*, 268.
[394] *Ibid.*

technical methods give rise to Merton's definition of *knowledge*, which is 'empirically confirmed and logically consistent statements of regularities (which are in effect predictions)'.[395] Merton considers the methods to be both technical and moral prescriptions - that they have a rationale in methodology but are also morally binding – and that as a whole structure they implement the *final objective* of science, which is knowledge.

The system that Merton describes is not merely a set of research methods backed by public support, nor a social organisation that is capable of implementing the methods, but a community galvanised by a 'moral consensus' about its mission. I flag this up for future reference because, through his use of a moral rhetoric to describe the imperatives and ethos of science, Merton elevates the methods and practices advocated by Bacon to values and ideals of science, which serves to root them more deeply in the psyche and the narratives of the community. For the purpose of strengthening the received model of open science, this entrenchment of values is wholly advantageous. For the purpose of developing new models of governance for a changing paradigm of science, however, it is problematic because morally entrenched 'ideals' are less susceptible than 'methods' or 'practices' to challenge and change. To design integrated conceptions of science and technology and new ways of governing them requires re-examination of existing conceptual frameworks, including values, in order to establish or reaffirm the foundations that will support them. To hark back to the early formulation of empirical science, the vision that inspired Bacon would not permit any endorsement of slavish adherence to 'ideals and values' that do not advance the production of knowledge, nor (I submit) to systems that stimulate knowledge production while choking off its technological uptake.

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[395] *Ibid.*

A model of freedom

So highly regarded are the principles governing the community of scientists, that more than one commentator[396] has generalised them (amidst political and philosophical debate) to society as a whole, using the system of science as a simple model that epitomises a society striving for unlimited human and social improvement.[397] These pursuits and their benefits have been described as the 'noble enterprise'[398] of a free society bent on exploring every kind of self-improvement. Certain features indispensable to this model are said to characterise the 'proper cultivation of science', and are present in society as it pursues other kinds of truth. These are: continuity with the past, unlimited improvement in the future, and individual freedom in the present. First, the freedom that that the model affirms is rooted in tradition, and rejects the idea that each generation might be self-determining. The objective of freedom however is to cultivate radical progress through adherence to an ideal of unlimited self-improvement that is not confined to the pursuit of material or economic goals. Self-improvement is unlimited, though freedom is not. Freedom is not unlimited, but it is a 'positive' freedom, in which individuals are able to voluntarily pursue initiatives of their choice. The pursuit of progress happens through the actions of individuals, aimed at disparate problems, and is not based on a concept of 'popular will' or the direction of endeavour toward a common social purpose. The 'public interest' in this society, it is said, can only be known in a fragmentary way, through the outcomes of these individual initiatives. A society defined by such features will arguably appear 'conservative and fragmented, adrift, irresponsible, selfish, and apparently chaotic',[399] as the intellectual and moral endeavours to which society is dedicated expand in new directions and become ever more specialised. These characteristics are likely to become more apparent as time goes on, because diversification of initiatives must occur as society progresses.[400]

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396 Polanyi M (1962) The Republic of Science, 485.
397 *Ibid.*
398 *Ibid.*
399 *Ibid.*
400 *Ibid.*

Whatever truth there may be in this conception of scientific and social progress, a glaring flaw is that it fails to give equal regard to the private enterprise of the marketplace. The main protagonist[401] of the model states expressly that its principle of freedom is a *higher* principle of freedom, a principle that is *reduced* to the mechanism of the market when applied to the production and distribution of material goods.[402] The model is therefore not only an extreme example of the elevation of the principles governing science, but demonstrates the way in which (over)emphasis on certain values or ideals can have a detrimental impact on others. In this case, enthusiasm for the attributes of open science concretises the distinction between science and technology, and reinforces pejorative attitudes toward market-based enterprise.

4.5 Disclosure

Central to the ethos of science is the communication, publication or 'disclosure' of scientific findings, which gives rise to the 'public' conception of openness. Like other behavioural norms,[403] disclosure furthers the objective of science, which is knowledge.[404] It has specific functions that are key to both the intellectual and organisational structure of science, each of which facilitates and enforces the public nature of science. Disclosure involves the publication of research findings, which links the system of science with the public domain. In its *intellectual* role, disclosure facilitates peer review and enables the rapid expansion of reliable knowledge. In its *institutional* capacity, it facilitates individual efforts through the public recognition of discoveries that motivates and rewards individual scientists and facilitates a competitive collaboration in the community of scientists that maximises interaction with resources. The result is a cumulative archive of reliable knowledge that constitutes a common resource accessible to all through the public domain. This

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401 *Ibid,* 484.
402 Polanyi M (1962) The Republic of Science, 484.
403 In the theory of law and norms, as well as the sociology of science, a norm is a behaviour engaged in out of a sense of obligation and enforced through social rather than governmental sanctions. It is both descriptive and prescriptive – of what people do, and what they think they should do.
404 Rai AK (1999) Regulating Scientific Research, 92.

public domain of knowledge is not however without practical limitations, which I address in a separate section.

Intellectual functions

Peer Review, Verification, Validation

The first intellectual function of disclosure in the 'invention of knowledge' is to permit the scrutiny and verification of the results of scientific research by the colleagues or peers within the scientific community. The innovation of scientific research is the generation of 'original knowledge', and 'originality' is of supreme value because it is 'through originality, in greater or smaller increments, that knowledge advances'.[405] The release of new contributions to a scientific peer group enables others to critique, replicate and test them in order to ensure that they are both *genuine* (that it is possible to obtain the results as purported) and *original* (that they are not already a part of the existing body of knowledge). They can be rapidly discarded if unreliable, or validated and combined with other intellectual elements or existing bodies of reliable knowledge.

The process corresponds to what Merton called *organised scepticism*,[406] which emphasises the need for continual critical scrutiny of scientific contributions to the common stock of knowledge[407] by the community of colleagues. Polanyi suggests that this process is more than the verification of facts, and involves scientific *interpretation* based on fine value judgments that sift and reward, at various levels of merit, the contributions to science. In his view, science is a system of facts, determined by scientific interpretation and accepted by 'scientific opinion,[408] in which science is what it is by reason of the constant elimination and acceptance of contributions to science under the ultimate authority of scientific opinion. Such

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405 Merton RK (1957) 'Priorities in Scientific Discovery: A Chapter in the Sociology of Science' 22:6 *American Sociological Review* 635, 639.
406 Merton RK (1938) Science and the Social Order.
407 Universalism requires that scientific work be assessed by universal impersonal criteria. Disinterestedness requires that scientists be objective, and exhorts them to make the advancement of knowledge the primary concern.
408 Polanyi M (1962) The Republic of Science, 480.

opinion is essentially rooted in tradition, but it is a tradition that upholds *originality*.[409]

Ongoing work in the sociology of science that arose in the 1970s emphasises the process by which scientists draw conclusions or determinations of 'fact' from their enquiries. The 'sociology of knowledge' is wrapped up with philosophical questions about the study of nature and reality and how scientists engage with them. The work differs from earlier approaches in that it moves beyond the structure of the scientific community as a whole and tries to explain in sociological terms how particular scientific beliefs are generated. Some of this work emphasises the influences upon the internal process by which individual or groups of scientists 'manufacture facts'[410] or establish scientific 'truth'. Other projects focus on the resolution of disputes within the wider community over the status of published scientific results. My analysis is concerned largely with the use of published and validated knowledge, and not with the internal processes of endorsement by which scientific peers finally render scientific output 'immune to challenge',[411] or how external scientific disputes over such things are resolved.

Increase in Rate and Corpus of Knowledge

In addition to assurance of *reliability*, disclosure enhances the potential for the generation of new knowledge, or scientific innovation, as well as the *rate* of its production. Exchange of knowledge between scientist may increase the rate of production of more knowledge by reducing the duplication of scientific efforts within the community, and increasing the scope or domain for complementarities within the common pool of knowledge.[412] Complementary connections are increased because knowledge is, in economic terms, 'non-rivalrous': it can be accessed by any number of users simultaneously and is never fully consumed. The more scientists who can

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[409] *Ibid*, 481.
[410] Shapin S and Schaffer S (1985) *Leviathan and the Air-Pump: Hobbes, Boyle and the Experimental Life*, Princeton University Press, New Jersey.
[411] Latour B and Woolgar S (1986) *Laboratory Life: The Construction of Scientific Facts*, Princeton University Press, Princeton, New Jersey.
[412] David P (1998) Common Agency Contracting, 17.

access intellectual resources, the greater the likelihood of 'fruitful conjunctions', beneficial 'spill-overs' among distinct research programs[413] and exponential rates of growth. Equal access to knowledge in the public domain is not a formula for the equitable distribution of a static or finite resource. Rather it maximises the scope for engagement with and manipulation of intellectual resources, which holds the potential for the creative connections or reconfigurations that are essential to innovation. Wide sharing of resources puts knowledge into the hands of those who can put it to new uses requiring expertise, imagination and material facilities that are not possessed by the original discoverers and inventors.[414] Advocates of open science and proponents of other forms of research 'commons' place particular emphasis on the necessity of this sort of access to, and interaction with, various types of resources as the key to the promotion of innovation. Accessibility that permits the 'use and reuse' of resources is a notion that is pivotal to innovation in many fields of study, and applies equally to technological innovation, which I address in the next chapter.

Institutional functions

Still within the 'traditional' narrative of open science, these *intellectual* functions of disclosure for the production of knowledge are augmented by its *institutional* roles, which reinforce the social organisation of science. The distinction between these two sets of functions is important because institutional changes can impact on the intellectual functions and restrict the capacity of science to generate new knowledge. Economists hold that in the 'institutional complex of modern science',[415] social norms increase economic efficiency as well as social utility. The rationale relies on the efficacy of open inquiry and full disclosure as the basis for the cooperative, cumulative generation of predictably reliable additions to the stock of knowledge.[416] The features of openness that enhance the *intellectual* process - rapid validation of

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[413] David P (2003) *The Economic Logic of 'Open Science' and the Balance between Private Property Rights and the Public Domain in Scientific Data and Information: A Primer*, Stanford Institute for Economic Policy Research Discussion Paper No. 02-30, 4.
[414] *Ibid.*
[415] *Ibid*, 3.
[416] *Ibid.*

findings, reduction in duplication of efforts and the availability of knowledge to new users - render the *organisation* of open science an efficient means of pursuing reliable knowledge. The organisational functions of openness are played out through the recognition of individual achievements of scientists, as well as the facilitation of a collaborative and competitive community.

Individual Efforts

Disclosure is not extraneous to but an integral part of the social system that induces scientific effort. Merton argued that science is misunderstood as the product of individual geniuses who break free from conventions and norms, and held that the norms of science encourage productivity, critical thinking, and the pursuit of continually improved understanding. Paul David similarly asserts that openness is a discipline, rather than an ideology or ethical precept.[417]

incentives and rewards.

In the economic logic of open science, the conduct of science is dependent upon a specific nonmarket system of incentives and rewards for individual scientific effort. These rewards are based on peer recognition of claims to original work.[418] The rewards of enquiry are mainly reputational: the recognition of originality and validity of individual work, the esteem of one's peers, eponymous awards and other prizes. Sociological and economic analysis demonstrates that this system of rewards can act as an incentive for disclosure of scientific work. It is agreed that there is 'incentive compatibility' between the norm of disclosure and the existence of 'a collegiate reputation-based reward system grounded upon validated claims to priority in discovery or invention.'[419] In the traditional construct of science, peer recognition based on originality and priority is the main incentive for individual contributions to the public body of scientific knowledge.

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[417] *Ibid.*
[418] *Ibid.*
[419] *Ibid.*

competition.

A scientific work is only recognised as *original* if there has been no prior claim to it.[420] This concept of originality in science is akin to the 'novelty' of patent law, which focuses on the relationship between the invention and the state of the art, as opposed to the 'originality' of copyright, which is concerned with authorship.[421] Recognition of original work as a reliable contribution to science also acknowledges its claim to *priority*, and is thus a means of allocation of individual credit for it, and accrual of reputational and career benefits to the responsible scientist.

The 'abiding emphasis'[422] of science on originality and priority creates a strong incentive for scientists to exert claims and achieve collegiate esteem; and ambition in this regard is considered a crucial motivator rather than an expression of egotism or self-aggrandisement. Further, the claimant need not be deterred by the process of peer review, for the *norm* of disclosure legitimates the practice of scepticism by creating an expectation that *all* claims will be so scrutinised, thus avoiding insult to the claimant. In summary, the institutions of science press scientists to produce and publish original contributions to the common stock of knowledge, and reward them with recognition, acclaim, prizes and employment opportunity.

Communal Collaboration

facilitation of innovation. spontaneous coordination.

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[420] The emphasis on priority can lead to unfortunate circumstances in which, for example, one scientist decides to delay publication until the completion of a comprehensive work, while another reveals conclusions regarding a very similar enquiry in a much more preliminary form. Darwin is the prime example of this: he was plagued by the ambivalence brought about by a 'double concern with priority and modesty'. In the end result his competitor, Wallace, acknowledged the more extensive contribution of Darwin to the field of study. Scientific *knowledge* may not suffer in this situation, but individuals and the reputation of science as an institution may be adversely affected. See Merton RK (1957) Priorities in Scientific Discovery, 648.

[421] The author must have exercised the requisite intellectual qualities (in English law labour, skill or effort and in European law 'intellectual creation') in producing the work. [Bently and Sherman at 88.]

[422] Merton RK (1973) *The Sociology of Science: Theoretical and Empirical Investigations,* Storer NW (ed) Chicago University Press, Chicago; Ziman J (1994) *Prometheus Bound: Science in a Dynamic Steady State*, Cambridge University Press, Cambridge.

In addition to promoting individual efforts, disclosure fosters the *community* of science by facilitating a collaborative social infrastructure characterised by the sharing of information and property. *How* disclosure facilitates collaboration in the 'Republic' has been described as the 'spontaneous coordination of individual initiatives' of scientists,[423] based on the analogy of individuals working on different parts of a large jigsaw puzzle. Having access to all pieces of the puzzle, each chooses to work on a particular patch of it, the key being that each individual is able to work in sight of what others are doing. This enables continual adjustments to individual work in accordance with developments occurring in other areas of the 'puzzle',[424] thus progressing efficiently toward the resolution of an emerging picture.

personal disinterestedness.

The theory of 'spontaneous coordination' emphasises the cooperative over the individual character of science. It holds that the accumulation of scientific knowledge is a fundamentally social process that should not be inhibited by matters that are personal to individual participants. The Mertonian norm of *disinterestedness* implies that the immediate personal interests of the researcher should not be allowed to impede or diminish the availability and reliability of new knowledge, regardless of the nature and import of the discovery, and so favours the handling of research agendas and findings by disinterested agents. It is the conduct of scientific enquiry with 'disinterestedness' or objectivity that protects against bias and error. Further, the norm of *universalism* emphasises that personal attributes of individuals should not prevent entry into scientific work and discourse, which is open to all persons of competence.[425]

popular support.

Finally, proponents of open science acknowledge that its perpetuation requires societal support. The complete independence of scientists and the publicity of their

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[423] Polanyi M (1962) The Republic of Science, 465.
[424] *Ibid.*
[425] David P (2003) SIEPR, 3.

results, which jointly assure the coordination of scientific efforts throughout the world, can only be secured by popular respect for the authority of scientific opinion. Such respect can only be elicited by a strong and united opinion of members of the scientific community, imposing the intrinsic value of scientific progress on society at large.[426]

Competitive Collaboration

The enterprise of open science understood in this way is therefore characterised by both individual and communal efforts, through competition and collaboration.[427] In the jigsaw puzzle illustration, the 'mutual adjustments' involved in the coordination of individual efforts have the potential for rivalries and oppositional responses[428] due to the competition for recognition. As recognition rewards *originality and priority* rather than diligence, it encourages rivalrous behaviour between individuals and research units in the race to establish priority. In the traditional construct, scientists want to be the first to announce original discoveries and are concerned about being anticipated in this by another scientist.[429] The evaluation and certification of knowledge is thus the result of competition or struggle,[430] described in sociological terms as 'competitive cooperation',[431] by which the products of competition become communal property, and esteem accrues to the producer. The disadvantage of the system is that the traditional reputational incentives and rewards do not always deter scientists from practices of secrecy or failure to disclose, which have the potential to undermine the process. Economists however continue to regard open science as uniquely well suited to the goal of maximising reliable knowledge, while acknowledging that uncooperative or deviant behaviours introduce a small amount of inefficiency into the system.[432]

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[426] *Ibid.*
[427] Callon M (1995) 'Four Models for the Dynamics of Science', in Jasanoff S et al (eds), *Handbook of Science and Technology Studies*, Sage, 29.
[428] Polanyi M (1962) The Republic of Science, 484.
[429] Hagstrom WO (1974) *Competition in Science* 1.
[430] Callon M (1995) Four Models of Science, 36.
[431] Merton RK (1938) Science and the Social Order, 272.
[432] David P (2003) SIEPR, 4.

The community of science is thus an association of independent initiatives, combined towards an indeterminate achievement, characterised by voluntariness of participation, freedom of choice as to subject matter and working methods, and access to materials and to other investigators. Scientists, acting freely to choose and pursue problems on the basis of their own personal judgment, are in fact cooperating as members of a closely knit organisation.[433] The system is disciplined and motivated by serving a traditional authority – the opinion of scientific peers - but this authority is dynamic; its continued existence depends on its constant self-renewal through the cultivation of originality of its followers.[434]

4.6 Common resource

Cumulative archive

Further, disclosure facilitates the cumulative progress of science by creating in the public domain a public archive of knowledge or 'intellectual commons' that is accessible for future as well as immediate use. In principle, openness makes resources available for an indefinite period of time. The benefits of the foundation of prior work have long been understood. In a twelfth century debate as to whether the 'moderns' could since the Classical period, Bernard of Chartres is said to have affirmed that:

…'we can indeed see further because we are like dwarfs perched on the shoulders of giants, and thus we are able to see more and farther than the latter. And this is not at all because of the acuteness of our sight or the stature of our body, but because we are carried aloft and elevated by the magnitude of the giants.'[435]

Common property

A distinctive feature of the 'public' concept of openness associated with open science is that it creates a commonly held resource, which in the language of the

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[433] Polanyi M (1962) The Republic of Science, 465.
[434] *Ibid*, 484.
[435] Merton RK (1965) *On The Shoulders of Giants: A Shandean Postscript*, Free Press. The phrase is famously attributed to 17th century scientist Sir Isaac Newton, but Merton identifies 26 other authors from Bernard to Newton that have used the metaphor.

commons strategies that I discuss in Chapter 7, is a 'common' or 'common pool resource'. *Communication* of important findings is the foundation of the norm of *communism*[436] or communalism,[437] the idea that scientific knowledge is ultimately a shared resource.[438] The ideal of communalism requires individual relinquishment of claims to property, for the benefit of the community. In the open model of science, publication establishes a work as the equitable property of the scientist, enabling others to use, cite and commend it to the scientific community.[439] The findings of science are 'assigned' to the community, and as such they form a common heritage, in which the equity of the individual producer is severely limited.[440] In the 'competitive cooperation'[441] of the race for priority, the products of science are 'communised', and the discoverer never takes exclusive possession of, or any special rights of use and disposition[442] in, the outcomes of the work. Scientists' claims to intellectual 'property' in their discoveries are limited to recognition and esteem 'roughly commensurate with the significance of the increments brought to the common fund of knowledge'.[443] The cumulative result is a 'common stock of reliable knowledge' or an *intellectual* 'commons', in which knowledge is augmented rather than diminished through use by others. Unlike the 'tragedy of the commons',[444] which postulates that a natural resource may be depleted through communal use, the intellectual commons creates a bigger more fertile field for science, not by scientific altruism, but through appropriate institutional arrangements.[445] This treatment of science as property held in common is part of the social construct of the open model of science as a public good. In the Mertonian

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436 Merton RK (1942) 'The Normative Structure of Science', in Merton RK (1973) *The Sociology of Science: Theoretical and Empirical Investigations*, University of Chicago Press, Chicago. Merton proposed four norms of scientific discourse: universalism, communism, disinterestedness and organised scepticism.
437 Barber B (1953) *Science and the Social Order*, Allen & Unwin, London, 92; Hagstrom WO (1965) The Scientific Community, 99.
438 Rai AK (1999) Regulating Scientific Research, 90.
439 Merton RK (1938) Science and the Social Order, 272.
440 *Ibid*, 271.
441 *Ibid*, 272.
442 *Ibid,* 271.
443 *Ibid,* 272.
444 Hardin G (1968) 'The Tragedy of the Commons' 162 *Science* 1243.
445 Stephan PE (2004) 'Robert K Merton's perspective on priority and the provision of the public good knowledge' 60:1 *Scientometrics* 81, 85.

ethos, property rights are 'whittled down to the bare minimum' not by the law, but by 'the rationale of the *scientific ethic*'.[446]

Copyright

Although exclusive property rights in scientific results may be contrary to the ethos of science, they are not always contrary to *law*. Copyright accrues automatically in certain literary works, including scientific publications, and in certain circumstances, patent law permits the grant of exclusive rights in relation to scientific discoveries. Intellectual property is not recognised in ideas or information *per se*, but original literary works, recorded in written or other material form,[447] are eligible for *copyright* protection. Copyright vests automatically in the author of scientific results, published or unpublished, giving the holder exclusive rights: to reproduce, distribute and rent or lend the work, communicate it to the public, adapt it, and authorise others to carry out these activities. These rights do not prevent publication of the work, or access by others to its content. On the contrary, copyright should act as an incentive for the author to release the published work into the public domain, thus making the data and information that it conveys available for engagement by the scientific community.

Patent

The law does not, *in principle*, grant *patent* rights to research outcomes defined as 'discovery' of natural phenomena rather than invention. In principle, they are the common heritage of mankind that should not be the subject of private property rights. The finding of a substance freely occurring in nature is therefore, in principle, a discovery, and the substance identified *in situ* unpatentable. The legal distinction is however increasingly difficult to sustain, as the acts of discovery and invention may each involve a considerable amount of time, effort, skill and labour. With the advance of technology, therefore, the scope of patentability has been expanded to

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[446] Merton RK (1938) Science and the Social Order, 272.

[447] 'Literary works' includes all works expressed in print or writing, whether in words, symbols or numerals, and extends to works that are spoken, such as conversations, interviews and speeches, as long as they are recorded in a material form.

include discoveries that occur in close conjunction with patentable inventions, such as bodily substances that have been isolated through a novel process. The distinction has been minimised further, as demonstrated in the *Relaxin*[448] case, in which the European Patent Office found in favour of patentability even though the isolation process was conventional and the structure of the substance identical to that of the natural element, on grounds of the utility of the product and the novelty associated with its isolation, which made it available to the public for the first time.

The result is that scientists who commonly develop techniques to facilitate their research may be able in law to patent virtually the whole of their work, despite the fact that such practice diverges from the traditional incentives and ethos of science. Patent law does not discriminate as to the identity of the applicant. These developments facilitate increased patenting practices by academic scientists and private researchers alike, leading to recent reports of 'patent congestion' and consternation in the life sciences and elsewhere. Motivations and influences in relation to scientific patent policies and practices have long been source of debate: Merton suggested that some scientists patent defensively, in response to increased patenting by the private sector, taking advantage of the disclosure requirement of the patent process in order to keep their discoveries in the public domain, rather than to control exploitation. This assertion is questionable, given that publication might be used to fulfill the same function without the creation of property rights. This flags up however that different patenting policies may be adopted on the basis of different understandings of the role of patents. I discuss the place of patents in technological enterprise and some of the problems associated with them in the context of modern research in next two chapters.

Tangible Property

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[448] *Relaxin/Howard Florey Institute,* T 0272/95, Board of Appeals of the EPO, 23.10.2002; (1995) Official Journal of the European Patent Office 388; (1995) European Patent Office Reports 541; (1996) 27 *International Review of Intellectual Property and Competition Law* 704, 705-6 which concerned claims related to DNA sequences of a substance, naturally occurring in and obtained from the human ovary, that relaxes the uterus during childbirth; Biotechnology Directive, Article 5(2).

The focus of the narrative of open science is the pursuit of *knowledge*, the sharing of intellectual resources and the creation of a knowledge commons. To the extent that property rights attach to the outcomes of research, they are intellectual property rights: copyright and rights of patent, which in law comprise 'incorporeal personal property'. Tangible goods, or 'corporeal personal property', in the open science model, have the role of tools and materials that are used or consumed in the conduct of basic research. Such materials are not the *goal* of the enterprise: the resource or product that is to be generated, conserved or produced. In economic terms, they constitute a cost of the conduct of research: they are significant for the 'transaction cost' that they represent for the development and transfer of knowledge. In many fields of science such materials will be inexpensive and ubiquitous and their exchange not in issue. In other fields, such as the life sciences, materials may be created for a specific research project, and replicability and validation of the work will require samples of the original material. Some scientific journals now recognise this, and make publication conditional on the commitment of the author to supply samples of specialised materials to any who request them. In practice, fulfilment of the requirement may be problematic: the material may have been fully consumed, supply might be insufficient to meet claimant demand, or it might impose an onerous or prohibitive cost to research. The transportation and handling of sensitive living biomaterials creates further practical difficulties.

Outside of 'pure science', in fields such as stem cell technology, the sharing of resources that constitute both *research* materials and basic materials for product *manufacture* can be even more problematic. The situation is exacerbated when the materials in question, namely human stem cells, are highly specialised and very expensive to generate. In this situation, the sharing of a genetically unique line of stem cells among researchers, under the auspices of open science, has more costly implications for the private biopharmaceutical company - who would like to obtain exclusive control over that particular cell line and place it at the centre of a commercial programme for therapeutic development - than it does for the publicly funded scientist who generates the cell line in the course of research. This is the scenario encountered in the banking of stem cell lines with the UK Stem Cell Bank.

It is not science in the model of open science, but a conjunction of science and technology, which I refer to as 'scientific technology'. I set out my ideas about scientific technology in Chapter 6, after looking for concepts of openness in the process of technological innovation from the perspective of an industrial firm.

4.7 Public domain

Underlying my previous discussion of the functions of disclosure and the development of a knowledge commons is the 'public domain',[449] which might be likened to a sort of space, in which resides a vast collection of resources that are unlimited as to accessibility. In reality, the 'public domain' of knowledge is not defined in any geographical sense, but by the *content* that is placed in it, the *means of publication*, and the capacity of *recipients* to receive or access it. The scope and content of the public domain is shaped by decisions of policymakers and those who create and deposit resources, as well as potential users.

Content

The content of the public domain is determined in part by the type of material that should be subject to peer review. In principle, materials to be disclosed are those necessary to permit scrutiny and replication and verification of originality. The literature however refers to release of 'original knowledge', 'findings', 'important findings' and 'results', without further specification. If 'original knowledge' means broadly anything new that the methods of science have generated, as I think it does, then all datasets and information should be released for potential scrutiny and use by others. Despite the practical issues associated with an inclusive approach, such as long term storage and management of vast amounts of data in the digital domain, this has to be the correct position. All original data and information are potentially revealing, and contribute to the pool of intellectual resources available for use in ongoing research. Raw datasets, together with any information and methodologies

[449] At this point I do not explore the nature of the public domain because much of the relevant literature relates to the impact of IP rights on the knowledge commons, which I touch on in Chapter 7. See for example: Boyle J (2003) 'The Second Enclosure Movement and the Construction of the Public Domain' 66 *Law and Contemporary Problems* 33.

associated with their production, are original material that – even if not immediately useful to the producer - may constitute a rich vein to be mined in the unforeseeable future. If anything they are more useful, as a platform for ongoing research, than results that provide a more interpretive analyses of the data. The release of negative as well as positive results is also important in that it prevents bias in a given subject area, particularly in the health field, where failure to disclose negative outcomes can pose a risk to public safety as well as future research. Clearly some degree of discretion must be involved, but the fact that we are capable of generating huge volumes of reliable data should not in principle prevent attempts to make it accessible for use and reuse.

The content of the public domain is not however unlimited, but is shaped by restrictions upon the release of certain findings, or categories of findings, on grounds of public interest. These grounds include the protection of personal data, national security and public safety,[450] each of which might form a field of separate study outside of the scope of my thesis.

Publication

Disclosure of scientific results for purposes of peer review is generally associated with their 'publication' through scientific journals, which connotes dissemination of material to all the corners of the earth, and unlimited access by every inhabitant. In reality, the scope of the public domain is influenced by the medium of publication: its geographical reach, language, the size and nature of its readership and price of subscription, the timeframe for publication and allocation of intellectual property rights. In the early institutions of science, academies and societies published their proceedings and the scientific works of their members, but many official journals published only infrequently, and it could take a scientific paper up to several years from the date of submission for review to reach publication. Independent periodicals aroused interest in science in a more general public audience by publishing a variety

[450] The Royal Society (2012) *Science as an open enterprise: open data for open science*, The Royal Society Science Policy Centre report 02/12, 44.

of reviews, abstracts, translations of foreign texts and reprinted materials, but most of these were published in the local language, which limited the spread of readership within continental Europe.

Modern subscription-based journals cover production costs by imposing a fee on readers, and taking some interest in the copyright, an arrangement that restricts access to the journal to those who can pay, and limits the ability of the author to disseminate the work independently. Moves to overcome these restrictions through 'open access' publishing arrangements are however becoming more prevalent. Under 'green' terms of open access,[451] journal publishers permit authors (backed by research funders who make funding conditional upon the arrangement) to publish peer-reviewed papers in open access online repositories, generally some months after the journal has issued,[452] by which time the publisher has sold enough access to the paper to make a profit. Researchers can also post pre-publication versions of their papers in institutional repositories.[453]

The 'gold' alternative is open access from the start. It requires the author to pay in advance for publishing services, in order that the readers can obtain access for free. This is a dramatic change that shifts the costs of publishing to the scientists and research institutions, and alters incentives for publishers.[454] It has nevertheless been recently embraced by the UK government, which announced in July of 2012 that it would require much of the national publicly-funded research to be published on an open access basis from April 2013.[455] The European Commission has made a similar proposal, to open up €80 billion worth of work supported by its Horizon 2020 research programme that will run in the EU from 2014 to 2020.[456] It is urging its

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[451] Van Noorden R (2012) 'Britain Aims for Broad Open Access', 486 *Nature*, *News & Comment* 302.
[452] *Ibid.*
[453] *Ibid.*
[454] Van Noorden R (2012) 'Europe Joins UK Open Access Bid' 487 *Nature, News & Comment*, 285.
[455] *Ibid.*
[456] *Ibid.*

Member states to do likewise, and hopes that 60% of all European publicly funded research articles will be open access by 2016.[457]

Recipients

Finally, the constitution of a public domain of knowledge as a useful resource depends in part upon the capacities of potential users to access it. The accessibility of even 'open access' publications may require, for example, access to the use of Internet and other infrastructural resources. The advance of science through the use of public knowledge is further dependent upon the skills and expertise of individuals to engage and manipulate it.

4.8 Conclusions

From this examination of the historic literature and traditional narratives I am able to make some observations about the nature of openness as it relates to science.

1. My *first main conclusion* is that, in the philosophy of open science, the production of knowledge is not hostile to utility or technological enterprise. The formalisation of empirical methods of scientific research was a response to a stagnant intellectual environment, during a period in history in which the received wisdom of natural philosophy was being taught or transmitted, but little new knowledge about the natural world was being generated. The significance of the 'scientific method' advocated by Sir Francis Bacon was that it was to stimulate the 'invention' of knowledge through organised research. He proposed an innovative process - a productive process focused on the advance of knowledge – but the production of knowledge was never envisioned as an end in itself. Rather it was to be 'for the benefit and use of life', as a means to all sorts of discoveries and inventions that would enhance society. The collective scrutiny of the work of the new scientists was to ensure the purity of the methods and the reliability of the product against the backdrop of an antithetical *intellectual* culture rather than a hostile *economic* environment. Bacon recommends that the experimental sciences be sustained

[457] *Ibid.*

through external financial support, but does not anticipate the process by which technological advances would be generated from scientific discoveries, nor what the potential impact of a competitive economic market might be on the publicly supported community endeavour that he proposes.

2. My *second main conclusion* is that the system of open science that emerged in 17th century Europe is a social construct, with three significant implications. First, public support for the treatment of science as a *public good* underscores the value that society places on freedom of enquiry and knowledge, rather than any determinative assessment that it is a pure public good. That the system of production of knowledge receives external financial support ensures that it is largely independent of the forces of a competitive economic market.

Secondly, the construct of open science institutionalises the *distinction between the public endeavour of science and the private enterprise of technology*. In the narrative of open science, the scientific ethos that perpetuates the generation of knowledge is separate from and incompatible with the exclusive, market-based private property regimes that are conducive to technology. I address this in detail in other chapters. Even in the traditional model of pure open science, however, there are inklings, primarily in its relation to the law of intellectual property and the use of materials, that the synergy between science and technology transcends the public and private distinction.

Thirdly, the construct of open science creates a *common property regime*. The archive of knowledge in the public domain, treated as the common property of mankind is, to use the language of the commons referred to in Chapter 7, a 'common pool resource' or 'common', 'nested' or situated within the predominant culture of the market. The public type of openness that is reflected in the 'uncontrolled' common and the 'unlimited' public domain of accessible knowledge is one extreme in a spectrum of possible vehicles or approaches for the collective governance of resources. In Chapters 5 and 6 I contrast this with the other extreme of exclusive rights or proprietary control, and in Chapter 7 I discuss governance strategies with diverse objectives that attempt to integrate the two through innovative arrangements

that attempt to control a common resource or limit exclusive rights in private property. Here, I simply emphasise that the system of open science, although more extensive than most 'strategies' and institutionalised in western society, is essentially a social contrivance specifically designed to enhance the growth of knowledge resources.

3. My *third conclusion* is that even the public conception of openness is not absolute. Public interests and other practical limitations impose restrictions on the type of content that is released into the public domain, and the scope and accessibility of the public domain is limited by the means of publication and its recipients. In public science therefore, as in private industry, publication is neither unstructured nor unlimited. The disclosure, accessibility and innovative use of resources are the result of decisions that are influenced by legal, economic and social structures.

4. My *final conclusion* is that the function of disclosure is embedded in a system. The specific intellectual and organisational functions of disclosure are an integral part of the cohesive structure of open science, which is itself influenced by a set of social, economic and political circumstances at a particular time in history. The patronage theory of ostentatious revelation is another example of support for the act of disclosure through a social structure that depended upon individual incentives and rewards within a particular economic and social culture, not for the increase of knowledge, but to advance the reputation of the patron.

In open science, disclosure is supported by social norms that reinforce the whole organisation or 'ethos', in which disclosure is not an optional act of altruism but a professional expectation of exchange within the community of scientists. The norms are construed also as moral imperatives, which galvanises the community in its mission and entrenches its commitment to share intellectual innovations and denounce market incentives in the spirit of science. This strengthens the system but makes it resistant to the re-examination of its deeply held beliefs in the face of changing circumstances.

The narrative suggests that the continuity of science requires not only the active participation of capable persons, but also certain cultural conditions, and implies that changes to its institutional structure might curtail, modify or prevent[458] innovation in science. Although we may attempt therefore to extract the meaning of openness from the open science model as it was articulated and institutionalised in the 17th century, we cannot expect that by invoking open methods in modern governance we will recreate the unique cultural ethos, institutional infrastructures or rapid innovation that characterised the original 'Republic of Science'.[459] The institutions of open science and the cultural ethos they have served to transmit may simply be legacies of European history',[460] resulting from a convergence of circumstances that occurred in western European culture in contrast with those that prevailed in other monolithic political systems. China in an earlier epoch[461] is a well-known example of 'a society that clearly possessed the intellectual talents for great scientific accomplishments, yet failed spectacularly to institutionalise the practice of open science.'[462] Attempts to create open methods and institutions should therefore proceed on the strength of an assessment of the functions they fulfil in the contemporary circumstances that they are confronted with.

As science begins to come out of the box of 'open science' that has served it for so long, and we consider new strategies of governance, we need to regrasp the original vision of science *for* technology, reassess the systems that were established to advance it, consider which practices and values that have served those systems are still vital and assess whether and how they might be applicable in contemporary circumstances. Nothing can or should be taken for granted in attempts to capture a new vision of science for modern technology that will be useful in mapping the way ahead. It is not possible to stuff science back in the box, or even to extend the box to recapture science. The door is open, and science is mingling with technology, in

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458 Merton RK (1938) Science and the Social Order, 277.
459 David P (1998) Common Agency Contracting, 20.
460 *Ibid.*
461 *Ibid.*
462 *Ibid.*

public and private spaces. I take this to mean that the method envisioned by Bacon has been so successful that it is now fulfilling his greatest aspirations for it.

In the next chapter I look to the dynamic industrial processes of technological innovation for concepts of openness in private enterprise.

Chapter 5. INDUSTRIAL TECHNOLOGY

5.1 Introduction

This chapter examines the origins, ethos and functions of technology as a system of industrial innovation, with a view to identifying patterns of openness and exclusivity that facilitate innovation and exploitation in the delivery of goods. My objective is to understand the elements of the technological process, in the absence of the effect of scientific inputs that may enter into it, which I come to in due course. Technology is commonly distinguished from open science on grounds of exclusivity: that it obtains *exclusive* control over resources and withholds the results of its research from the public domain to enable it to generate goods in a competitive market. Here I show that 'exclusivity' must be understood in the context of the technological enterprise as a whole, within the ethos of capitalism and the open market system.

I demonstrate that the function of 'exclusion' of competitors by the industrial firm is to create a crucible of 'innovation' for the generation of new knowledge and the addition of value that transforms that knowledge into goods capable of exchange in the market. The protection of inchoate products through secrecy and the attachment of property rights facilitates their release into the public domain of commerce, in which they are widely accessible, subject to negotiation of terms with the property holder. Property rights attach not only to tangible end products but also to pieces of patentable knowledge generated in the process, thus expediting their potential for release into the market and rapid availability to others in the field.

My examination of industrial technology throws up two main paradoxes of openness and closure. The first is that within the firm the openness of technical innovation produces closure in the stabilisation of products. Complex non-linear dynamics between technology, firm and market characterise the process of innovation and exploitation that takes place within the parameters of 'upstream and downstream', resulting ultimately in economic goods. Contrary to the common perception of technology, however, the story does not end there.

The second paradox is that the exclusion of competitors from the process of innovation facilitates openness by enabling the release of products into the *public domain of commerce*. Like new knowledge in the 'public domain' of open science, the results of technological innovation are accessible to the public on the open market. Unlike the public domain of science, exchange of knowledge and tangible products in the domain of commerce is mediated by property rights, which act as a gatekeeper for the controlled dissemination of resources. The combination of the legal infrastructure of property, the divisibility of ownership into discrete rights, and the nonrival nature of knowledge facilitates the transfer of knowledge as well as delivery of concrete goods in the domain of commerce.

The chapter demonstrates the misconception that 'public' science and 'private' technology are entirely incompatible with one another. The picture that emerges is one of complementarity in the enterprises of science and technology[463] each of which excludes the market in order to facilitate innovation, in the pursuit of the advancement of knowledge. Their use of different media of exchange in the public domain enables technological exploitation to produce practical outcomes and the social benefits of public goods. That neither the openness of science nor the exclusivity of technology are absolute reveals a potential for governance strategies to facilitate each to mutual advantage.

5.2 Objectives

Technology is the use of knowledge to achieve the practical aims of human life or to change or manipulate the human environment. In conventional narratives referred to below, the focus of technology is the active pursuit of utility:[464] the invention of means or methods to achieve a practical goal, solve a problem, enhance a solution, or perform a specific function. The word 'technology' comes from the Greek *tekhnología,* comprising *téchnē,* an art, skill, or craft and its study or systematic treatment.

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[463] David P (2003) SIEPR paper.
[464] Faulkner W (1994) 'Conceptualizing Knowledge Used in Innovation: A Second Look at the Science-Technology Distinction and Industrial Innovation' 19:4 *Science, Technology & Human Values* 425, 434.

In technology there is an immediately apparent overlap with science in the pursuit of knowledge. Just as scientific 'discovery' involves an active process likened to the 'invention' of knowledge, so the invention of technical means and methods involves the 'discovery' of useful knowledge. The synergy between science and technology that drives modern scientific technology is generated by this mutual interest in the pursuit of knowledge, albeit arising from different perspectives or orientations. Science and technology each conduct 'research', and they rely on observed facts and the same natural 'laws'[465] or understandings of the nature of things.[466] Each is a cumulative process, and its outcomes are 'diffused' through the same mechanisms of education, publications and informal communication. Science and technology are each organised around professional communities with clear disciplinary autonomy.[467]

Technology is not, however, interested in knowledge for its own sake, but in its potential for use as a tool, method or product, to achieve some beneficial result or effect.[468] Whereas the scientific pursuit of knowledge is concerned with how and why things happen, the technological focus is on making things happen. Technology attempts to understand how knowledge can be concretised in a form that embodies practical value for the advancement of its own agenda. The objective is to produce something that works, or works better, and 'understanding' is important only in so far as it helps in that effort.[469]

Technical knowledge may have strong foundations in the understanding generated by rigorous science, as I discuss below, but it has a far wider base in empirical or experiential learning. Although the explanatory power of science can contribute much to technological innovation, and in fields such as stem cell technology it is clear that the two are intimately connected, technology is - in conceptual terms at least - distinct from its scientifically validated knowledge inputs. Many ancient crafts, such as beer brewing, spinning and weaving of cloth, and smelting of ore were

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[465] Faulkner W (1994) Conceptualizing Knowledge, 434.
[466] Polanyi M (1947) Science: Academic and Industrial, 404.
[467] Faulkner W (1994) Conceptualizing Knowledge, 434.
[468] http://www.uspto.gov/web/offices/pac/mpep/documents/2100_2106.htm USPTO Patenting Guidelines.
[469] Nelson RR (2003) The advance of technology, 1691.

based on 'purely empirical technology',[470] lacking any understanding of the scientific basis for the processes applied. Likewise, many modern technologies look to science only as 'necessary' to advance the process.[471] In the next chapter, I maintain that scientific technology should be understood as a marriage in which the two partners, however closely connected, retain separate identities.

5.3 Origins

'Technology'

Technology predates the formal methods of science by hundreds of thousands of years, originating with the human conversion of natural resources into simple tools. The controlled use of fire, which began with *Homo erectus* 400,000 years ago and became widespread 125,000 years ago,[472] was a turning point in the evolution of human culture, increasing the available sources of food, providing warmth and protection from predators and insects, and expanding human activity into the colder hours of the night. Invention of the wheel facilitated travel and further control of the human environment.

Industrial revolution

Technological advance accelerated with the substitution of machines for animal and human labour. The 'Industrial Revolution' that occurred in Britain from 1760 to 1840, and spread from there around the globe, instigated a process of change that transformed agricultural societies into economies dominated by industry and manufacture. New materials, energy sources and machines, along with increasing use of scientific inputs, contributed to the increased production of goods and services that affected every aspect of life. The factory system reorganised work through the division of labour and specialisation of function, making possible dramatic increases in the use of natural resources and the mass production of manufactured goods.

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[470] Polanyi M (1960-61) Science: Academic and Industrial, 405.
[471] Scranton P (2006) Technology, Science and American Innovation, 48:3 *Business History* 26.
[472] Encyclopedia Britannica Concise, available at: http://www.britannica.com/EBchecked/topic/287086/Industrial-Revolution, accessed 14 November 2012.

Through important developments in transportation and communication, such as the railroad and the telegraph, the printing press and telephone, technology has overcome physical barriers to facilitate human interaction on a global scale. The industrialisation of technology effected widespread changes in economic, political, and social organisation, including greater distribution of wealth, increased international trade, political changes as a result of shifts in economic power, and the institution of new social hierarchies and patterns of authority.[473][474]

'Pasteur's quadrant'

Scientific developments during this period, combined with the expanded technical capacities, spawned new disciplines of technological research and associated industries. The work of generally trained scientists on practical problems resulted in the emergence of specialised fields in which research was focused on rigorous scientific understanding, but the field as a whole, and programmes of research within it, were dedicated quite explicitly to solving particular kinds of practical problems, and advancing bodies of practical technology.[475] Metallurgy, for example, arose from the work of chemists on quality control in the steel industry; developments in chemistry and biochemistry gave rise to chemical engineering; the physics of electricity and magnetism generated electrical engineering and 'systems' technologies; the invention of the computer generated the field of computer science. New knowledge in chemistry and biology also led to specialisms in agriculture and medicine: medical pathology, immunology and cardiology grew up for teaching at medical schools.[476] Such fields are described as falling within 'Pasteur's quadrant',[477] in reference to the work of Louis Pasteur on matters including the

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[473] *Ibid.*

[474] There is also support for the idea that further changes during the late 19th and 20th centuries are of a magnitude that indicate a second Industrial Revolution. These changes include the exploitation of a new range of natural and synthetic materials, computer automation of the industrial manufacturing process and tools of research, and the reorganisation of the ownership of means of production through a shift from oligarchies to open share structures: Landes DS (1969) *The Unbound Prometheus: Technological Change and Industrial Development in Western Europe from 1750 to the Present,* Cambridge University Press, Cambridge and New York; Geddes P (1915) *Cities in Evolution*, Williams & Norgate, London.

[475] Nelson RR (2003) The advance of technology, 1696.

[476] *Ibid.*

[477] Stokes DE (1997), Pasteur's Quadrant.

pasteurisation of milk and the immunisation of patients with attenuated strains of bacteria, which were simultaneously 'basic' scientific and 'applied' technical research.

Pharmaceutical industry

The pharmaceutical industry as we know it was a comparatively late development. Although its roots lie with the apothecaries and pharmacies that offered traditional remedies as far back as the middle ages, it was not until the mid-19th century that the developments in chemistry from the 17th century, and the acceleration of industry during the late 18th century, combined to produce benefits for human health.[478] This created a new relationship between scientists situated largely in universities and research institutes, who traditionally conducted drug 'discovery' through the isolation of active ingredients from traditional remedies, and pharmaceutical companies who undertook 'drug development' activities to determine the suitability of the identified compound for use as a medication. The amount of capital required for developmental research, involving studies *in vitro* and *in vivo,* as well as clinical trials, made this the historical strength of the larger pharmaceutical companies.[479] In this relationship there is an evident overlap between discovery and development: 'discovery' of potential drugs is likely to involve, in addition to isolation of compounds, an element of 'design'; and both discovery and development may be undertaken by industrial firms. Large multinational corporations may participate in a broad range of drug discovery and development, manufacturing and quality control, marketing, sales, and distribution; smaller organisations are likely to have a more specific focus on discovery of drug candidates or development formulations. Further, collaborative agreements between research organisations and large

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[478] Walsh R (2010) 'A history of: The pharmaceutical industry', *Pharmaphorum*, available at: http://www.pharmaphorum.com/2010/09/17/a-history-of-the-pharmaceutical-industry/, accessed 15 November 2012.
[479] *Ibid.*

pharmaceutical companies may be formed to explore the potential of new drug substances.[480]

I include this outline of the pharmaceutical industry because pharma companies are the likely hosts of the cell therapy or 'CT-RM' industry for the development of stem cell therapies, as indicated by the initial Geron trials for hESC treatment of spinal injury (since acquired by BioTime Acquisitions) and the advancing ACT clinical trials involving hESC treatment of macular disease. Such firms already have some experience of working with large biological (as opposed to small chemical) molecules, having begun the expansion of their remit to include 'biological drugs' with insulin in the 1970s. The combination of computer and bio-technology is seen as the way of the future[481] as the use of high throughput screening, genetic modification and the computerisation of genomics facilitates development of new biologics at a much higher rate than was previously possible. Biological drugs such as monoclonal antibodies, introduced at the turn of the millennium, point to a whole new array of more specifically targeted biologics that may have as great an impact on human health as the medicines of last century.

It is a significant shift nevertheless from biological molecules to the development of therapies incorporating whole human cells. Even if firms are willing to undertake it, the existing infrastructures have been developed for chemical drug development. They provide little precedent in the way of standards by which to assess technical and commercial uncertainty in the production of cell-based therapies as a means to encouraging investment; nor is the regulatory framework for the pre-clinical testing of drugs entirely appropriate to therapeutics based on cells. I refer to these matters in relation to the barriers to translation of stem cell science in the next chapter. Not all medicinal products are produced on a commercial basis, but I assume for the purposes of the following discussion that the large majority of stem cell-based

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[480] TUFTS Center for the Study of Drug Development 'Drug Companies are Teaming with Academic Research Centers to Create New Medicines', *News*, Boston, 7 August, 2012.
[481] Walsh R (2010) A history of the pharmaceutical industry.

regenerative medicine treatments will be produced by pharmaceutical companies for the commercial market.[482]

5.4 Ethos

Against this historical backdrop, I examine the ethos of industrial technology in search of concepts and functions of openness. My first observation is that the pursuit of technology, like science, operates in an *open system* that facilitates innovation. This seems immediately contradictory to open science theories that contrast the Republic of Science with a Regime of Technology geared to secrecy, or exclusive possession of the right to commercial exploitation of existing data, information and knowledge.[483] I contend that 'technology' is both open and closed: that as a social organisation it is more complex than science, involving interrelated (or in the commons language used in Chapter 7, 'nested') systems and functions that create certain paradoxes of openness and closure. I consider the ethos of technology to be the social order of capitalism, which invokes the laissez-faire market system for the production of goods and services that dominated the Industrial Revolution and still dominates the world today.[484] The system of capitalism is much bigger than the market and is dependent upon social values beyond the market for the pursuit of a free society. The market itself is an economic system of 'open' exchange that encourages initiative, innovation and productivity. It is the activity undertaken by actors in the market system – the combination of innovation and exploitation for the generation of both new knowledge and products – that requires exclusivity in order to fit products for exchange on the market.[485] Later in this chapter I examine models that try to explain the dynamics of this process from the perspective of the industrial firm, after considering the relationship between the ethos of capitalism and the 'open' market.

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[482] Chris Mason, comment, SCRIPT Roundtable Workshop: Open Science and the Regulation of Stem Cells, University of Edinburgh, September 2011.
[483] David P (2003) SIEPR, 5.
[484] Heilbroner R (1992) Twenty-First Century Capitalism, 3.
[485] Nelson RR (2004) 'The market economy and the scientific commons' 33 *Research Policy* 455.

The market

In principle, an economic market is 'open' if it permits all economic actors equal opportunity of entry to trade, without any external constraint. This is in contrast to a market that is 'closed' by a dominant monopoly or oligopoly, or 'protected' by financial or legal conditions of entry or the imposition of tariff barriers, taxes, levies or state subsidies that effectively prevent participation.[486] In practice, few markets are fully open, because they require legal frameworks to mediate commercial transactions by guaranteeing security of property, enforcement of contractual obligations and prevention of abuse, and because these frameworks may constrain or prevent participation by some actors. The notion of openness of markets is therefore often reconstrued as 'freedom of competition',[487] which is assessed with regard to the extent of the government regulation that impacts on it, the scope of competition it offers, and existence or absence of local barriers to trade. Participation is thus attributable to the competitiveness of the actor rather than the market, and inability to participate is a subjective preference or personal incapacity.

The industrialisation of technology, like the institutionalisation of science, formalised the pursuit of technological objectives in new social structures.[488] It intensified production, increased productivity and created new markets. The main actor for the purposes of my thesis is the corporation or firm,[489] which - unlike the scientist - encompasses further tiers of organisation, including production units and individuals with various responsibilities within its operations. Within the market, firms compete

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[486] Demsetz H (1997) 'Industry Structure, Market Rivalry, and Public Policy' in Foss NJ (ed) (1997) *Resources Firms and Strategies: A Reader in the Resource-Based Perspective*, Oxford University Press, Oxford and New York, 74; Heilbroner R (1992) Twenty-First Century Capitalism; Williamson OE (1985) *The Economic Institutions of Capitalism* Free Press, New York.

[487] Ibid, Demsetz H (1997) Industry Structure and Market Rivalry.

[488] Freeman C (2002) *As Time Goes By: from the Industrial Revolutions to the Information Revolution* Oxford University Press, Oxford and New York; Ashton TC (1997) *The Industrial Revolution 1760-1830* Oxford University Press, Oxford and New York.

[489] Williamson OE (2002) 'The theory of the firm as governance structure: from choice to contract' 16:3 *The Journal of Economic Perspectives* 171; Foss NJ (ed) (1997) *Resources Firms and Strategies* 5; Williamson OE (1993) *The nature of the firm: origins, evolution and development* Free Press, New York; Connor KR (1991) 'A Historical Comparison of Resource-based Theory and Five Schools of Thought Within Industrial Organization Economics: Do We Have a New Theory of the Firm?' 17:1 *Journal of Management* 121; Williamson OE (1985) *The Economic Institutions of Capitalism* Free Press, New York; Coase R (1939) 'The nature of the firm' 4 *Economics* 386.

with one another for economic rather than social rewards, yet in their competition contribute to the larger 'collaborative' enterprise of the market, which supplies the needs of society with goods and services.[490] In the dynamics of the market, firms are both producers and consumers of goods and services, which are made widely available in the commercial domain. The release of products onto the market not only makes them accessible to the domestic public but facilitates mutual exchange of resources among firms, for use in ongoing technical development and production. Interaction in the market takes place through multiple networks[491] of communication, negotiation and transaction among firms.[492] Commercial profits, enhanced by the prospect of a patent monopoly for a limited period, provide corporations with incentives for innovation, invention and thus investment. Rewards for individual participation are, similarly, primarily economic rather than reputational.

Just as the public domain of knowledge facilitates the advance of science, so the market provides a public domain of commerce that facilitates accessibility of resources for the production of technical goods.[493] Like science, the advance of technology is not a mere consumption of resources in the process of manufacture, but involves their use in *innovation* or the generation of new knowledge. Innovation is characteristic of the whole of the R&D enterprise, to the extent that the literature, which I discuss in a later section,[494] uses the term indiscriminately to refer to the goal, the process and the production of innovation. In the next chapter, I argue that despite the industrial focus on *production of goods*, the key to all aspects of technical innovation is *knowledge*, and that given the technological drive for utility, it is 'useful' knowledge that is sought, generated and used.

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[490] Richardson GB (1997) 'The Organisation of Industry' in Foss NJ (ed) (1997) *Resources Firms and Strategies*, 60; Wernerfelt B (1997) 'A Resource-Based View of the Firm' in Foss NJ (ed) (1997) *Resources, Firms and Strategies* 117.

[491] Powell (1990) 'Neither market nor hierarchy: network forms of organization', 12 Research in Organizational Behavior 295.

[492] Powell WW (1990) 'Neither Market nor Hierarchy: Networked Forms of Organization' 12 *Research in Organizational Behavior* 295.

[493] Wernerfelt B (1997) A Resource-Based View of the Firm.

[494] See section 5.6 'Innovation' below, particularly footnotes 520 through 525.

The key to the operation of the market system is in the core assumption that a 'maximising mindset'[495] or 'acquisitive mentality'[496] is inherent in human nature, and that this human predisposition acts as an 'inner force or directive'[497] without which the market system will not work. It is the predictability of this force in human behaviour that enables the market to bring order out of a 'universe of individuals seeking to augment their fortunes'.[498] Markets are not therefore the source of the energies of capitalism, nor of the division between public and private sector authority, but channels or conduits through which energies flow, and by which the private sector can organise its activities without direct intervention of the public realm.[499]

Capitalism

Capitalism is the wider social order rooted in economic and political ideology for the pursuit of a free society, in which industrial technology is situated. I do not debate here the merits of the capitalist political economy that forms this ethos, but simply distinguish it from the market. Although capitalism is commonly spoken of as 'the market', and aligned with competition and the drive for the acquisition of wealth, the market is only one aspect of the social order of capitalism.[500] Capitalism as a whole is dependent upon values that are external to the market in order to balance the drive for capital and prevent the 'market economy' from becoming a 'market society'. These values include the virtues such as hard work, thrift and deferred gratification[501] that directly undergird the market, but also encompass wider social values such as trust, integrity, honesty to customers, loyalty to employees, and a sense of responsibility to the community. The notion that creation and ownership of wealth brings with it responsibilities of stewardship, the sharing of possessions and the alleviation of poverty in society is entrenched in Western social, cultural and

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[495] Heilbroner R (1992) Twenty-First Century Capitalism, 3.
[496] *Ibid.*
[497] *Ibid.*
[498] *Ibid.*
[499] *Ibid*, 74.
[500] *Ibid,* 3.
[501] Weber M (1905) *The Protestant Ethic and the Spirit of Capitalism*, in the English translation (1958) Scribner, New York.

religious traditions that inform the capitalist ethos.[502] The extent to which open markets and the capitalist social order can be attributed to the cluster of values brought to Europe by specifically Judeo-Christian religious philosophy is a matter for debate outside the scope of my thesis, but it has been observed that cultures that respect the individual, value work, and reward creativity and initiative are more likely to create free markets than are social systems that are highly collectivist, aristocratic, or conservative.[503] Scholars once again point to the example of China, which until the 15th century was more technologically advanced than the West, but did not give rise to formal science, the Industrial Revolution or the market economy.[504]

Sociologists of capitalism suggest that not only is capitalism unsustainable in the absence of human values external to the market, but that the market has a tendency to erode the values that are necessary to its own survival. More than one has predicted the demise of capitalism due to its economic successes, rather than its failures, and its replacement by a post-industrial society defined by a socialist polity.[505] Schumpeter argues that economic successes create an unfavourable social and political climate or 'atmosphere of almost universal hostility to its own social order',[506] while Bell contends that the material abundance that capitalism generates gives rise to a culture of consumerism characterised by a need for instant

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[502] Religious views on capitalism are diverse, many of which defend a natural right to property while criticising the negative social effects of materialism and greed. See for example: Weber M (1905) The Protestant Ethic; Tamari M (1987) *With All Your Possessions: Jewish Ethics and Economic Life,* Jason Aronson, Northvale New Jersey.

[503] Chief Rabbi Lord Sacks, citing the work of David Landes in 'Rediscovering Religious Values in the Market Economy' *Huffington Post*, The Blog, posted 12 December 2011, available at http://www.huffingtonpost.com/chief-rabbi-lord-sacks/religious-values-market-economy_b_1144469.html, accessed 18 November 2012.

[504] Landes DS (2006) 'Why Europe and the West? Why not China?' 20:2 *Journal of Economic Perspectives*, 3. See also Landes DS (1998) *The Wealth and Poverty of Nations: Why Some Are So Rich and Some So Poor,* WW Norton, New York; Landes DS (1983) *Revolution in Time*, Harvard University Press, Cambridge Mass USA; Landes DS (1969) *The Unbound Prometheus: Technological Change and Industrial Development in Western Europe from 1750 to the Present,* Press Syndicate of the University of Cambridge, Cambridge, New York.

[505] Bottomore T, 'Introduction', in Schumpeter JR (1942) *Capitalism, Socialism and Democracy,* Harper & Row Publishers Inc, New York; see also Soros G (1998) *The Crisis of Global Capitalism: Open Society Endangered* PublicAffairs Books, New York; Soros G (2001) *Open Society: Reforming Global Capitalism,* PublicAffairs Books, New York; Bell D (1976) *The Cultural Contradictions of Capitalism,* BasicBooks, New York; Bell D (1973) *The Coming of Post-Industrial Society: A Venture in Social Forecasting*, BasicBooks, New York; Bell D (1960) *The End of Ideology: On the Exhaustion of Political Ideas in the Fifties*, Harvard University Press, Cambridge USA.

[506] Schumpeter JR (1942) *Capitalism, Socialism and Democracy,* Harper & Row Publishers Inc, New York.

gratification and irrational self-expression among the successful[507] that undermines the values that gave rise to it. Scholars have also forecast that an information-led and service-oriented 'post-industrial society'[508] will replace industrial society as the new face of capitalism, through a shift from manufacturing to services, centrality of new science-based industries and technical elites, and a new principle of stratification.

Examination of these ideas, as well as the origins and future of capitalism more generally, is outside the remit of my thesis, but I raise them here to indicate the embeddedness of industrial technology and the market in the wider ethos of capitalism, and the extent to which they are shaped by economic and political ideology. In the balance of this chapter, I proceed on the basis that despite cultural and economic contradictions, capitalism is still apparently alive. The outcomes of technical innovation are released into the public domain of commerce, are available on the open market for use as resources in ongoing innovation, and the benefits of economic success are in principle extendable to society, through endorsement of social values beyond materialism. Where, then, is 'exclusivity' in the open market system of commerce?

5.5 Exclusion

Versus 'exclusivity'

At the heart of this ethos of capitalism is the practice of exclusion which, like disclosure in the system of science, serves certain functions in the enterprise of technology. I purposely distinguish exclusion from 'exclusivity'[509] - the capacity or right to exclude – because while the *actual* exclusion of users from new knowledge, either by trade secrecy or by the exercise of property rights, may create conditions that are problematic for open science, the *right* to exclude, in itself, does not. 'Exclusivity' or the 'right to exclude' refers to the legal right of a property holder to

[507] Bell D (1976) *Cultural Contradictions*; for a succinct review of the work of Bell, see Schumpeter JR (2011) 'Ahead of the Curve: Daniel Bell, who died on 25 January, was one of the great sociologists of capitalism', *The Economist,* 3 February 2011, available at: http://www.economist.com/node/18061086?story_id=18061086 accessed on 18 November 2012.

[508] Bell D (1973) The Coming of Post-Industrial Society.

[509] Katz L (2008) 'Exclusion and Exclusivity in Property Law' 58 *University of Toronto Law Journal*, 2.

enforce, as against third parties, the whole bundle of legal rights[510] associated with property, including the right to use, to make money from and to transfer it.

The 'exclusivity' associated with property rights (and technology and the market generally) is widely conflated with exclusion – with barriers that prevent access to and use of new knowledge. The extent to which exclusion occurs and is problematic however depends upon the *exercise* of the right to exclude, and *which* of the other rights in the 'bundle of property rights' are enforced. For open science and the growth of knowledge, what is objectionable is the enforcement of the exclusive right to *use* property rather than the right to make money from it or (as I argue later) to transfer it. The difficulty is not with the fact that industrial technology generates 'economic rents' or private profits from products through the market: recall that in science there is a pricetag on all results of scientific research made 'public' through subscription-based journals. What is problematic is the control that is exercised over the *use* of knowledge or resources – the *exclusion of* others from the use of knowledge in order to create the conditions of secrecy that are necessary to *generate* the products and profits.

The importance of this distinction for facilitative governance is that the 'exclusivity' of private property – like the non-excludability of public goods – involves elements of choice. The right to enforce implies a right not to enforce, enabling holders to relinquish their rights if they so choose. Combined with the divisibility of property rights, this means that holders can choose which of their rights, if any, they enforce and upon what terms. Holders might prevent activity in relation to resources, but they might also use their property rights as a conveyance by which to transfer rights in technologies to a wide range of users. Control over how, and to whom, and on what terms of access the technology is disseminated remains with the holder of private property rights. This level of control is the key to strategies for facilitation of access to resources within the private sector, the implications of which become

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[510] Honore AM (1961) 'Ownership' in Guest AG (ed) *Oxford Essays in Jurisprudence* Oxford University Press, Oxford; also Grey TC (1980) 'The Disintegration of Property' in Pennock JR & Chipman JW (eds) *Nomos XXII: Property*, New York University Press, New York, 69; and Merrill T and Smith H (2001) 'What Happened to Property in Law and Economics' 111 *Yale University Law Journal*, 257.

apparent in Chapter 7.

Functions

The function of exclusion in industrial technology is to create the conditions of secrecy that are conducive to industrial 'innovation', involving the generation of products and profits. The production of private commercial products, as opposed to public goods, requires economic 'excludability' which, as I discussed in Chapter 2, is based on the premise that if none can be prevented from access, all potential users will have free use of the goods and there will be no rational basis for anyone to pay for them. In the absence of any barriers to third party use, or price attached to access, the ability of the producer to profit from his investment in the process is severely limited.[511] Without such control there can be no collection of revenues, and transactions can be economically efficient only if the goods are virtually costless to produce,[512] if the lost revenue is compensated for within a wider business strategy, or if the goods are *supported* as public goods through non-market sources of funding.

Economic excludability is achieved by either trade secrecy, technical means (physical security) or legal property rights, depending on the intrinsic nature of the goods in question. *Tangible* goods are excludable by secrecy and by technical means, as well as by enforcement of property law. Intangible *intellectual* resources including new technical knowledge cannot be excluded by physical means, for 'the knowledge which one man has may also be the possession of another' and is undiminished through being shared.[513] Knowledge is excludable only by secrecy or by intellectual property rights. For purposes of the production of medical therapies, and my thesis, it is patent rights that are significant and at issue, rather than copyright or database rights, which may also apply to publications or collections of data.

Exclusion in industrial technology has intellectual and economic as well as

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511 Nelson RR (2003) The Advancement of Technology, 1701.
512 Winickoff DE, Saha K and Graff GD (2009) 'Opening Stem Cell Research and Development: A Policy Proposal for the Management of Data, Intellectual Property and Ethics', IX:1 *Yale Journal of Health Policy, Law and Ethics* 52, 55.
513 Forman P (1997) 'Recent Science: Late-modern and Postmodern' in Mirowski P and Sent E-M (eds), *Science Bought and Sold* (2002) University of Chicago Press, Chicago and London 109, 122.

organisational functions. In its intellectual capacity, exclusion through secrecy and private property rights creates in the industrial firm an exclusive forum for the intensification of innovation, protected from revelation or unauthorised exploitation during the 'gestation' of new technical knowledge and products. Secrecy is necessary to prevent competitors from taking and exploiting technical knowledge before property rights have attached to it, but exclusion prior to release into the public domain of *commerce* also prevents accessibility of knowledge in the public domain of *knowledge*. Firms seek to exclude competition, and would not be adverse to third party uses apart from commercial exploitation, if it were possible to achieve one without the other. The legal device of the patent is an attempt to facilitate this: it has the dual intellectual and economic function of expediting disclosure of new technology into the public domain of knowledge, while preventing its unauthorised exploitation by potential competitors. This extends the ability of the firm to exclude commercial competitors from its technology after the knowledge has been released into the public domain, and thus in addition to enhancing innovation acts as an economic incentive for private investment in research and development.

It is generally said that full technical disclosure is given as a *quid pro quo* for a limited monopoly over commercial exploitation, but the converse is equally correct: a monopoly is given to the firm for a defined period to protect it from the potentially adverse effect that full public disclosure of the technology would otherwise have on its competitiveness in the commercial domain. Either way, the traditional goal of intellectual property is to strike a balance between commercial profitability and public interest concerns.[514] The multiple 'problems' of patents associated with patent practices and the administration of patent systems do not change this objective. As I discuss in the next chapter, the abolition of the patent system would not necessarily enhance innovation through the removal of barriers to technology; it would encourage secrecy within firms for a much longer period, until tangible products protected by ordinary 'personal property' rights are capable of release onto the market.

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[514] Maskus KE and Reichman JH (2004) 'The Globalization of Private Knowledge Goods and the Privatization of Global Public Goods' 7:2 *Journal of International Economic Law* 279, 283.

The functions of exclusion in industrial technology suggest a surprising parallel with the system of open science. The establishment of the firm, and the containment of activity within it, serves a purpose comparable to the creation of public institutions for the advancement of science. Whereas open science, through establishment of public institutes, excludes market forces in order to promote rapid production of knowledge, so industrial technology, through establishment of private firms, excludes potential competitors in order to intensify production of technical products. In each system, exclusion protects its activities from disruption or domination by external actors in the market, while facilitating a constructive competition within its own parameters. Science publishes the outcomes of this process in the 'public domain' of knowledge, while technology releases its products onto the open market, in the public domain of commerce. Each uses exclusion to create a crucible of innovative activity, from which it releases its results into the public domain in order to facilitate their exchange and use. Further, both science and technology are, in principle, maintained by a commitment to a set of values, which as I discuss in the next chapter is beginning to show signs of strain. The two systems differ in the conditions that facilitate their innovative activities, in the vehicles (of publication and property) by which they disseminate their outcomes in the public domain, and in the process of 'innovation' that they undertake. In the following section, I examine the process of innovation and exploitation in the activities of the industrial firm.

5.6 'Innovation'

'Technological innovation' is the production of new knowledge or the combination of existing knowledge in new ways – and of transforming this into economically significant products and processes.[515] Industrial analysts are largely concerned with industrial products and processes and the economic outcomes and effects of innovation, rather than the nature of creative event – the intellectual innovation - from which they spring. The term 'innovation' may refer to every aspect of the generation of new products, particularly those products with economic

[515] Edquist C (1999) *Innovation Policy – A Systemic Approach*, incomplete draft of 9 May 1999, Department of Technology and Social Change, Linkoping University, Linkoping, Sweden.

significance:[516] it is often used to mean specific technical inventions[517] (the new method or product itself)[518] and might encompass all aspects of the industrial process that turns an idea into an object,[519] including new commodities, forms of organisation, and the opening of new markets.[520] In the policy context, the concept of technological innovation is generally confined to the definition of 'TPP Innovations' provided by the OECD:

'Technological Product and Process (TPP) Innovations comprise implemented technologically new products and processes and significant technological improvements in products and processes. A TPP innovation has been implemented if it has been introduced on the market (product innovation) or used within a production process (process innovation).'[521]

Attempts to construct 'innovation policy' are usually seeking economic frameworks or business models for stimulating industry, which have been juxtaposed against mechanisms that will foster technical innovation 'as a platform for social improvement'.[522] From the perspective of the facilitation of technology and the production of public goods, however, there can be little distinction between the two. The stimulation of industrial innovation in fields such as regenerative medicine is the very goal of facilitation that seeks to promote the activity of actors who are capable of private production of public goods, or some part thereof. Framing 'innovation' as a business prospect or industrial process does not alter its nature as an essentially intellectual or cognitive creation that cuts across the public and private divide: the generation of new technical or useful knowledge. In the next chapter, I adopt the

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[516] *Ibid.*
[517] Carlson RH (2010) *Biology is Technology: The Promise, Peril and New Business of Engineering Life,* Harvard University Press, Cambridge and London, 131.
[518] Nelson RR and Rosenberg (1993) 'Technical Innovation and National Systems', in Nelson RR (ed) (1993) *National Systems of Innovation: A Comparative Study*, Oxford University Press, Oxford, 4-5. 'Technical innovation' includes process as well as product innovations.
[519] Carlson RH (2010) Biology is Technology, 131.
[520] Schumpeter (1939) *Business Cycles: A Historical, Theoretical and Statistical Analysis of the Capitalist Process*, McGraw Hill, New York, 87.
[521] OECD (1997) *Proposed Guidelines for Collecting and Interpreting Technological Innovation Data* - Oslo Manual, OECD, Paris, s. 15.
[522] Holbrook AJ (2009) 'Are Intellectual Property Rights Quanta of Innovation?', in Castle D (ed), *The Role of Intellectual Property Rights in Biotechnology Innovation* Edward Elgar, Cheltenham UK, Northampton MA, USA, 24.

conception of innovation described as interactive process that does not happen in isolation,[523] which 'combines factors in a new way', resulting in 'new combinations'[524] or fruitful 'conjunctions'.[525] The failure to articulate the conceptual distinction between the creative events and the industrial processes that generate new technical products is a source of potential confusion in the academic literatures, and could be problematic for policy attempts to facilitate 'innovation'. From the perspective of the industrial firm however, it is a distinction without practical importance.

Innovation plus

'Technological innovation' in the literature of industrial innovation is the combination of innovation and exploitation, which I touched on in relation to exclusivity. The question here is not simply how firms pursue innovation, but how innovation can occur at all, in the apparent absence of disclosure, which in the narrative of science plays such an emphatic role in the advancement of knowledge. It has long been known that free markets, although arguably the best available mechanism for solving complex coordination and resource allocation problems, do not efficiently produce information or knowledge-based resources essential to research and development;[526] these are essentially public goods that are better suited to the public domain, where access helps to minimise transaction costs and attendant uncertainties.[527] How then can innovation flourish within the industrial firm?

Models derived from studies of industrial innovation provide a number of possible answers. First, in industrial technology, the disruptive process of 'innovation' is inseparable from the stabilising process of 'exploitation'. It is precisely this complex of innovation and exploitation that the industrial literature refers to as 'innovation',

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[523] Woolthuis RK, Lankhuizen M, Gilsing V (2005) 'A system failure framework for innovation policy design', 25 *Technovation* 609, 609.
[524] Schumpeter (1939) *Business Cycles*, 87-88; Lundvall BA (ed) (1992), *National Systems of Innovation: Towards a Theory of Innovation and Interactive Learning*, Pinter, London, 8; Elam M (1992) *National systems of innovation in social and political theory.* Paper presented at the EASST/4S Conference, Gothenburg, Sweden, 12-15 August, 3.
[525] David P (2003) SIEPR, 4.
[526] Winickoff DE, Saha K and Graff GD (2009) 'Opening Stem Cell Research, 94.
[527] *Ibid.*

and the synthesis of the two that makes the character of the enterprise different than the open science endeavour that results in the 'invention of knowledge'. Successful firms are able to *synthesise* technical innovation and commercial exploitation, bridging their differences, and utilising their strengths. I address these models later.

Secondly, the process involves a set of complex dynamics between the firm, the technology or 'innovation', and the public domains of knowledge and commerce. These interactions constitute networks of communication and exchange with suppliers, consumers, competitors and public bodies that not only facilitate commercial transactions but provide a means of obtaining external knowledge inputs into the innovation process. Studies tracing knowledge flows in industrial firms have shown that inputs are obtained from external sources, public and private, as well as the internal contributions of those employed to engage in targeted research within the internally 'open' parameters of the firm. In the next chapter I argue that these networks for transfer of knowledge are the facility for opening access to resources in the private sector.

Thirdly, firms are able to innovate in the absence of publication, because they are *pragmatic,* rather than principled. It is not the objective of the firm to 'maximise innovation' for the sake of posterity, but to stimulate *sufficient* innovation to support efficient production of *enough* intellectual property to generate products with practical and social utility. Within the dynamics of the market, firms selectively exploit the outcomes of research by funnelling their resources into specific development pathways. The interest of the firm is in optimal and efficient production, which is not dependent upon *unlimited* access to knowledge, or the practice of public *disclosure* of its own resources for use by others. The *maximisation* of technological advance, for the delivery of goods and services culminating in the social benefits of complex global public goods, is an overarching *policy vision* rather than the private goal.

Research

Methods

The industrial pursuit of technological innovation, like science, is housed in research, but the methods and inputs used in technical research are coloured by the pragmatic and utilitarian orientation of technology that is uncharacteristic of pure science. Technological innovation has been described as a 'competitive exploration of multiple paths',[528] a phrase that captures something of the common assumption that technological research uses empirical methods, as opposed to the theoretical methods employed by science.[529] In response to contestation of this idea, scholars have demonstrated that while no clear distinction can be substantiated, there is nevertheless a correlation to support such an assumption. It has been shown that although there is little to distinguish the *types* of methods employed by science and technology, and that they each use a *variety of* theoretical tools and empirical methods of observation, the *proportion* of theoretical to empirical methods used in research varies along a science-technology spectrum. At the science end are the pure mathematical tools, and mathematically structured theoretical knowledge about the physical world.[530] Such theories originate in science and attract scientific interest for their explanatory powers, but need to be reformulated to apply to technological problems.[531] Toward the technology end of the spectrum, theory is based on scientific principles but is motivated by and limited to a technologically relevant phenomenon or specific device.[532] Technical interest depends upon the utility of the artefact to which it relates. At the far end of the spectrum, technology can apply 'phenomenological theory', based primarily on *ad hoc* assumptions from trial and error practice, and only marginally on scientific principles. The explanatory power of such theory is limited, although its practical utility is high.

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[528] Nelson RR (2003) The advance of technology, 1695.
[529] Faulkner W (1994) 'Conceptualizing Knowledge, 433.
[530] *Ibid.*
[531] *Ibid.*
[532] Vincenti W (1991) *What engineers know and how they know it: Analytical studies from aeronautical history,* John Hopkins University Press, Baltimore, 254, 214.

Knowledge Inputs

The pragmatism of technology is also reflected in the sources and patterns of appropriation of knowledge by which industrial firms obtain inputs to inform the research process. Inputs may be obtained directly from employees, or the conduct of research *within* the firm, or from public and commercial sources *external* to the firm.

Two major studies,[533] conducted twenty years apart, showed that external sources accounted for only about one third of the total knowledge used by firms in the course of their operations. The studies analysed the total knowledge requirements of industrial firms as the appropriate basis for assessing the contribution of public sector research to technological innovation. The first (Gibbons) looked at thirty award-winning *products*, analysing the content and sources of scientific and technological information used by R&D staff in the course of their development. The second (Faulkner) studied three *fields* of technology (including biotechnology) to identify the main institutional source of original ideas for product innovation: it investigated knowledge flows, or scientific and technological inputs associated with the links between public sector research and industry, through interviews with R&D staff in 23 firms. The results provide a detailed picture of the full range of knowledge types utilised, and confirm earlier research showing that the dominant contribution to knowledge used in technical innovation comes from internal sources.

The Gibbons and Faulkner studies conclude that, averaging across industries, about *two thirds* of knowledge used by companies in the course of innovation derives from their own in-house R&D and expertise, while the remaining *one third* comes from external sources. The internal knowledge contributed by in-house entrepreneurs and researchers was associated primarily with developmental research and design rather than basic or pioneering research, which came primarily from external public sources. Gibbons found that internal inputs made particularly high contributions to design, test procedures and techniques, and contributed substantially to the properties

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[533] Gibbons M and Johnston R (1974) 'The roles of science in technological innovation' 3:3 *Research Policy*, 220-42; Faulkner W, Senker J and Velho L (1994) *Knowledge frontiers: Industrial innovation and public sector research in biotechnology, engineering ceramics and parallel computing*, Clarendon Press, Oxford.

of materials and components. Similarly, the Faulkner study showed that internal sources dominated routine problem-solving, technical backup, and contributed substantially to skills in experimentation and testing.

A crude interpretation of the studies says that firms rely upon inputs from the public sector for basic or 'pioneering' research, but also that academic and government laboratories contributed only a small part of external knowledge inputs. The largest external source was found to be other industrial companies, especially users or suppliers, but inputs were also obtained from competitors. 'Public sector research' accounted for only 5-20 percent (depending on the industry) of *external* inputs or roughly 1.5–6 percent of the *total* knowledge inputs into technical industrial operations.

In another study[534] it was demonstrated that *local and tacit knowledge*, despite some importance in the conduct of scientific experiments,[535] has a far greater significance in technological innovation than it does in science. Industrial researchers reported almost unanimously that tacit skills, acquired largely on the job (but also obtained from other companies and from public sector research) make a greater overall contribution to innovation than does formal knowledge acquired from literature and education[536] and others suggest that 'practical intuition' is frequently more important than calculation and analysis.[537] The development of technology has thus been described as still involving 'activities better described by the metaphor of art than of science'. The heavy reliance upon tacit knowledge has been explained by the fact that replication of reported technical experiments is not the common practice[538] that it is in science, and that systems for validation of technological outcomes are limited. This could be interpreted to mean either that tacit knowledge fulfils a positive and necessary function of validation by providing informal checks and balances, or that it

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534 Faulkner W, Senker J and Velho L, (1994), *Knowledge frontiers*.
535 Collins H (1974) 'The TEA set: Tacit knowledge and scientific networks' 4 *Science Studies* 165.
536 Faulkner W, Senker J and Velho L (1994), *Knowledge frontiers,* 438.
537 Sorenson K and Levold N (1992) 'Tacit networks, heterogeneous engineers, and embodied technology' 17:1 *Science, Technology & Human Values*, 13-35, 19-22.
538 Sorenson K and Levold N (1992) Tacit networks, 13.

is unfortunate that the use of unmeasurable[539] and potentially unreliable tacit knowledge can go unchallenged in the absence of verification by peer review. Either way, it is indicative of the different orientations of open science and industrial innovation that protection against potentially disastrous social and economic consequences[540] in the event of failure of a technical product or process is provided not by peer review of new technical knowledge, but by external legal frameworks that govern the quality and safety of goods destined for commercial uptake and public consumption.

Finally, *patent disclosure* is, in principle, an important public source of up to date technical knowledge, available for use in ongoing research without licence, in the absence of commercial exploitation. As a criterion for grant of patent, disclosure makes technology accessible for use in ongoing research and development, while the patentee enjoys exclusive rights to control how the product is *exploited* for a twenty year period. A patent application must describe the invention in terms that are clear and complete enough for it to be performed by a person skilled in the art, so that instead of waiting for a product to come to market and then having to use reverse-engineering techniques in order to understand, copy, use and modify the embedded technical innovation, researchers and would-be competitors are able to obtain an 'enabling disclosure' by reference to public patent documentation. Patent disclosure as knowledge transfer - placing knowledge in the public domain for further research and development - is considered a *quid pro quo* for the private monopoly of patent, which would otherwise prevent R&D as well as unauthorised commercial exploitation. Disclosure as a system of knowledge transfer is therefore particularly important in relation to technologies, such as medicine, in which patenting happens early in the technological process. Barriers to accessibility of the information will block further use of the patented technology, except by the owner, until the twenty year monopoly of the patent expires.

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[539] Castle D, 'Introduction', in Castle D (ed) (2009), *The Role of Intellectual Property Rights in Biotechnology Innovation*, Edward Elgar, Cheltenham UK, Northampton USA, 20.
[540] Faulkner W (1994) Conceptualizing Knowledge, 433.

Beehive

This examination of methods and sources of knowledge used by firms is neither comprehensive nor current in regard to any one sector or field, but it helps nevertheless to create a conceptual image of the firm as a beehive of activity. The firm constitutes an enclosed 'open space' within which confidential information can be exchanged and knowledge generated without relinquishment of control, but which remains connected to the external environment by various networks for communication and transfer of knowledge. Studies have shown that the capacity for innovation is not a matter of the size of the firm but of incentives, and the stage of development of the technology. It is not the largest corporations, but the new entrants to an industry, firms with no established stake in a product market segment, that are most likely to produce radical process or product innovation.[541] Larger firms were likely to provide fewer incentives for their people to introduce radical developments - the type of major innovations that generate new industries around an emerging technology - than were smaller firms with a more organic structure. Neither large absolute size nor market power was therefore a necessary condition for successful competitive development. The large firm was however shown to have an advantage over smaller entrants in the subsequently expanding industry, when R&D has widened the technological frontiers, research has become specialised and sophisticated, and specific components of the technology are identified for individual investigation and incremental improvement. During the transition from radical to incremental innovation, smaller firms may consolidate and fight for market share, or the industry may become dominated by an oligopoly of large firms.

Exploitation

The process of 'innovation' in industrial technology, as I have already said, involves the simultaneous production of new knowledge and its transformation by *exploitation* into products. In both the language of scholars of technology and the activities of industrial firms, the intellectual creation and the product are bound up

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[541] Mueller DC and Tilton JE (1969), 'R&D Cost as a Barrier to Entry' 2 *Canadian Journal of Economics*, 576.

together. The commercial imperative upon firms involved in 'technological innovation' is to produce economic goods. The commercial mandate or motive is separate to the desire for technical solutions that enabled prehistoric cultures to control fire or take up agriculture. The modern commercial setting of technology poses a challenge for the technological firm that was not encountered within simple prehistoric economies: the need to reconcile the conditions required for rapid *innovation* with those of proprietary control necessary for output and *productivity*.[542] The tension between innovation and exploitation is felt even within the parameters of the firm, and not only in relation to the distinction between the systems of public science and private technology.

Definitions of the term 'exploitation' connect utilisation with the realisation of a benefit. In common usage, exploitation means 'the action of making use of, and benefiting from, resources'.[543] Legal sources define it as 'making use of' or 'utilisation by application of industry, argument, or other means of turning to account'.[544] To 'turn to account' means to obtain an advantage or profit.[545] 'Benefit' similarly refers to an advantage, profit, privilege, gain or interest.[546] The negative definition of exploitation, which is the taking of an *unjust* or *unfair* advantage of another for personal benefit, or a 'use' that derides or depletes resources, provides little assistance here for understanding the technical function of exploitation.

In product development, 'exploitation' is as much about the process of infusing technical knowledge with economic *value* as it is about the commercial or financial benefits that are possible as a result. Exploitation is not simply commercial *usery* of goods to produce a financial gain: it is the creation of economic value in those goods, which makes them *capable* of generating the financial gain. Exploitation is a

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[542] Utterback JM (1994) *Mastering the Dynamics of Innovation,* Harvard Business School Press, Boston USA, 80.

[543] Oxford Dictionares On-line, Oxford University Press 2012, available at: http://oxforddictionaries.com/definition/exploitation?q=exploitation, accessed 9 May 2012.

[544] Nolan JR and Connolly MJ (1979) *Black's Law Dictionary*, Fifth Edition, West Publishing Co, St Paul Minn, 519.

[545] Avis WS, Drysdale PD, Gregg RJ, Scargill MH (1973) *The Senior Dictionary*: Dictionary of Canadian English, Gage Educational Publishing Limited, Toronto, 9.

[546] Nolan JR and Connolly MJ (1979) *Black's Law Dictionary*, 143.

utilisation that produces something of greater *value*, even if it consumes a less valuable thing in the process. Scientists 'exploit' existing knowledge in order to develop new ideas, theories and information. Regenerative medicine 'exploits' the natural attributes of stem cells to combat debilitating diseases. In the production of economic goods, 'exploitation' of less valuable materials is undertaken in order to produce more valuable products.

In technology, the advantage or benefit of exploitation of goods is an *economic* gain, whether they realise a financial profit or are delivered on a non-profit basis. The achievement of technical innovation is *utility,* and utility is the usefulness or the *practical value* of a thing. 'Relative practical value' is an economic concept related to production, in which a more valuable product is produced from less valuable materials. Practical value has *economic* value, which is increased by exploitation. The *value of science*, by contrast, is measured by scientific standards, according to the contribution it makes to the deepening of our understanding of nature, rather than by economic criteria. Some scientific outcomes have, in addition, an identifiable practical value that can be exploited by technology, but this does not obviate their innate intellectual value.

In a context of *commercial* exploitation, practical value is determined by consumer demand, and economic advantage is measured in terms of financial *profit*. An industrial process will form part of a commercial technology only if the product it produces is profitable. A factory is a 'centre of production' if it puts out products that are more valuable than the resources used up, and normally this will mean that the proceeds of the sale of the goods will exceed what was paid for the resources that went into them. In *non-profit* situations, an economic gain is identified by a non-financial assessment as to whether the *social or public value* of the goods and services outweighs the cost of the materials used in their production.

In either case, because exploitation is a *relative* economic concept, the value of technology, unlike science, is always vulnerable to economic considerations and conditions. The utility of a technology can be wiped out by changes in the relative values of the resources used and the products produced. If the cost of materials,

wages or other inputs increases dramatically in comparison to the price of the product, the technology could be rendered useless; a hundredfold increase in fuel prices would, for example, make all sorts of engines and vehicles redundant. A technical process is therefore valid, strictly speaking, on the basis of valuations at any given moment, and wider application requires flexible management.[547] Industrial technology projects therefore require skilful assessment of the value relations involved, including an appreciation of the value of resources and urgency of demands as against the alternatives.[548] There is also a danger that the value of industrial processes might be lost if they are transferred from developed countries to developing economies without being appropriately adapted to local conditions. The value of science on the other hand is not affected by economic circumstances such as changes in the cost of materials or the wages of researchers. If salt becomes as expensive as gold, or the price of gold becomes as cheap as salt, it may affect the feasibility of and interest in studying them, but it will not alter the known chemical or physical properties of salt or gold.[549]

Models

Scholars attempting to explain the behaviour of firms that achieves the synthesis of innovation and exploitation envision a set of complex relationships, governed by market dynamics and strategic choices. *Innovation* is chaotic and unpredictable and therefore a source of uncertainty, while exploitation involves *stabilisation* of products as a basis for commercial competition and sustainable business administration. The uncertainties of innovation create a dilemma for decision-makers in both policy and business. *Policymakers* are charged with making sense of and managing equivocal new technologies, which are 'obscure or esoteric, incompletely transparent even to their designers and thus subject to misunderstandings, uncertain, complex and recondite'.[550] The *business* response to persistent uncertainty is to try stabilise the technology by standardising design,

[547] Polanyi M (1962) The Republic of Science, 465.
[548] *Ibid.*
[549] *Ibid.*
[550] Weick (2001) 'Technology as Equivoque: Sensemaking in New Technologies', in *Making Sense of Organizations*, Blackwell, Oxford 148, 148.

production, practices and use, calculating risk and efficiency, and instigating a process of deepened learning that generates understanding and permits control of practice and process.[551]

Stabilisation of products involves the *consolidation* of technical advances leading to reliability, characterised by few 'stochastic events'[552] or 'surprises',[553] which recede as learning develops. Products stabilise as production and use iterations are accumulated, and the technology is refined and improved as individuals and organisations draw patterns from random events and look for understandings that will avert or resolve technical problems. The reduction in the uncertainty of innovation coincides with *clarification* in the articulation of performance criteria for products or processes as a basis of competition. The conundrum is that excessive stabilisation can threaten innovation and development by collapsing them into operations and commodification; technology becomes vulnerable to stagnation and to being superseded by competitors who continue to seek technological innovation despite ongoing uncertainty. The aim is the *optimisation* of innovation and productivity through selective development of goods in accordance with principles of economic efficiency.

Precisely how all factors come together to generate commercially viable outcomes is not well understood, despite extensive study and economic and policy debate since the 1960s regarding the nature of technological change. Efforts to explain it have come from a variety of disciplines, including economics, business management, sociology, geography and political science.[554] Attempts to depict the process have enabled scholars to appreciate just how complex the subject is, and to understand a number of characteristics of the process, but 'the complete phenomenon is still covered under a veil of mystery, intuition and intelligent decisions in situations of risk, uncertainty and lack of information'.[555] Taxonomies of the generations of

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[551] Scranton P (2006) Technology, Science and American Innovation, 48:3 *Business History*, 29.
[552] *Ibid,* 26.
[553] *Ibid.*
[554] Marinova D and Phillimore J (2003) 'Models of Innovation', in Shavinina LV (ed), *The International Handbook on Innovation*, Elsevier Science Ltd, Oxford, 44.
[555] *Ibid.*

models include, in increasing levels of complexity: the black box model, linear and interactive models, as well as systems innovation theory and network models. All models are of course simplifications of reality,[556] but they can nevertheless provide insights into the conditions conducive to innovation, from an industrial perspective.

Black Box Model

The *'black box'* model of the 1950s held that innovation was a transformation that occurred within an inscrutable 'black box' of technology, emphasising the importance of inputs and outcomes, with little understanding of what happened in between. Economists applied a self-imposed ordinance not to enquire too seriously into what transpired there[557] as long as money invested in research and development produced new technological products. In a post-WW2 climate, with its awareness of political threats to scientific freedom and new technical developments such as radar and nuclear energy, the black box theory of technology sat well alongside the conventional model of autonomous and independent science. The circumstances supported the vision of 'big science': that if given sufficient resources and free reign to define its own methodologies and goals, science would produce not only new understanding, but radical *technologies* as well. The fact that the process by which this happened was unknown was not problematic, because the unexamined 'space' of the black box was construed as a protective cover under which *science* could flourish.[558]

Although the idea of 'big science' was to bolster government funding for *science*, its technical focus was of interest to private firms, who soon established large corporate research laboratories and became internationally renowned for innovation, even though their internal workings were not fully understood by their management. Science was conflated with technical research as a primary means of technological innovation, and a conceptual shift occurred from 'science and technology' to 'research and development'.

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[556] *Ibid.*
[557] Rosenberg N (1982) *Inside the Black Box,* Cambridge University Press, Cambridge.
[558] Marinova D and Phillimore J (2003) Models of Innovation, 44.

The black box model however had its limitations. The reluctance of economists and researchers to examine the links between science, technology and industrial development within the black box[559] discouraged public policy support for *technical* innovation.[560] It was also problematic that the emphasis was on the 'research and development' component of the technical process, to the exclusion of important non-R&D processes such as marketing and manufacturing.[561] Eventually researchers sought a greater understanding of firms,[562] in which incentives, contracts and firm-specific resources are seen as crucial to the processes and learning involved in technological change.

Linear Models

Initially, simple *linear* models were developed to understand the technological process and were expected to facilitate the formulation of policies that would stimulate research and development and result in new products and processes. The *'technology push'* model came about during the rapid economic growth that permitted industrial expansion in the Western world and in Japan between 1950 and the mid-1960s. It views technology as a sequential process, with an emphasis on research and development as supply, and the market as receptacle of the results of R&D activity. Companies adopted the 'more R&D in, more new products out' approach. Commentators[563] propose various steps, but agree that the process is driven by novelty:

basic science > design and engineering > manufacturing > marketing > sales

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[559] *Ibid.* See also David PA (1998) Common Agency Contracting, 6 in which he suggests that economists and economic historians have been preoccupied with resource allocation mechanisms in the interior of the 'black box of technology' to the detriment of the 'black box of science' as a relatively under-studied component of modern research and innovation systems.
[560] Marinova D and Phillimore J (2003) Models of Innovation, 44.
[561] *Ibid.*
[562] Foss NJ (ed) (1997) *Resources Firms and Strategies: A Reader in the Resource-Based Perspective*, Oxford University Press, Oxford and New York, 5; Williamson OE (2002) The theory of the firm as governance structure.
[563] Beije PR (1998) *Technological Change in the Modern Economy,* Edward Elgar Publishing, Cheltenham UK, Northampton MA, USA; Feldman MP (1994) *The Geography of Innovation,* Kluwer Academic Publishers, Norwell MA USA, Dordrecht The Netherlands.

As in the black box model, there is no real differentiation between technical R&D and basic science, described in the earlier 1945 Bush Report[564] as the 'unexplored hinterland'. Both were considered to hold the key to economic prosperity, with potential to overcome the ills of society. R&D was seen as a corporate overhead, and as ivory tower work to be isolated from the rest of the company. This meant that R&D did not incorporate market information until late in the process, with the result that applications intended for commercial use were often technical inventions not properly adapted to the market.

The *'market pull' model* was the result of intensifying competition in the mid 1960s to 1970, during which companies were induced to shift their focus from new product development and related technological change to the needs of the market. It also views the technological process as simple, linear and sequential, but emphasises the role of the market as consumer demand, to which R&D responds. It sees the sequence of steps as:

market need > technological development > manufacturing > sales

Stronger integration of R&D into other operations, by including product engineers in science-led research teams, reduced the timeframe for market development. A disadvantage of this model is its emphasis on optimisation of existing products through incremental improvement, rather than more radical innovation, resulting in a variety of short-term projects.

These simplistic linear illustrations of the technological process and are now largely disregarded because they assume that all technical products develop in the same way in all firms, and fail to observe technical and organisational change and its interaction with the competitive marketplace.[565] They operate very much on the basis of repeated continuous 'innovation' on the assumption that 'we are doing what we do, but better'[566] and fail to take into account that innovation is sometimes

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[564] Bush V (1945) *Science: The Endless Frontier: A Report to the President*, United States Office of Scientific Research and Development.
[565] Utterback JM (1994) Mastering the Dynamics, 79.
[566] Tidd J (2006) A Review of Innovation Models, 6.

unpredictable or discontinuous in nature. Under conditions of technological or market disruption the usual 'good practice' approach that works in 'steady state' conditions may be inadequate or inappropriate to deal with the new challenges.

Interactive Models

More recently, *interactive models* have attempted to capture the complex interactions between science, technology and the market by describing all the aspects and actors in the technological process. These focus on the 'dynamic relationship between innovation, the marketplace and the actors that emerge and compete on the basis of particular products.'[567] The sequential events of earlier models are viewed as stages, each of which interact with the others in a complex network of communication paths, both inter-organisational and intra-organisational, linking together in-house functions and linking the firm to the broader scientific and technological community and to the marketplace.[568]

The instrumental model in this area identifies three phases of industrial innovation: 'fluid', 'transitional' and 'specific'[569] and draws a distinction between *product* innovation and innovation in the *process* by which it is produced. It describes how early participants in new industries, uninhibited by universal technical standards or uniform market expectations, experiment freely with new forms and materials in a flurry of *radical product innovation*. This period of innovation ends with the emergence of a *dominant design* amenable to the market, when consumer preferences regarding form, features and capabilities begin to limit the bases upon which product innovation can be pursued. As the rate of change is reduced and major product innovation drops off, research and development becomes focused on *incremental* changes to the existing features of the product. With this decline there is a new emphasis on the *process* used to produce the product, resulting in more specialised tools, methodologies and machinery, in aid of increased efficiency and volume of production.

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[567] Utterback JM (1994) Mastering the Dynamics, 79.
[568] *Ibid.*
[569] Abernathy W and Clark K (1985) 'Mapping the Winds of Creative Destruction' 14 *Research Policy*, 3-22.

Interactive models demonstrate that 'innovation' is not merely the product at the end of a final stage of activity but occurs throughout in the process, which can be iterative (circular) rather than sequential.[570] Feedbacks and loops allow potential innovators to seek existing inter- and intra-firm knowledge and to carry out or commission additional research to resolve any problems arising from the market design, production and distribution process. Product and process innovation are clearly interconnected. Early innovation resulting in product design seems to shape the course of development of the production process. Later on, the early choices made in relation to process technology may constrain further developments in the product. When both product and process design are highly elaborated, they may become so intertwined and co-dependent that neither can change without deeply influencing the other.[571] This is observed in organisational structure and supplier-buyer relationships as well.

Historical studies of industrial products affirm the interactive model[572] through the observation of *patterns* across industries and sectors in the way that products change and in the organisational structure of the firm.[573] The patterns, which link product innovation, the stage of evolution of the industry and the competitive climate, do not indicate predictability, but identify the relationships that are key to understanding how firms integrate the processes of innovation and exploitation in the industrial manufacture of economic goods.

Systems and Network Models

Whereas the interactive models elaborate the process that occurs in the 'black box', systems and network models inform local and international strategies in regard to the efficient commercial *production* of the outcomes. 'Systems of innovation' (SI) theory since the 1980s has sought to identify the 'determinants' of innovation,

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570 Beije PR (1998) Technological Change.
571 Utterback JM (1994) Mastering the Dynamics, 76.
572 *Ibid*, vii. Although these originally studied assembled products such as typewriters and lightbulbs, a slightly altered version of the model has also been shown to apply to nonassembled homogenous products such as plate glass or petrochemicals.
573 *Ibid*, 79.

defined as: 'all important economic, social, political, organisational, and other factors that influence the development, diffusion, and use of innovations'.[574] Initially the emphasis was on 'national systems' of innovation,[575] and the identification of the main national factors that influence technological innovation in a particular jurisdiction. Strategic corporate choices were known to be strongly affected by the prevailing conditions (political, social and cultural) at home, so understanding these and how other national systems differ from them was considered vital to international activities. Primary determinants were found to include local market demands and national competencies in production and research,[576] especially local public and private investment activities, input prices, natural resources, research facilities, social concerns, sustainable business practices and regulation.

Sectoral and regional variations on the generic systems approach[577] have since emerged in addition to the national one. The sectoral innovation systems (SIS) approach focuses on various technology fields or product areas; the geographical boundaries of regional innovation systems (RIS) are regions within countries or include parts of different countries. These approaches are arguably complementary rather than mutually exclusive of one other[578] and all versions of the SI approach consider processes of innovation to be evolutionary,[579] echoing the notion that technological process requires a *co-evolution*[580] of the body of *practice* manifested in artefacts and techniques, with the body of *understanding* that supports and rationalises it.

The national SI approach supports the management of international strategies through global *networks,* as firms attempt to meet the challenges of scientific frontiers, new global markets and competitors, political uncertainties and regulatory

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[574] Edquist C (ed) (1997) Systems of Innovation, 14.
[575] Freeman A (1987) *Technology and Economic Performance: Lessons from Japan*, Pinter, London; Lundvall BA (ed) (1992) National Systems; Nelson RR (1983) *National Systems of Innovation: A Comparative Analysis*, Oxford University Press, Oxford.
[576] Tidd J (2006) A Review of Innovation Models, 7.
[577] Edquist C (ed) (1997) Systems of Innovation, 11-12.
[578] *Ibid,* 14.
[579] *Ibid*, 5-7.
[580] Nelson RR (2003) The advance of technology.

instability. These models of wider inter-firm networks of exchange, collaboration and competition accord with the interactivity models that explain innovation in terms of complex dynamic relationships, first across firms with cross-functional links, and then through connections outside the firm.[581]

The benefits of global networks may be greater than previously expected: a recent shift in systems theory[582] suggests that they do not simply promote extensive outsourcing of operations, but have 'emergent properties': if management and coordination problems can be overcome, the network as a whole may operate as a system that is greater than the sum of the parts.[583] Large corporations now recognise that collaborative global networks enable them to source a much larger proportion of their ideas from outside the firm,[584] and encourage policy links within the national system. Commentators envision 'open innovation'[585] in which connections are as important as the actual production and ownership of knowledge, as well as 'engineered networks'[586] structured around a specific goal, industry function or geographical location, in order to facilitate adoption of new ideas, new products or processes, or radically different combinations of knowledge.

Across the generations of models of innovation, explanatory factors have changed, and the focus has shifted from the process within the black box to systems for the expansion of innovation through international networks. The interactive and network models affirm that technical innovation requires interactive engagement, and that learning is enhanced when this occurs between, as well as within, organisations.[587] Networking among firms is thus a natural vehicle for enhancement of knowledge transfer in market conditions.

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581 Tidd J (2006) A Review of Innovation Models, 9.
582 *Ibid*, 10.
583 *Ibid*, 10.
584 *Ibid.*
585 Chesborough H (2003) *Open Innovation: the new imperative for creating and profiting from technology,* Harvard Business School Press, Boston Mass USA.
586 Conway S and Steward F (2006) *Managing Innovation*, Oxford University Press, Oxford.
587 Edquist C (ed) (1997) Systems of Innovation, 20-22.

5.7 Organisation

The dynamics of the innovation process indicate that industrial technology, unlike the community of science, is a two tiered social organisation, comprising the legal person of the corporation and the individuals within it. The firm is the external face of the enterprise, which relates to other actors in the productive competition of the marketplace, within the capitalist ethos. The success of the firm in the external environment is dependent upon its internal organisation, which is adaptable according to the dynamics between its internal technical activities and its external commercial activities. The two tiers of this social structure are shaped by different but interconnected systems of incentive and reward.

The immediate incentives for technological innovation are, at both firm and individual levels, primarily economic. The firm seeks to achieve and sustain profitability in the commercial market, while rewarding its employees in financial terms through salaries and other forms of financial compensation that reflect the extent to which individual efforts have resulted in corporate success.

External

In the external environment of the market, technical firms, like scientists, compete for priority and recognition but, unlike open science, industrial technology measures these things in economic rather than social terms. The means of achievement of economic profit and thus firm sustainability is competition for *technical* priority - the generation of original knowledge embodied in products - *recognition* of which is provided by consumers, as reflected in the revenues of the firm. Competition ensures that the 'winning' products are those best suited to the needs of consumers, and promotes high standards of quality, product diversity, efficiency and adaptability of production. Competition produces not one winner, but a diverse array of winners, spreading productivity and profitability among firms, which ultimately benefits the consumer and society as a whole. The role of competition in the organisation of the market is *not* to promote the sheer amassing of material wealth, any more than open science is aimed at the self-aggrandisement of scientists, despite the fact that each is

susceptible to these sorts of abuses. Competitive rivalry in the market is driven by economic incentives, but it promotes economic productivity by stimulating firms to invest in innovation and change as a means of ensuring their own survival. The notion of the 'invisible hand' that in the theory of laissez-faire economic markets directs the adaptations of firms and their products is not unlike the concept of 'spontaneous coordination' that explains the competitive collaboration of scientists in the production of knowledge.

Internal

The external competitiveness of the firm is dependent upon *individual* activity within the firm. The internal organisation of individuals is also based on economic incentives and recognition, but involves recognition by the firm, which in turn reflects the recognition of consumers and the profits generated by the firm in the market. According to the models of innovation, the internal organisation of the firm is variable, adapting as necessary in accordance with patterns of product innovation and conditions of uncertainty or stability.

In the earliest stages of innovation, conditions of high commercial and technical uncertainty require individuals, or production units within the firm to coordinate and focus their efforts to gather and process information for decision-making. An '*organic*' firm structure characterised by frequent adjustment and redefinition of tasks, limited hierarchy and high lateral communications[588] is appropriate to the task. As the firm moves away from this early stage of intense product innovation, individuals and units in the firm lose their loose organic connections, become more interdependent, and require coordination and control. As a *dominant product design* emerges and production operations expand to meet increased demand, the capacity of the firm to innovate is moderated. Organisational subunits become more interdependent, making it more difficult and costly to incorporate radical innovations. Once a production process and a set of market relationships and expectations become highly developed around a specified and standardised product,

[588] Utterback JM (1994), Mastering the Dynamics, 84.

firm structure becomes more '*mechanistic'*. Goals and rules may be used to provide coordination and control and to establish consistent routines that minimise inefficiency and costs in operations.

Organisations with an organic structure value *entrepreneurial* skills, and the substantial rewards given for radical product innovation may be more valuable than salaries. Realisation of potential rewards depends on the survival and growth of the firm, which in turn depends largely on the ability of the entrepreneur to generate a superior product and to capture a share of an emerging market.[589] As the firm loses its organic character and a dominant design emerges, greater value is placed on those with *management* skills and the original entrepreneur or entrepreneurial group may depart. Traditional rewards in the form of bonuses, stock options, and other managerial extras go to those who facilitate growth by expanding production operations and marketing functions. In a stable technical and market environment, the *mechanistic* organisation rewards those with *administrative* skills for their ability to hold a consistent course, and achieve financial results and predictable incremental performance building on past investments. Ideas that threaten to disrupt the existing stability will be discouraged, and ideas that extend the life of existing products and technology will be encouraged and rewarded.[590]

The dynamics within the organisation of the firm are therefore not unlike the competitive collaboration of scientists: while individuals are motivated by economic prizes and salaries in recognition of technical contributions, skills and service, the overarching imperative is to advance the objectives of the corporation, without which there can be no individual benefits. The parallels between open science and industrial technology suggest that although they utilise different conditions, the two systems are not diametrically opposed, but pull in the same direction. Given the technical complementarity between them, as demonstrated by fields of study in 'Pasteur's quadrant', the grafting of science into the economic and organisational structures of industrial technology, as I discuss in the next chapter, is not a wholly

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589 *Ibid.*
590 *Ibid.*

unnatural development. It does raise questions, however, about the perpetuation of open science as a separate system.

Upstream / downstream

The dynamic nature of the internal structure of the firm, which shifts from organic to mechanistic structures, and entrepreneurial to managerial drivers, is indicative of a distinction in industrial technology between early stage development of a technology or industry, characterised by conditions of uncertainty and rapid innovation, and the later stages in which product development and market conditions have stabilised and ongoing innovation has become incremental. References to these arenas as '*upstream'* and *'downstream*' is shorthand terminology for discussion of policy approaches to conditions, needs and incentives at different stages, even though the technological continuum from one to the other is complex and transitional. Although these differences are evident in the extremes of the earliest research and the delivery of tangible products, it is inaccurate to use the terms to correspond in any precise way to a distinction between 'research and product development', 'pre-patented and patented' products, or 'pre-competitive and competitive' materials. In the industrial innovation literature, research and product development are continual processes, and patents may be obtained on different types of innovation at any point in the technological enterprise. Further, it is apparent that there is no such thing as truly 'pre-competitive' technical research, because research would be of no interest to the technological firm if it had no potential for utility and economic gain.

5.8 Property

'Property'

The unequivocal objective of industrial technology, unlike open science, is to generate goods that constitute 'property': that have 'exchangeable value'[591] and that are capable of possession, use and disposal in every legal way. 'Property' refers to

[591] Nolan JR and Connolly MJ (1979) *Black's Law Dictionary*, 1095.

that which is peculiar or 'proper' to any person,[592] and is thus commonly aligned with ownership: the unrestricted, indefinite and exclusive right to possess, use, or dispose of a thing and to exclude everyone else from interfering with it.[593] In addition to ownership, 'property' commonly denotes everything that is the *subject* of ownership, which extends to the corporeal or incorporeal, tangible or intangible, visible or invisible, real or personal, extending to 'every species of valuable right or interest'.[594]

Technology generates both corporeal and incorporeal *personal property*. Without providing a complete classification, 'personal property' refers to everything subject to ownership that is not immovable 'real' property or land; *corporeal* personal property comprises tangible goods and chattels, while *incorporeal* personal property consists of intangible *rights* such as personal annuities, stocks, shares and intellectual property, including patent rights.[595] Personal property may be 'public property' in that it is owned by a state, nation or municipal corporation, but 'public property' may also refer more widely to things that are considered to be owned by 'the public' or the entire state or community and not restricted to the dominion of a private person.[596] In this latter sense, public property corresponds to concepts of 'common property' that is either held by a municipal corporation in trust for the common use of the inhabitants, or jointly owned by more than one person.[597] The literature of science and the 'commons', which I come to in Chapter 7, generally avoid the confusion by referring to the 'commons', 'collective ownership', or 'commonly owned' or 'jointly held' resources, rather than 'public property'.

The topic of property is fundamental to the open market system and to notions of social liberty[598] and political economy that are bound up with capitalism, but I cannot address it here in a comprehensive way. I acknowledge, for example, the

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592 *Ibid.*
593 *Ibid.*
594 *Ibid.*
595 *Ibid*, 1096.
596 *Ibid.*
597 *Ibid,* 1095.
598 McCormack W (2005) 'Lochner, Liberty, Property and Human Rights' 1:1 *NYU Journal of Law & Liberty* 1.

philosophical debate over justifications for the original acquisition of private property rights,[599] but rely on the theory of property in the Lockean tradition that asserts that appropriation of property rights can occur through the exertion of labour upon natural resources.[600] Neither do I examine the subject matter debates regarding the types of living things that should be subject to property rights, even though they raise important issues in regard to 'commodification' of the human body[601] and the patentability of stem cells.[602]

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[599] Narveson J (1999) 'Property Rights: Original Acquisition and Lockean Provisos' 13:3 *Public Affairs Quarterly* 205; Wenar L (1998) 'Original Acquisition of Private Property Rights' 107 *Mind,* 799; Simmons JA (1994) 'Original-Acquisition Justifications of Private Property' 11:2 *Social Philosophy and Policy* 63; Nozick R (1974) *Anarchy, State and Utopia*, Basic Books, New York.

[600] Laslett P (1988) 'Introduction' in Laslett P (ed) *Two Treatises of Government,* Cambridge University Press, Cambridge; Dunn J (1969) *The Political Thought of John Locke,* Cambridge University Press, Cambridge; Macpherson CB (1962) *Political Theory of Possessive Individualism,* Clarendon Press, Oxford.

[601] See for example, Hoppe N (2009) *Bioequity: Property and the Human Body*, Ashgate, London; Spar D and Harrington AM (2009) 'Building a Better Baby Business' 10 *Minnesota Journal of Law, Science and Technology* 41; McGarrigle P (2008) 'Laws of Nature and the Business of Biotechnology' 24 *Santa Clara Computer and High Technology Law Journal* 275; Halewood P (2008) 'On Commodification and Self-Ownership', 20 *Yale Journal of Law and the Humanities*, 131; Hardcastle R (2007) *Law and the Human Body: Property Rights, Ownership and Control*, Hart Publishing, Oxford; Korobkin R (2007) 'No Compensation or Pro-Compensation: Moore v Regents and Default Rules for Human Tissue Donations' 40 *Journal of Health Law* 1; Waldby C (2006) *Embryos, Cell Lines and Oocytes: ESC Research and the Human Tissue Market*, Global Biopolitics Research Group, Working Paper No 10, University of New South Wales; Oberman M (2006) 'When Truth is not Enough: Tissue Donation, Altruism and the Market' 55 *De Paul Law Review* 903; Quigley M (2007) 'Property and the Body: Applying Honore' 33 *Journal of Medical Ethics* 631; Langley LS and Blackston JW (2006) 'Egg, Sperm and a Petri Dish: Unveiling the Underlying Property Issues Surrounding Cryopreserved Embryos' 27 *Journal of Legal Medicine* 167; Berg J (2005) 'Owning Persons: The Application of Property Theory to Embryos and Fetuses' 40 *Wake Forest Law Review* 159; Rose CM (2005) 'Whither Commodification?' in Ertman MM and Williams JC (eds) *Rethinking Commodification: Cases and Reading in Law and Culture*, New York University Press, New York; Radin MJ and Sunder M (2005) 'The Subject and Object of Commodification', in Ertman MM and Williams JC (eds) *Rethinking Commodification*; Wancata A (2004) 'No Value for a Pound of Flesh: Extending Inalienability of the Human Body' 18 *Journal of Law and Health* 199; Carruthers BG and Ariovich L (2004) 'The Sociology of Property Rights' 30 *The Annual Review of Sociology* 23; Block W (2003) 'Toward a Libertarian Theory of Inalienability: A Critique of Rothbard, Barnett, Smith, Kinsella, Gordon and Epstein', 17:2 *Journal of Libertarian Studies* 39; Cohen G (2003) 'The Price of Everything, the Value of Nothing: Reframing the Commodification Debate,' 117 *Harvard Law Review*, 689; Price D (2003) 'From Cosmos and Damian to Van Velzen: The Human Tissue Saga Continues' 11 *Medical Law Review* 1; Harrison C (2002) 'Neither Moore nor the Market: Alternative Models for Compensating Contributors of Human Tissue' 28 *American Journal of Law and Medicine* 77; Mason JK and Laurie GT (2001) 'Consent or Property? Dealing with the Body and its Parts in the Shadow of Bristol and Alder Hey' 21 *The Modern Law Review* 710; Yelpaala K (2000) 'Owning the Secret of Life: Biotechnology and Property Rights Revisited' 32 *McGeorge Law Review* 111; Sandel M (2000) 'What Money Can't Buy: The Moral Limits of Markets' in Peterson GB (ed) 21 *The Tanner Lectures on Human Values*, 89; Heller MA (1999) 'The Boundaries of Private Property' 108:5 *Yale Law Journal*; Brenkert G (1998) 'Self-Ownership, Freedom and Autonomy' 2 *The Journal of Ethics* 27; Thorne ED (1998) 'When Private Parts are Made Public Goods: The Economics of Market Inalienability, 15 *Yale Journal of Regulation* 149; Otsuka M (1998) 'Self-Ownership and Equality: A Lockean Reconciliation' 27:1 *Philosophy and Public Affairs* 65; McClain LC (1995) Inviolability and Privacy: The Castle, the Sanctuary and the Body' 7 *Yale Journal of Law & the Humanities* 195; Gold R (1995) 'Owning Our Bodies: An Examination of Property Law and

So far in this chapter, I have made various references to the functions of property in industry: I have described how property rights act as a means of exclusion of competitors from innovation and new technical knowledge produced by a firm; I have said that patent rights are a legal device that expands the zone of protection for technical innovation in exchange for its full disclosure; and that technical disclosure provides a public source of technical knowledge for inputs into ongoing innovation. In the rest of this section I elaborate very selectively on aspects of patents that are relevant to my thesis, and then consider the function of property rights in knowledge or technology transfer.

The idea that property is something 'owned', which is rooted in the rhetoric of property as exclusive and absolute,[603] encourages the view that property is unitary and static, rather than a divisible and transferable set of rights capable of providing a framework for mobilisation of resources. A preferable starting point is to consider that the law of property is not about the control that an individual has over a thing, but about 'the legally recognised relationships we have with each other in respect of things,[604] which is a broader perspective from which to construct property-based approaches to governance for the delivery of public goods. 'Property' is thus the aggregate of legal rights of individuals with respect to things and the obligations owed to them by others in relation to those things, which are guaranteed and protected by government.

Legal ownership is described as having four main component rights: the right to *use*,

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Biotechnology' 32 *San Diego Law Review* 1167; Christman J (1994) 'Distributive Justice and the Complex Structure of Ownership' 23:3 *Philosophy and Public Affairs* 225; Campbell CS (1992) 'Body, Self and the Property Paradigm' 22:5 *The Hastings Center Report* 34.

602 See for example, Plomer A and Torremans P (eds) (2009) *Embryonic Stem Cell Patents: European Patent Law and Ethics*, Oxford University Press, Oxford; Plomer A, Taymor KS and Scott TC (2008) 'Challenges to Human Embryonic Stem Cell Patents' 2 *Cell Stem Cell* 13; Grossman J (2007) 'Human Embryos, Patents and the Thirteenth Amendment' 55 *University of Kansas Law Review* 731; Spalding TN and Simkin MM (2007) 'How Will Patents Impact the Commercialization of Stem Cell Therapeutics?' 19:1 *Intellectual Property and Technology Law Review* 7; Porter G, Denning C, Plomer A, Sinden J and Torremans P (2006) 'The Patentability of Human Embryonic Stem Cells in Europe' 24:6 *Nature Biotechnology* 653; Plomer A (2006) *Stem Cell Patents: European Patent Law and Ethics Report,* FP6 Life Sciences, Genomics and Biotechnology for Health, SSA LSSB-CT-2004 005251, University of Nottingham; Laurie GT (2004) 'Patenting Stem Cells of Human Origin' 26:2 *European Intellectual Property Review* 59.

603 Williams J (1998) Rhetoric of Property.

604 Clarke A and Kohler P (2005) Property Law, 3.

the right to *earn income* from, the right to *transfer* and the right to *enforce* the other three property rights.[605] Rights of 'ownership' of intellectual property are provided by legislation, which extend the rights to inventions that are products or processes. A product patent grants the holder the right to make, dispose of, offer to dispose of, use, import or keep the product whether for disposal or otherwise.[606] A process patent gives the holder the right to use the process or to offer it for use in the UK.[607] In each case patent protection extends also to the products that flow directly from the use of the product or process.[608] Liability for infringement of a product patent is absolute, whereas liability for infringement of a process depends on whether the defendant user knew (or it would have been obvious to a reasonable person) that the unauthorised use would infringe the patent. This has specific implications for biotechnological inventions, which I discuss in the next chapter.

Patents

The patent system has long been contentious, having grown out of Crown prerogatives to grant privileges to subjects in return for the conduct of corresponding duties. As there were no formal limits on the privileges that could be granted - delivered by 'letters patent' or an 'open letter' from the monarch – monopolies frequently rewarded activities that were already being performed, at considerable detriment to competitors. Criticism led eventually to parliamentary abolition of the royal practice in Britain under the *1624 Statute of Monopolies*, with the exception of grants 'related to a manner of new manufacture.' Knowledge transfer in return for the privilege was first contemplated when the duration of the grant was limited to fourteen years – equivalent to two terms of apprenticeship – in which the patentee was to teach the new art to two sets of apprentices.[609]

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[605] Levasseur AA (2006) The Boundaries of Property.
[606] *UK Patents Act* 1977, s. 60 (1)(a).
[607] *Ibid*, s. 60 (1)(b).
[608] *Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the Protection of Biotechnological Inventions* (1998) OJ L213/13, Articles 8(1) and 9, implemented in the UK *Patents Act* 1977.
[609] Bently L and Sherman B (2004) *Intellectual Property Law*, Second Edition, Oxford University Press, Oxford, 325.

The present patent system in Britain, as elsewhere, is a function of bureaucracy rather than prerogative, the product of 19th century developments in law and administration reinforced by the *1977 Patents Act* and British entry into the European Patent Convention (EPC). Public criticism continues to call for its reform or abolition on the basis of practical or administrative difficulties, as well as ideological arguments against government interference in laissez-fare market economics. The patent does not simply endow new knowledge with the usual property rights - to use and exploit, transfer and enforce - but gives it an *augmented* right to exploit the patented technology by instating a temporary monopoly in favour of the holder. That patents intervene in the market, reducing competition and causing inefficiency, is in itself problematic for some; the potential for them to result in elevated prices and reduced accessibility of goods by consumers is another concern, especially in the context of international development and the delivery of global public goods.[610]

As Incentive

The dominant argument for patent justification since the nineteenth century[611] is based on the idea that the public should only have to endure the harm caused by the grant of a patent if it – the public - is going to receive some corresponding benefit.[612] The modern 'social contract' purports to use patent *incentives* to make certain goods available to society that would not otherwise be produced, given that they are not capable of production solely by public means. The rationale of patent law is that the monopoly encourages private investment in markets characterised by prohibitive cost and risk through the expectation of future compensation in the form of enhanced profits. This incentive to invest in *innovation* that would not otherwise be pursued is

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[610] Abbott FM and Reichman JH (2007) 'The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines Under the Amended TRIPS Provisions' 10:4 *Journal of International Economic Law* 921; Vaver D and Basheer S (2006) 'Popping Patented Pills: Europe and a Decade's Dose of TRIPS' *European Intellectual Property Review*, 202; Kapczynski A, Chaifetz S, Katz Z and Benkler Y (2005) 'Addressing Global Health Inequities: An Open Licensing Approach for University Innovations' 20 *Berkeley Technology Law Journal* 1031; Duffy JF (2002) 'Harmony and Diversity in Global Patent Law' 17 *Berkeley Technology Law Journal* 685; Correa C (2000) *Integrating Public Health Concerns into Patent Legislation in Developing Countries'*, South Centre, Geneva.
[611] Bently L and Sherman B (2004) *Intellectual Property Law*, 327.
[612] *Ibid.*

given in return for disclosure of technical *information* that would not otherwise be produced, or would be withheld from the public domain. The justification for patents is strongest therefore where the production of a technical product makes a clear contribution to an overarching policy goal for the delivery of public goods such as health benefits.

Intellectual property law attempts to strike a balance between commercial profitability and public interest concerns by permitting the monopoly for a limited period, recognising that in the absence of *exclusion* there would be poor incentive for the creation of intellectual property, but also that *permanent* patent rights would lead to the standard deadweight losses of monopoly.[613] Policy support for patents is therefore based on the assumption that the system constitutes a defensible attempt to promote social value as well as economic growth.[614]

As Disclosure

Patents are nevertheless commonly cited as barriers to the public circulation of knowledge, despite the fact that it is a central objective of the patent system to expose technical information that would otherwise be treated as trade secret. Full disclosure of an invention is a condition of patent application, and must be sufficient to enable a person 'skilled in the art' to manufacture the invention.[615] There is only one ground for the sufficiency examination in the UK, regardless of the type of invention in question: the patent specification must enable the invention to be performed. The technical material required to satisfy the test of 'enabling disclosure' will however vary with the type of invention and other circumstances.[616] While a formula might for example be sufficient in one situation to enable an invention to be

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[613] Maskus KE and Reichman JH (2004) Globalization of Private Knowledge Goods, 283.
[614] Guellec D and van Pottelsberghe de la Potterie B (2007) *The Economics of the European Patent System – IP Policy for Innovation and Competition*, Oxford University Press, Oxford; Jaffe AB and Lerner J (2007) *Innovation and its Discontents – How our broken patent system is endangering innovation and progress, and what to do about it*, Third Edition, Princeton University Press, Princeton.
[615] *Biogen v Medeva* (1997) Report of Patent Cases 1, 47 (House of Lords); *Asahi Kasei Kogyo* (1991) Report of Patent Cases 485, 536 (House of Lords); *Pharmacia Corporation v Merck* (2002) Report of Patent Cases 775, 800 (Court of Appeal).
[616] *Mentor v Hollister* (1993) Report of Patent Cases 7, 12; *Mycogen/Modifying Plant Cells* T694/92 (1998) European Patent Office Reports 114, 120.

worked, another case may require disclosure of starting materials or means as well as a formula.

As a result of the disclosure requirement, there are vast public repositories of technical specifications in regard to patents that are pending, in force or lapsed, and thus constitute a significant source of information about current technology and the commercial potential of specific areas of research. The patent holder controls the right to exploit the invention described in a patent, but information set out in the applications is freely available for use as the basis of further research. In terms of 'conventional' industrial technology this means that potential competitors are not prevented from using the information in R&D to generate competing products during the term of the patent, as long as the results are not released onto the market until the foundational patent has expired. In addition to the research use offered by the specifications, there is plenty of opportunity during the term of the patent - typically twenty years, but capable of extension in the event of further innovation – to obtain from the patent holder more extensive rights to use and exploit the patented technology by negotiation of appropriate licensing arrangements.

What is not clear however, is the extent to which these resources are being used. Even though the databases are construed as a major source of *scientific* as well as technical knowledge[617] there is at least anecdotal evidence to suggest that academic scientists do not use them as such: either they have little awareness of, or interest in, patent databases or there are infrastructural difficulties in accessing them.[618] 'Publicly-funded' upstream researchers may for example scrutinise patents merely as a means of avoiding infringement of downstream applications, from which they feel far removed. There may be difficulty in *locating* relevant patents due to technical classification issues, and in accessing them due to the *technical language* in which patents are necessarily drafted. The extent to which patent databases are used as a

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[617] The Royal Society (2012) *Science as an open enterprise: open data for open science*, The Royal Society Science Policy Centre report 02/12, 46.
[618] Hescott A, PhD candidate, Sheffield University, Presentation at SCRIPT Conference, University of Edinburgh, June 2012.

specific source of knowledge by industrial firms is equally obscure, despite the studies that I discussed earlier in relation to industrial research.

What is wrong with this picture, I suggest, is that private researchers cannot rely on the disclosure of patent specifications as a basis for ongoing research, not because the foundational disclosure is inaccessible or insufficient, but because technology advances so quickly that new 'products', which may be tiny links in a web of knowledge, are forged within a fraction of the twenty year timeframe that is the term of the original patent. Further, the scope of a patent extends not only to the original invention – a product or process – but to the 'derivatives' that flow directly from their use. To ensure that they do not infringe a patented technology and new results or derivatives do not sit on the shelf waiting for the original patent to expire, firms are obliged to negotiate licenses that authorise them to use, patent and disseminate new advances incorporating the original patented technology in step with the rapid pace of technological advance. While the option of obtaining a patent licence to use a technology without patenting the results of ensuing research may remain open to academic scientists, it is not generally one that is open to the private firm. Rather the decision for the firm is at what point in the process patenting should be undertaken to ensure that advances do not stagnate but can be disseminated and used by others in the field. The negotiation of patent licenses to access multiple pieces of technology as a basis for ongoing research is, however, expensive in terms of time and money, and may ultimately act as a deterrent to the use of foundational technology by both publicly and privately funded researchers. This 'patent congestion' allegedly creates an 'anticommons' effect: [619] an underuse of technical resources that poses a threat to ongoing innovation.

Problems

It is not surprising therefore that the literature is rife with claims of adverse effects and problems associated with patents, despite the fact that the system is intended to

[619] Heller MA (1998) 'The Tragedy of the Anticommons: Property in the Transition from Marx to Markets', 111 *Harvard Law Review*, 621; Heller MA and Eisenberg RS 'Can Patents Deter Innovation? The Anticommons in Biomedical Research' (1998) 280 *Science* 698.

facilitate disclosure. Merton for example argued that patents result in the 'suppression of invention, contrary to the rationale of scientific production and diffusion'[620] on the basis of a judicial pronouncement that an inventor has discovered something of value in which he has absolute property, and that he is free to withhold it from the knowledge of the public.[621] A significant question is the extent to which patents potentially undermine the development of 'innovation' or technical products that they were designed to facilitate, and the extent to which governance might overcome the barriers that they pose. The potential barriers are many, and include the patent congestion[622] discussed above, the granting of patents of overly broad scope,[623] and the misuse of patents to 'block' exploitation of the technology through failure to work or license it. Patent laws generally include rules that permit compulsory licensing to other users in the event that the patent is not 'worked' by the holder, but such provisons are seldom used.[624] To the extent that the social contract regarding the patent system is defensible, as discussed above, it is the role of law, policy and governance to identify the problems that it raises and to facilitate some means of 'solving' them, or to enable them to be circumvented, to the mutual benefit of the actors in the system.

The more particular question for the design of facilitative governance is whether, in a given situation, patents and the patent system not only can but *do* have an adverse impact on research and, if so, whether the effect is to limit the translation of knowledge into public goods. Understanding of the potential or capacity for patents to create barriers needs to be applied in the context of the particular circumstances of specific technologies, in order to identify with clarity the problems that need to be addressed. It is not clear for example that despite concerns about 'patent thickets' in biotechnological research there is any significant degree of frustration of innovative research in regard to stem cell technology in the UK. The equally relevant but less

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620 Merton RK (1938) Science and the Social Order, 273.
621 *U.S. v American Bell Telephone Co* 167 US 224 (1897), cited by Stern BJ (1938) 'Restraints upon the Utilisation of Inventions' 200 *The Annals* 21.
622 Heller MA and Eisenberg RS (1998) 'Can Patents Deter Innovation?
623 Plomer A, Taymor KS and Scott TC (2008) 'Challenges to Human Embryonic Stem Cell Patents' 2 *Cell Stem Cell* 13 explores, for example. the problems with the WARF patents over the process of derivation of hESCs from embryos.
624 Bently L and Sherman B (2004) Intellectual Property Law, 561.

debated question is whether uptake by pharamaceutical companies may be limited in some way by the emphasis on facilitation of basic academic research. These are questions for the next chapter.

To conclude this section, then, the patent system in principle provides incentives for innovation and the ability to exploit technology while overcoming the potential for exclusion to prevent access to and use of technical information. Intellectual innovation that would otherwise have been held in confidence through a long process of product development and pre-market approvals may be endowed with property at an early stage, thus facilitating its mobility in the complex of rapid technical advance. The patent owner can extend rights to other users, under conditions of licence and for a price, without undermining its commercial operations. The potentially serious problems associated with patents are a subset of wider issues to be addressed through mechanisms of governance for the delivery of public goods.

Knowledge transfer

Gatekeeper

Property rights therefore act as a 'gatekeeper', rather than an absolute barrier to the transfer of privately held technological resources. The implication of the conceptualisation of property as a conglomerate of rights and obligations is that they are severable from one another. It is possible to transact in them individually: to retain some while others are relinquished, thus giving up partial but not all control, either voluntarily or by external authority. Relinquishment of some rights by an 'owner' corresponds to the enhancement of control by others, thus expanding the number of actors that can interact with the property. Further, as intellectual property is essentially non-rival, any number of non-exclusive use licences can be extended to users at the owners discretion.

Legal Structures

Property rights are also governed by legal norms and frameworks that provide structures or vehicles, such as licences and material transfer agreements, for their

transfer or conveyance. These frameworks facilitate the mobility of private technology through interchange between the parties that may involve any number of actors, making contractual construction a potential medium for large collective if not 'public' endeavours, as is demonstrated by some of the strategies that I examine in Chapter 7. The nature of the access is determined by the terms of the agreement, rather than the motives or objectives for entering into the agreement: property is no less 'property' in the law if it is given away or exchanged according to principles that are counterintuitive to usual business practices.

Discipline and Design

The legal frameworks that govern property permit the parties to discipline and design the mode of dissemination of technical resources. The arrangements are shaped by the precise terms of patent licenses and MTAs, which can reflect a wide variety of policies or approaches to access and use. Contracts constitute both access to and *dissemination* of resources, with rights and obligations, involving exchange between the parties. The exchange is accomplished not through general release into the public domain of knowledge, but in the public domain of commerce, in a controlled or modulated fashion, through negotiation of specific arrangements that impose certain limitations on use. The cumulative effect of transactions involving multiple patents in a rapidly developing field is a network of interactivity and engagement with technology. The publication of science is by comparison a less strategic, shotgun approach to maximising the reach of its new knowledge. Given the limitations on publication however it may not be unrealistic to think that the 'texture' of accessibility within the domain of knowledge and the domain of commerce may not be very different.

Private Control

Finally, the bottom line in the domain of private property is that whatever potential there may be for expansive dissemination and use of resources, the holder of property rights maintains control. Any transaction or collective arrangement for the transfer or sharing of privately held resources requires the willing participation of the

proprietor, which is important in relation to the design of governance structures. Participation is dependent upon a sustainable economic model for industry that not only protects the viability of the proprietor but advances its core objectives. A firm will not normally be in a position, even if it were willing, to accede to a sharing of resources that undermines the production of its core product or requires a complete alteration of its objectives. An example in which this happened is in regard to the development of 'open source software', which took off in the 1970s. Delivery of the crucial 'source code' along with a piece of software enabled users to access, copy and manipulate the software and so create new computer solutions to complex problems, but it rendered the software nonexcludable and therefore nonsaleable as a proprietary package. The commercial viability of open source software is therefore dependent upon a different business plan, which focuses on delivery of services to users of the manipulable open source software, rather than sales of proprietary software packages designed to serve fixed functions. What works for computer software may not however work for other technologies, such as stem cell therapeutics, in which the fixed function of the therapy is the primary and non-negotiable objective, and the expense involved in producing even the basic materials of that product is such that production cannot be sustained on the basis of a peripheral business plan in which the core product is not a direct source of revenues.

In Chapter 7, I look at various strategies for unlocking the use of resources at specific junctures in the process of research and development. Some of these address concerns about the privatisation of science in general and others the shortcomings of the patent system. The question for a later chapter is not how successful these arrangements are in defending open science within the marketplace, but the extent to which they are mutually beneficial for both science and for overcoming hurdles to production of stem cells.

5.9 Domain of commerce

Public forum of exchange

Through the chapter I have made reference to the 'public domain of commerce' in

the paradigm of the open market, as opposed to the 'exclusion zone' of the private firm within it. The enterprise of technology, unlike science, does not create out of its products a freely accessible pool of 'common property'. It creates instead a public forum for exchange in which its products remain privately held but are nevertheless available and accessible, subject to negotiation of terms of access with the holder. Science and technology are each innovative systems that result in the release of products into the *public domain,* but technology ensures that strings remain firmly attached. The use of exclusion by the industrial firm is to protect the inchoate product through the extended innovation and exploitation process until it is characterised by economic value and property that renders it capable of the kind of control that is necessary for transmission in the public domain of commerce. Technical knowledge, like science, may be withheld from the public domain or released as determined by the producer, but in neither case is it in the interest of the enterprise of science or the advance of technology to withhold indefinitely.

Accessibility

I have described the network of potential transactions that facilitate the transfer of knowledge within the open commercial market. The question that scientists pose in relation to the private dissemination of knowledge is whether it can make knowledge sufficiently 'accessible', even on the basis of an individual transaction, that it can be *engaged* in ways that promote its use, manipulation and reuse, as opposed to mere consumption. This question implies first that scientists are interested in accessing technical knowledge, and secondly that scientists apply - to the system for production of practical knowledge motivated toward products - the same objectives that they apply to the 'invention' of pure scientific knowledge. The primary consideration, for production of any new knowledge is that there is engagement with the existing resources; but from the point of view of the industrial firm, it is equally necessary that the knowledge that results can be packaged in tangible (or intangible) form and sold to consumers who may not want to do anything but consume it.

What accessibility means in relation to 'technology transfer' in the private sector must therefore be carefully defined. Whether and how accessible is 'accessible' may

depend on the objectives of the potential user. An 'available' resource may be inaccessible if the purchase price or licensing fee poses an insurmountable barrier. It is also inaccessible if the scientist or other researcher cannot engage with it sufficiently to unlock its potential utility, or to understand and adapt it to different purposes. In some cases, the release of a tangible product into the commercial domain without prior patent or technical disclosure will enable a potential user or competitor to 'reverse engineer' the product in order to obtain the intellectual property that enables it to be copied and exploited. It is the knowledge that firms protect by exclusion from competitors and which is key to innovation and production.

Complementarity

Finally, 'exclusion' in technology, like 'openness' in science, has specific functions in the system of production of practical knowledge and goods but in practice is not absolute, as property rights mediate the accessibility of technology in the domain of commerce. The public domain of knowledge and the public domain of commerce are not incompatible polar opposites, but complementary systems moving in the same direction, with a degree of overlap in which they can accommodate each other by accepting limitations and conditions imposed by the other. The purpose of facilitative governance is to promote not two separate systems but an integrated approach to innovation and exploitation across science and technology and the public and private sectors, to promote and utilise the strengths of each for the production of knowledge and the delivery of public goods. My conceptualisation of this integrated approach is set out in the next chapter.

5.10 Conclusions

From this chapter I draw the following conclusions:

1. '*Exclusive' technology is part of an open system.* The main conclusion of this chapter is that the private enterprise of 'industrial technology', which is conventionally construed as 'exclusive', in fact operates within an innovative system characterised by both openness and exclusivity. The industrial firm excludes

competitors from its internal activities, but releases its products into an open market or public domain of commerce. The market is one aspect of the social order of capitalism, which supports the enterprise by infusing it with social values that balance the drive for capital. In contrast to the community of open science, the organisation of technology is two-tiered: the firm is both an organisation of individuals, and the external face of the enterprise in relationship to other actors in the open market.

2. *'Innovation' in technology is a process involving both 'innovation and exploitation'.* In the language of industrial technology 'innovation' encompasses the whole process that generates both new technical knowledge and products; it involves simultaneously the innovation that generates new knowledge and its exploitation, which transforms knowledge into products by infusing it with economic value and endowing the outcomes with property rights. According to industrial models that attempt to explain the process of innovation, the process is a set of complex dynamics between the firm, the technology and the market. Although the process cannot be construed as linear in any way, there is an apparent distinction between the 'upstream' chaotic activity that characterise radical innovation and the 'downstream' stabilisation of products.

3. *Exclusion facilitates innovation.* The 'exclusion' of external competitors from the internal operations of the firm, by secrecy and property rights, serves specific functions in the delivery of products to the open market. First, exclusion protects the inchoate products, during their protracted gestation, from revelation to and exploitation by other actors prior to attachment of patent or other property rights. Secondly, exclusion of competitors contains activity within the firm, creating a private forum that facilitates intensification of innovation and exploitation, with the specific objective of producing economic goods.

The functions of exclusion in industrial firms suggest a surprising parallel with the system of open science. The establishment of the firm, and the exclusion of other actors in the market from its internal activities, serves a function comparable to the creation of public institutions for the advancement of science. The isolation of

science from market forces, through its treatment as a public good, ensconced in public institutes, is undertaken to promote rapid production of knowledge; equally industrial technology, contained within the private firm, excludes market forces in order to intensify production of technical products. Science publishes its outcomes in the 'public domain' of knowledge, while technology releases products onto the open market, in the public domain of commerce. Each uses exclusion to create a crucible of innovative activity, from which it releases its results into the public domain in order to facilitate their exchange and use.

4. 'Exclusive' property rights serve several facilitative functions.

First, property rights render products *excludable* in economic terms, and thus capable of *commercial exchange* without relinquishment of control that might threaten the enterprise of the firm. Secondly, patents expedite the *release of intellectual resources* into both the public domain of knowledge and the open market, making them available for rapid access by others, through public databases or negotiation of licenses. While commonly seen as a barrier to knowledge dissemination, the patent system is in principle at least a defensible attempt to advance both commercial innovation and disclosure of technical knowledge.

Thirdly, property is governed by *legal norms and frameworks* that can facilitate discipline and design in the mode of dissemination of technical resources. This legal infrastructure enables the holder to maintain control over the terms upon which property will be disseminated and accessed in the public domain of commerce, and can provide the vehicle for innovative governance strategies. The publication of science is by comparison a less strategic, shotgun approach to maximising the reach of its new knowledge.

Lastly, property rights facilitate *knowledge transfer* in the public domain of commerce. The 'gatekeeping' function of property rights makes property 'accessible', subject to the negotiation of terms with the holder. The different means of conveyance - the publication of science and the private transaction of technology -

alters the 'texture' of the interactive networks that each system generates, but as neither the openness of science nor the exclusivity of technology is absolute there is room for compatibility between the systems.

5. Open science and industrial technology are complementary rather than incompatible systems.

The paradoxes of openness and exclusivity that I identify in industrial technology shed new light on the conventional dichotomy between the public or communal enterprise of science, and the private or individual enterprise of the market. The first paradox is that from the dynamic and chaotic process of innovation comes stable products endowed with exclusive property rights. The second is that the exclusion of competitors from the innovation process of the firm creates a beehive of innovation for the specific purpose of facilitating release of products into the open domain of commerce. This suggests a further parallel with science, in that the isolation of science by its treatment as a public good is also an exclusion of market forces, which creates a forum for the intensification of innovation for the express purpose of increasing knowledge production.

The result is a construction of two open systems that are not incompatible but have complementary capacities. Each employs exclusion of the market in order to establish a forum in which innovation may be fostered in the pursuit of new knowledge. Science focuses specifically on knowledge, while industrial technology involves more complex dynamics of innovation and exploitation in order to generate, in addition to knowledge, concrete products. Despite the offence caused to science by the reticence of technology to make its results public without the control afforded by property rights, private infrastructures for technology transfer offer a means of negotiating mutually advantageous access to knowledge resources. It is clear that science has not been deterred from alliance with the enterprise of technology, which is the subject of my next chapter.

Chapter 6. SCIENTIFIC TECHNOLOGY

6.1 Introduction

In this chapter I set out my conceptualisation of 'scientific technology', distinguishing it from pure science, proprietary science and industrial technology, as well as theories regarding new paradigms in the nature and practice of science. I conceive of scientific technology as *technology* rather than proprietary science because it pursues practical outcomes within a market economy; I construe it as *scientific* because it is a confluence of scientific understanding and technological utility. I understand 'scientific technology' to result from a *synergistic* relationship of science and technology, in which technology is not simply augmented by strong science, but which is capable of combining the strengths of each to generate something different than either science or technology is able to produce on its own. It is characterised by six primary features: synergy, research, innovation, utilisation of resources, a domain of exchange and an institutional ethos. The equal promotion of these features is central to my conception of governance, and the design of organisational structures capable of their facilitation.

This conception of scientific technology is informed by the results of the previous two chapters, in which I examined the discrete systems of open science and industrial technology that emerged following the revolutions of the 17th and 18th centuries. In this chapter I recognise that the traditionally asserted bifurcation between the norms of science and proprietary technology is increasingly untenable; I look to the natural interconnections inherent in science-based technology, recent changes indicating deeper levels of integration, and trends in patent law, practice and public policy, to determine how openness and exclusivity are manifested within the context of modern 'scientific technology'. Although the effect of many of these changes is to raise concerns among science scholars and academic researchers about the long-term viability of science-based technology, I suggest that despite presenting ongoing challenges (particularly in relation to the patent system), such changes are indicative

of a coherent system of scientific technology with certain identifiably consistent features. This chapter addresses first the natural connections between science and technology, then the significant changes that have been observed, as well as the issues and implications that they give rise to, before I set out the six integrational concepts that characterise 'scientific technology' as I understand it.

There have long been interconnections between science and technology, given their natural complementarity with regard to the pursuit of knowledge. The resulting overlap between 'discovery' and 'invention' has been recognised in patent law, which has sought to balance market-based technological advance with the public disclosure of knowledge for access by the scientific community, as I discussed in the previous chapter.

Changes in recent years, however, indicating greater scientific and technical integration and interdisciplinarity in research, have given rise to concerns about the impact of commercial incentives on the sustainability of openness in science. Influxes of private investment in the field of biomedicine, increased patenting of scientific discoveries, changes in patent law doctrine, government and university policies encouraging patenting of academic work, and more collaboration between academia and the private sector have all given rise to a debate about the commoditisation of knowledge and the privatisation of science. The concern is felt largely by those who share the interests of publicly funded scientists, rather than industrial corporations involved in 'innovation', who continue to engage with resources generated by publicly funded 'scientific' research as well as their own in-house facilities in R&D to create products and processes. The concern is that the impact of commercial incentives for the protection of intellectual property will undermine the traditions of open communication and the free flow of knowledge within the scientific community, and further that encroachments which threaten to close down public science have long term adverse implications for the science-based technology which relies upon it.

The debate over privatisation of science is important in that it examines the process of change that is occurring in modern science and technology, promotes an

understanding of the difficulties that such change gives rise to, and considers various ways of addressing them. The difficulty however is that the debate perpetuates the traditional distinction between public science and private technology, which is no longer an accurate depiction of reality. The way ahead is construed mainly in terms of greater government support for the public system of science, protection and promotion of the role of scientists in directing it, and in devising solutions to the problems that inhibit it - with an emphasis on thorny patent problems such as the effect of broad and multiple patents on ongoing research. The whole debate obscures the fact that the liason of science and technology has already infiltrated public science: that the vast majority of academic and government research funded by the public system of 'science' has since WWII been directed toward practical problems in fields located in 'Pasteur's quadrant'. Greater government support for 'science' thus also supports basic technological research, generates resources that undergird the interests and ongoing innovations of private industrial technology, thus stimulating more private sector patenting that entices public sector researchers to obtain a slice of the commercial pie. Even if governments and universities could be persuaded to turn back the clock to stop public sector patenting of technical processes or products, there is nothing to stop private sector companies from taking information freely available in the public domain and applying to patent it themselves.

My proposition is that adherence to traditional narratives of 'public science' and 'private technology' inhibits the *facilitation* discourse, which seeks to support robust scientific enquiry, but with a clear view to the exploitation of knowledge for its practical outcomes and social benefits. Much of the literature in this area advances the cause of *science*,[625] attempting to promote or reinstate public science, or to create

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[625] Rai AK (1999) 'Regulating Scientific Research: Intellectual Property Rights and the Norms of Science' 94:1 *Northwestern University Law Review* 77; Eisenberg RS (1987) 'Proprietary Rights and the Norms of Science in Biotechnology Research' 97 *Yale Law Journal* 177; Kieff SF (2001) 'Facilitating Scientific Research: Intellectual Property Rights and the Norms of Science - A Response to Rai and Eisenberg' 95:2 *Northwestern University Law Review* 691; David P (2003) *The Economic Logic of 'Open Science' and the Balance between Private Property Rights and the Public Domain in Scientific Data and Information: A Primer*, Discussion Paper No. 02-30, Stanford Institute for Economic Policy Research; Cohen WM and Walsh JP (2008) 'Real Impediments to Academic Biomedical Research', in Jaffe AB, Lerner J and Stern S (eds) (2008) *Volume 8: Innovation Policy and the Economy*, National Bureau of Economic Research, University of Chicago Press,

pockets of openness against the background environment of the market, which arguably in the long term facilitates technology too.[626] Little attention and certainly no priority is given to impediments to the short term production of the outcomes of industrial innovation, although the more successful innovative 'commons' approaches that I refer to in the next chapter might, through removal of barriers to the research commons, also enhance the associated industry.

In an attempt to streamline the discourse about facilitative governance, therefore I propose a conceptual framework for 'scientific technology' that acknowledges the trend toward integration and commercialisation in modern biomedicine. I argue that attempts to devise mechanisms that facilitate activity at all levels should be based on an understanding of 'scientific technology' as an integrated meta-system for the production of goods and services, which encompasses research, innovation and exploitation, across science and technology and the public and private sectors. I submit that an accurate conception will permit the identification of the relevant problems or hurdles to be overcome, and ground the formulation of strategies for overcoming them in relation to a given technology: the arrangements and structures that might be used to achieve optimal conditions for innovative use and exploitation of resources.

6.2 Science-based technology

Interconnections

I have already indicated some of the ways in which science and technology although institutionally separate, and distinct in orientation and objective, are nevertheless allied and interconnected with one another. Technology has long benefited from the explanatory power of science, and most commentators agree that the power of modern technological developments depends to a large extent on its ability to draw

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Chicago; Eisenberg RS & Nelson RR (2002) 'Public vs. Proprietary Science: A Fruitful Tension?' 131:2 *Daedalus* 89; Kitcher P (1993) *The Advancement of Science*, Oxford University Press, Oxford.

[626] *Ibid.*

upon the knowledge generated by modern science.[627] There is less consensus – some would say there are 'quite wrong beliefs'[628] - about the nature of the connections between science and technology. Modern technology is no longer considered a predictable 'application' of science but is said to constitute a 'co-evolution' of understanding and practice, and even though science provides a strong component of the process, technology still needs to engage in a 'competitive exploration of multiple paths'.

Scientific enquiry is equally inspired by technical advances. Science may be alerted to questions of scientific interest by practical realities as well as theoretical ones, and an awareness of utilitarian pursuits of technology can enhance its progress. The fact that scientists address questions, the answers to which have immediate practical importance for technology, does not undermine the purity of the scientific pursuit of knowledge, nor the value of its outcomes. Who sets the agenda – whether it is a scientific, policy or private agenda – and whether results are accessible to the wider scientific community are the concerns raised in the debate about the long term freedom of scientific enquiry and future knowledge base for science and technology.

I have described the development of fields of research in 'Pasteur's quadrant'[629] in which scientific enquiry into the natural properties of things coincides with the advancement of technological utilisation of those properties. Biomedical research is such a field, which pursues both deep understanding and solutions to particular kinds of practical problems. The *selection criteria* regarding the projects that will be pursued or funded in these fields, however, cannot be kept distinctly separate; those who think that they might be able to apply science according to *practical* criteria (does it work?) are able to provide a stringent testing ground for the claims of science (is it true?), and the failure to understand *why something works* is a strong motivation for scientific research. Although the first *institutional structure* of open science demarcated it from the economic environment of technology, it did not sever the

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[627] Nelson RR (2004) 'The market economy and the scientific commons' 33 *Research Policy* 455; Nelson RR (2003) 'The advance of technology and the scientific commons' 361 *Philosophical Transactions of the Royal Society A: Mathematical, Physical and Engineering Sciences* London, 1691, published online 4 July 2003.
[628] Nelson RR (2004) The market economy, 457.
[629] Stokes DE (1997).

natural affinity of science and technology for one another that results from their different orientations - toward understanding and utility – which inspire and complement one other in their respective pursuits.

Public policy

It was a natural extension therefore to include these fields of 'applied science' or 'research and development' under the umbrella of public support for academic 'science'.[630] Government-supported programmes of R&D during World War II, particularly in the U.S., were hugely successful, resulting in the development of weapons that won the war and medical capability that reduced casualties, and postwar recognition of the importance of public science in technological progress, particularly in the U.S. and the UK.[631] A new debate was generated in regard to science and technology policy going forward. There had been earlier debate about science policy in the US,[632] and Francis Bacon himself, as I have already mentioned, had much earlier envisioned support for science as a means through which societies would progress materially. The debate did not contest the fact that companies, with their own R&D capabilities, had a central role to play in the process of technological advance. It focused instead on the extent to which government would fund and control the agenda of the public system of 'science' conducted in universities and public laboratories, separate from but complementary to the corporate system of R&D. Some advocated stronger government support on grounds that it would make the overall system of innovation more powerful, while others were wary that this would limit the freedom of scientific enquiry. In the UK, physicist JD Bernal[633] favoured a closely monitored government program that would allocate public funds to science on the basis of assessment of social needs. This approach was countered by philosopher of science, Michael Polanyi,[634] who advocated a publicly-funded but

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630 Nelson RR (2004) The market economy, 461.
631 *Ibid*, 460.
632 Price D (1962) *Government and Science*, Oxford University Press, Oxford; Hart D (1998) *Forged Consensus*, Princeton University Press, Princeton; Guston D (2000) *Between Politics and Science*, Cambridge University Press, Cambridge.
633 Bernal JD (1939) T*he Social Function of Science*, Routledge, London.
634 Polanyi M (1962) The Republic of Science.

largely self-governing organisation, in which scientists would set their own priorities and standards of good science.

In the U.S., the influential 1945 report entitled 'Science, the Endless Frontier' (the 'Bush Report') stood in favour of a self-governing scientific community, but permitted a government role in setting national priorities in certain areas, including national security and health. The budget and broad agenda in these areas were to be established by political and government processes, but within these parameters, scientists were to have discretion in the construction of appropriate research programs. In the use of public science to pursue economic progress more broadly, the role of the government was limited to the support of basic research, in which self-governing science would identify the broad fields of greatest potential, the detailed allocation of funds and the conduct of research. The Bush Report, like the Polanyi response to Bernal, was to stave off attempts to propose a postwar system involving tighter government control, which would be potentially destructive for the creativity of science, concluding that it would be preferable to allow top scientists to run the show.[635]

Economic interdependence

The debate over the governance of public 'science' postwar obscured the fact that the large majority of 'scientific' research conducted at universities and institutes since WWII has been carried out in fields in which practical application is central to the definition of a field.[636] These are also the fields of research from which industrial technology draws most heavily.[637] Much of the credit for the power of modern capitalism as an engine of technological progress has been given to businesses and entrepreneurs, and their efforts to develop the proprietary capabilities of firms in the market, as the central actors in the development and introduction of new products

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[635] Nelson RR (2004) The Market economy, 461.
[636] Two recent surveys asked industrial R&D executives to identify the fields of academic research that contributed most to their successes: see Klevorick AK, Levin RC, Nelson RR, Winter SG (1995) 'Sources and significance of inter-industry differences in technological opportunities' 24:2 *Research Policy* 185; Cohen W, Nelson R, Walsh J (2002) 'Links and impacts: the influence of public research on industrial R & D' 48:1 *Management Science* 1.
[637] Nelson RR (2004) The Market economy, 461.

and processes. There is nevertheless a widely recognised dependence of industrial innovation and invention upon the strength of the science base from which it draws. Despite the institutional divide that separates science from the market, there is an economic interdependence between science and technology that arises from their reliance upon one another for inspiration and inputs of knowledge. The foundational science for technology is largely the product of publicly funded research, and the knowledge produced by that research is mostly in the public domain and available for potential innovators to use. The market part of the capitalist engine thus rests on a publicly supported scientific commons, as has been demonstrated by various studies of national systems of innovation.[638]

Popular perception

The close association of science and technology in research is reflected in the popular perception that construes them as almost interchangeable. As a result, science is often attributed with responsibility for the technical applications of its work, whether they are beneficial or undesirable. Support for science and the integrity of scientists is increased by technical applications that demonstrate scientific theories in a way that is accessible to the lay public,[639] and that produce welcome social enhancements. Science may also take the blame, however, for technological developments that are disapproved by agents of authority or pressure groups.[640] Scientists themselves affirm this conflation of science and technology: the presumption by some scientists that all social effects of science are ultimately beneficial, and that the purity of discovery is undermined by external judgment, fails to distinguish scientific truth from social utility.[641] The distinction is important in the life sciences, in which technical uses of scientific knowledge in relation to

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[638] Lundvall BA (ed) (1992) *National Systems of Innovation: Toward a Theory of Innovation and Interactive Learning,* Pinter, London; Nelson (1993) *National Systems of Innovation: A Comparative Analysis*, Oxford University Press, Oxford; Freeman C (1988) 'Japan: A New National System of Innovation', in Dosi G, Freeman C, Nelson R, Silverberg G and Soete L (eds) (1988) *Technical Change and Economic Theory*, Pinter, London and New York.
[639] Merton RK (1938) Science and the Social Order, 283.
[640] *Ibid.*
[641] *Ibid.*

biomaterials, including stem cells, are the subject of heightened public awareness and policy debate.

Laws of patent

I also referred briefly to the overlap between 'discovery' and 'invention' in the conduct of scientific research, and the effect of this in the law of patents and the norms and ethos of science. The norms of science and technology have coexisted for many years under the patent system. In simplistic terms, in addition to the doctrine that restricts patentability to 'inventions', as opposed to the 'discoveries' of basic scientific research, the reach of patent protection is further restricted by the requirement of specific and substantial utility - that the applicant should demonstrate that the invention is operable and capable of use. This means that an invention is not patentable until outstanding technical problems are solved, regardless of the extent to which it may be interesting and significant to research scientists; it also means that discoveries that result from much basic research, even if not prevented from patent on grounds of subject matter, will not be ripe for patent protection due to lack of demonstrable utility.[642]

6.3 Recent changes

The process of change in the paradigms of science and technology, and the difficulties that come with it, are the fruit of the evolution of understanding and practice in the advance of scientific technology. Scientific and technological integration has given rise to changes in patent law doctrine, government and university policies regarding the use of commercial incentives, and ultimately changes in patenting practices by publicly funded as well as private sector researchers. These changes shape the conduct of 'scientific technology' and affect the governance initiatives that respond to them. I outline these changes, then ask whether and ask what bearing they have on openness in scientific technology and policy attempts to facilitate the delivery of complex public goods.

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[642] Eisenberg RS (1987) 'Proprietary Rights and the Norms of Science in Biotechnology Research' 97:2 *The Yale Law Journal*, 177, 185.

The new biology

Scientific and technological 'integration' in the life sciences involves both the dual orientation of research in the fields of Pasteur's quadrant' as I have already discussed, and the incorporation of a wide variety of technologies in the research process. Regenerative medicine (RM) is typified by the combination of diverse technologies, united in the common aim of restoring impaired anatomy and physiological and biomechanical function.[643] Combinatory approaches result in inter-disciplinary transfer of knowledge, innovative solutions that would not be accomplished by any one discipline alone, and expanded potential for application to many and various targets and conditions. RM illustrates what has been referred to as an emerging movement to integrate different types of research inputs into the 'New Biology'.[644] Technological advances in biology, as in other life sciences fields such as microbiology and genomics, are creating opportunities for the integration of disparate sources of scientific knowledge and research at a time when pioneering methods[645] have emerged to produce and process increasingly vast amounts of raw materials, data and information.[646] This trend toward technological integration has been recognised recently by the U.S. National Research Council:

'Years of research have generated detailed information about the components of the complex systems that characterize life – genes, cells, organisms, ecosystems – and this knowledge has begun to fuse into greater understanding of how all these components work together as systems. Powerful tools are allowing biologists to probe complex systems in ever greater detail, from molecular events in individual cells to global biogeochemical cycles. Integration within biology and increasingly fruitful collaboration with physical, earth, and computational scientists,

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643 Haseltine WA (2003) 'Regenerative Medicine 2003: an overview', 4 *Journal of Regenerative Medicine* 15, cited in Daar AS and Greenwood HL (2007) 'A proposed definition of regenerative medicine' 1 *Journal of Tissue Engineering and Regenerative Medicine* 179, 181.

644 U.S. National Research Council of the National Academies (2009) *A New Biology for the 21st Century*, Committee on a New Biology for the 21st Century: Ensuring the United States Leads the Coming Biology Revolution, National Academies Press, Washington DC.

645 High through-put screening and full genome sequencing for example.

646 Reichman JH, Dedeurwaerdere T and Uhlir PF (forthcoming 2013) *Designing the Microbial Research Commons: Global intellectual property strategies for accessing and using essential knowledge assets,* Cambridge University Press, Cambridge.

mathematicians, and engineers are making it possible to predict and control the activities of biological systems in ever greater detail.'[647]

The process of integration within the life sciences is aided by the parallel integration of techniques and concepts from engineering, robotics, computer science, mathematics, statistics, chemistry and other fields. Mathematics has played an especially critical role in the processing of massive amounts of data and in building digitally accessible collections. The U.S. National Research Council foresees the possibility of much *greater* integration, with enormous benefits to public health, food, security, environmental protection and other urgent social needs. It bases its expectations on advances in foundational technologies: information technology, *in vivo* imaging of cells, organisms and ecosystems, high through-put technologies including nanotechnology, and engineered biological systems. Hopes for the new biology are pinned on three foundational sciences: systems biology, computational biology and synthetic biology.[648]

Patent law doctrine

Along with the prospect of more powerful combinatory technologies have come changes to patent law doctrine that challenge the traditional view of basic science by expanding the potential for patentability of the results of research 'discoveries' in general, and biotechnological inventions in particular. In 1980, the U.S. Supreme Court, in the case of *Diamond v Chakrabarty,*[649] granted to General Electric the first patent over a genetically engineered micro-organism, thus enabling inventors to exploit the 'manufactured' life form or 'composition of matter' in addition to the production process.[650] With this shift toward the patenting of discoveries, there was allegedly a tendency for patent office directives and the U.S. courts to authorise patents that are *presumed* to have utility as a basis for further developments, even if their immediate usefulness could not be proven at the time of the application.[651]

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[647] U.S. NRC (2009) A New Biology for the 21st Century.
[648] Reichman JH et al (forthcoming 2013) Designing the Microbial Research Commons.
[649] *Diamond v Chakrabarty* (1980) 447 U.S. 303, U.S. Supreme Court.
[650] Eisenberg RS (1987) Proprietary Rights and the Norms of Science, 187.
[651] *Ibid.*

This, it was suggested, amounted to a renunciation of the criterion of industrial utility, that would encourage patenting of scientific insights in the very early stages of research, and give the holder the ability to control and potentially block the use of research tools and the outcomes of activities that might rely on them.[652] The United States Patent and Trademark Office however, in its 2001 Utility Examination Guidelines,[653] now requires that utility in relation to a claimed invention be 'specific, substantial and credible',[654] thus adopting the 1966 Supreme Court test of substantial utility[655] - as having a real world use in currently available form.[656] The CAFC[657] recently upheld a similar standard in relation to gene fragments by deciding that their uncharacterised functions failed to satisfy the 'specific and substantial' utility test. It found that an applicant asserting utility must show that the claimed invention has a 'significant and presently available benefit to the public'.[658] An invention that is only an object of further research, or useful in order to determine what it might be useful *for*, does not therefore have a substantial, currently available utility.[659]

Apart from USPTO retention of the utility requirement for patentability, trends toward expansion of the scope and reach of patents can encourage industrial firms, particularly in biotechnology research to engage in early stage research in-house and to license their own patented research results to other firms that can make use of them. These trends are reflected in the rapid adoption of public policies by which universities are permitted to patent the work of their employee researchers. The Cohen-Boyer patents, over the technique of recombinant DNA that permits the useful manipulation of genetic material, are cited as an example of the attraction that rapid and substantial revenues to university rights holders can have for university

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652 *Ibid.*
653 USPTO (2001) 'Utility Examination Guidelines' 66:4 *Federal Register* 1092, issued in December 1999 and effective from 5 January 2001, available at http://www.uspto.gov/web/offices/com/sol/notices/utilexmguide.pdf, accessed 27 May 2013.
654 *Ibid*, 1098, B. Examination Guidelines for the Utility Requirement, para 1.(c)(2).
655 *Brenner v Manson*, 383 US 519, 148 USPQ 689 (1966).
656 Elliott G (2007) 'Basics of US Patents and the Patent System' 9:3 *The American Association of Pharmaceutical Scientists (AAPS) Journal,* Article 35, E317.
657 Court of Appeals for the Federal Circuit (CAFC), a specialty federal court hearing patent appeals.
658 *Ibid*, Elliott G, Basics of US Patents, E319-20, citing *In re Fisher*, Court of Appeals for the Federal Circuit, 421 F3d 1365, 76 USPQ2d 1225 (Fed Cir 2005).
659 *Ibid*, Elliott G, Basics of US Patents, E320.

officials and university scientists.[660] The first Cohen–Boyer patent was granted in 1980 prior to the passage of *Bayh–Dole Act*, which legitimated and warranted such university patenting, as discussed below.

In the EU, after ten years of debate, the 1998 Biotechnology Directive[661] was adopted in an attempt to harmonise national approaches of Member states to the patenting of biotechnology inventions.[662] The current European patent system is based on the 1973 *European Patent Convention*[663] ('EPC') which established the European Patent Office and a unified 'European Patent' procedure. The EPC permits an applicant to obtain, in one procedure, a group of national patents and thus patent protection in any of the Member states of the Convention; it does not however create a unified European-wide patent law, and because enforcement of European Patent rights occurs under national laws of individual Member states, there is room for various interpretations in the implementation and application of the laws in national legislation and courts. Attempts to establish a harmonised Community-wide patent law have not yet been successful, and the Biotechnology Directive does not impose a standard patent law for biotechnological inventions, but clarifies how the provisions of the EPC[664] with respect to the threshold criteria for patentability[665] and specific exceptions[666] are to be applied to them. The Directive does not unfortunately address the precise scope of the research exemption provided by patent disclosure, even

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660 Feldman MP, Colaianni A and Liu C (2007) 'Lessons from the Commercialization of the Cohen-Boyer Patents: The Stanford University Licensing Program' in Krattiger A, Mahoney RT, Nelsen L *et al* (eds) *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices,* MIHR: Oxford, UK and PIPRA: Davis, USA; available online at www.ipHandbook.org, accessed 6 December 2012.

661 EU Biotechnology Directive (1998).

662 Leskien D (1998) 'The European Patent Directive on Biotechnology' 36 *Biotechnology and Development Monitor* 16. The Biotech Directive may achieve a degree of harmonisation of national laws of EU member states, but as it does not bind the European Patent Office, cannot ensure uniformity of patenting policy as between the national patent offices and the EPO.

663 *Convention on the Grant of European Patents* of 5 October 1973 ('European Patent Convention').

664 Directive 98/44/EC was incorporated into the Implementing Regulations to the European Patent Convention (EPC) as Rules 23b-e. European Patent Office website, available at http://www.epo.org/news-issues/issues/biotechnology.html, accessed on 5 December 2012.

665 *European Patent Convention*, Article 52: an invention must be 'new', 'susceptible of industrial application' and involve an 'inventive step'.

666 *Ibid,* Article 53. The four main exceptions to patentability of biotechnology inventions are: any invention, the commercial exploitation of which would be contrary to public order or morality; surgical, therapeutic or diagnostic methods for treatment or practice in relation to the human or animal body; plant and animal varieties; and essentially biological processes for the production of plants and animals.

though the laws of Member states diverge on this point. It fails to clarify the circumstances in which patented biological material may be used by third parties for research purposes: which experimental acts are permissible without the authorisation of the patentee.

The Directive in other ways largely affirms the long-standing practises and jurisprudence of the EPO and most national patent offices,[667] stating expressly that inventions meeting the threshold tests of novelty, inventive step and capacity for industrial application shall be patentable 'even if they concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used.'[668] Biological material may be the subject of an invention if it is isolated from its natural environment or produced by means of a technical process 'even if it previously occurred in nature'.[669] This includes elements isolated from the human body, 'even if the structure of that element is identical to that of a natural element'.[670] Inventions related to individual human genetic sequences, and their functions, can therefore be patented, subject to the usual criteria.[671]

The Directive contemplates patentability of broad scope, pertaining to biological materials, biotechnological processes and products containing or consisting of genetic information. A patent on biological material extends to materials derived from it as long as they share its characteristics;[672] likewise the protection afforded by a *process* patent that enables *production* of a biological material extends to the material produced through the process, as well as its derivatives.[673] Patents on products involving genetic information extend to all material (except the human body[674]) in which the product is incorporated, and in which the genetic information is

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667 Leskien D (1998) The European Patent Directive on Biotechnology.
668 *Biotechnology Directive*, Article 3(1); Leskien D (1998) The European Patent Directive on Biotechnology.
669 *Ibid*, Article 3(2).
670 *Ibid,* Article 5(2).
671 *Ibid,* Article 5(2).
672 *Ibid,* Article 8(1).
673 *Ibid,* Article 8(2).
674 *Ibid,* Article 5(1).

contained and performs its functions.[675] Protection does not extend to derivatives, however, that are the result of propagation or multiplication that necessarily occurs in the use of an application of the patented material or process marketed in a Member state for precisely that purpose.[676]

Specific exemption of inventions from patentability on grounds that their commercial exploitation would be contrary to *ordre public* or morality[677] is also addressed by the Directive.[678] It rules out: the patenting of an entire human body at any stage in its development,[679] procedures designed to allow human cloning,[680] human germ line engineering,[681] and the use of embryos for industrial or commercial purposes.[682]

The Directive does not, however, make specific reference to human stem cells or processes by which they might used to produce cell-based therapeutic applications. Analysis of the interpretations of Article 6(2)(c) by national patent offices[683] and the EPO reveals a fragmented view as to which, if any, hESCs or processes are patentable in Europe.[684] Increasing legal uncertainty on the scope of application of the moral exclusion clause to hESCs is the inevitable consequence, and carries the risk of a threat to research and investment in the life sciences and innovation in Europe,[685] both of which have been earmarked as a strategic priority for Europe.

The matter was recently considered by the European Court of Justice in *Brustle v Greenpeace*[686] in which it ruled against the patentability of the *process* by which

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675 *Ibid,* Article 9.
676 *Ibid,* Article 10. There is some ambiguity about the interpretation of this provision: see *Monsanto Canada Inc. v. Schmeiser* [2004] 1 S.C.R. 902, 2004 SCC 34.
677 *Biotechnology Directive*, Article 6(1). Exploitation is not however deemed to be contrary to morality or public order merely because it is prohibited by law or regulation.
678 Inch A (2007) 'The European Patent Convention: A Moral Roadblock to Biotechnological Innovation in Europe' 30 *Houston Journal of International Law* 203.
679 *Biotechnology Directive*, Article 5(1).
680 *Ibid*, Article 6(2)(a).
681 *Ibid*, Article 6(2)(b).
682 *Ibid*, Article 6(2)(c).
683 See for example: Intellectual Property Office (2009) 'Practice Notice: Inventions involving human embryonic stem cells', 3 February.
684 Plomer A (2006) *Stem Cell Patents: European Patent Law & Ethics Report*, FP6 'Life sciences, genomics and biotechnology for health' SSA LSSB-CT-2004- 005251, University of Nottingham, 13.
685 *Ibid.*
686 *Oliver Brüstle v Greenpeace* (2011) C-34/10, Court of Justice of the European Union.

neural precursor cells are *differentiated from* a stem cell line of embryonic origin, regardless of the fact that the process specified in the application made no reference to human embryos or the process of derivation of stem cells from an embryo, and in itself met the threshold criteria for patentability. The Court held that the implementation of the patent would entail either the prior destruction of a human embryo, or use of an embryo as a base material, contrary to the Biotechnology Directive. The decision is unfortunate on many levels but primarily for the fact that it creates a wide precedent capable of frustrating technological advances in jurisdictions such as the UK that have chosen to permit derivation of embryonic stem cells for the very purpose of achieving such therapies. It also contradicts the interpretation of the moral exclusion clause that construes its purpose as precluding *direct* instrumentalisation of the embryo through its use as a raw material in a repetitive (technical) process, or its commodification through *trade of human embryos* involving monetary exchanges,[687] thus reinforcing the technical and commercial uncertainty already felt in the field.

Public policy

In conjunction with scientific and technological integration, and changes in patent law doctrine, significant changes occurred in government attitudes and policies toward the patenting of publicly funded research. The literature documents a major ideological shift in the U.S. during the 1970s and 1980s, from the general hostility of the 1930s and the early postwar years to 'a belief that patents were almost always necessary to stimulate invention and innovation'.[688] Universities were increasingly expected to contribute to the reinstatement of U.S. economic competitiveness in international markets, and technological leadership in certain fields.[689] They were strongly encouraged to take out patents on their research results, on grounds that this would arguably enable capable firms to make practical use of the results under a

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[687] Plomer A (2006) *Stem Cell Patents*, 104.
[688] Nelson RR (2004) The market economy, 468.
[689] Asheim B, Valentin F and Zeller C (2009) 'Intellectual property rights and innovation systems: issues for governance in a global context' in Castle D (ed), *The Role of Intellectual Property Rights in Biotechnology Innovation*, Edward Elgar Publishing, Cheltenham UK and Northampton USA 37, 52.

protective license.[690] A key feature of this policy shift was federal legislation known as the *Bayh-Dole Act*,[691] which was enacted by the U.S. Congress in 1980. Although there is empirical evidence to show that in many industries patents are a relatively unimportant stimulus for investment in R&D,[692] the *Bayh-Dole* legislation focused on the pharmaceutical industry, for which patent protection was and continues to be important.[693]

The *Bayh-Dole Act* encourages universities to patent inventions generated in the course of publicly funded research through a mandatory notification system, whereby the university must report anything that 'is or may be patentable' to the government sponsor within a reasonable time, failing which patent rights in it may be claimed by the government agency. The Act does not prevent the publication of research results, but permits universities to retain patent rights, subject to a non-exclusive license to the sponsor for use of the patented invention, only if they agree to file for patents promptly after publishing. Further, if the university fails to exploit its patent the sponsoring agency can 'march in'[694] and license the university invention itself. *Bayh-Dole* also requires universities to share patent royalties with inventors, which gives researchers a personal financial stake in the results and creates an incentive for them be alert to patent opportunities.

In Europe most countries, except for Sweden, adopted laws that mirrored *Bayh-Dole*. This 'wave of legislation'[695] inspired by the U.S. *Bayh-Dole Act* increased the involvement of universities in obtaining patents on the work of their employee

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690 Nelson RR (2004) The market economy 462, citing Eisenberg RS (1996) 'Public research and private development: patents and technology transfer in government sponsored research' 82:8 *Virginia Law Review 1663*.

691 1980 *U.S. Patent and Trademarks Amendment Act.*

692 Cohen WM, Nelson RR, Walsh J (2000) *Protecting Their Intellectual Assets: Appropriability Conditions and Why U.S. Manufacturing Firms Patent or Not*, National Bureau of Economic Research, NBER paper 7522, Boston.

693 For a review of developments leading up to the *Bayh-Dole* legislation and its effects see: Mowery DC and Sampat BN (2005) 'Universities in National Innovation Systems' in Fagerberg J et al (eds) (2005) *The Oxford Handbook of Innovation*, Oxford University Press, Oxford 209; Mowery DC, Nelson RR, Sampat BN, Ziedonis AA (2001) 'The Growth of Patenting and Licensing by American Universities: An Assessment of the Effects of the Bayh-Dole Act of 1980', 30 *Research Policy* 99.

694 Eisenberg RS (1987) Proprietary Rights, 196.

695 Asheim et al (2009) Intellectual property rights and innovation systems, 55.

researchers,[696] to allow universities to become the owner of patents for inventions made by their employees according to certain conditions. Studies show that 'university-*invented* patents' are nevertheless far more prevalent in Europe than 'university-*owned* patents', meaning that patents on the results of academic research in Europe are still being obtained far more frequently by companies than by the universities.[697] In Europe, the corporate patenting of work that was initiated by universities represents a more important academic contribution to technological invention than university-owned patent rights.[698] Moreover, the effects of specific *Bayh-Dole* inspired legislation studied in national context indicate that the introduction of such a law may have negative impacts on university-industry collaboration. [699]

Patenting and licensing

In association with these other changes, there are evident changes in patent practices, both with regard to the volume of patents obtained and the point in the innovation process at which they are sought. It has been clearly demonstrated that across industrial sectors there has been a dramatic *increase in patents* granted during the last two decades, both in the U.S. and in Europe.[700] In Europe, Switzerland and Sweden generate the most patents, measured by 'patent families' per million inhabitants.[701] This reflects the strength of the pharmaceutical biotechnology industry in these two countries, in contrast to Germany, where the biotech industry has remained relatively weak compared to those of Switzerland and Britain.[702]

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696 *Ibid.*
697 Crespi G, Geuna A and Nesta L (2005) *Labour Mobility from Academia to Business: New evidence from a large dataset of EPO inventors,* DRUID Summer Conference Copenhagen Business School, June 27-29, provides an overview of these findings, and presents the results of its analysis of 9,000 EPO patents across 6 European countries.
698 Asheim et al (2009) Intellectual property rights and innovation systems, 66.
699 *Ibid; Bayh-Dole* inspired legislation had negative effects on university-industry collaboration in biotech innovation in Denmark; these results were contrasted with the Swedish situation, which did not adopt Bayh-Dole style legislation.
700 *Ibid.*
701 *Ibid.*
702 *Ibid.*

With changes in patent doctrine that permit patent applications at a much earlier stage in the innovation trajectory, there has also been a shift in practice toward patenting further 'upstream', particularly in the field of biotechnology. The effect of this is that instead of the patenting of 'end products' ready for manufacture, around which the patent system was originally designed, the large majority of biotechnological 'inventions' are now '*research tools'* that play a critical role in the furtherance of knowledge and innovation in both the public and private sectors. The term 'research tool' in its broadest sense embraces the whole range of resources used by researchers use in the laboratory including, for example, cell lines, monoclonal antibodies, reagents, animal models, growth factors, combinatorial chemistry libraries, drugs and drug targets, clones and cloning tools, methods, laboratory equipment and machines, databases and computer software.[703] What is to the user or researcher a 'tool' may nevertheless, from the perspective of a provider, be a valuable commercial 'product'.

Even in the context of upstream biological research, where the label 'research tool' would seem to apply unequivocally to the multitude of discoveries (including DNA sequences, databases, clones, cell lines, animal models, receptors and ligands involved in disease pathways[704]) that precede the identification of new therapeutic compounds, or the techniques used to create or identify them, such 'tools' might constitute commercial end products to the institutions that discover them. Many research tools are costly to develop and have significant competitive value to the firms that own them. Some might ultimately prove to be therapeutic or diagnostic products in their own right, marketable to consumers for use outside the laboratory. Others might be identified as resources with sufficient commercial potential in the discovery of future products, to motivate investment in their development for sale or license for use in further research. Research tools are however difficult to value: value varies according to the tool and the type of use, and the party - provider or user – that is doing the assessment. The characterisation and valuation of resources as

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[703] NIH (1998) *Report of the National Institutes of Health (NIH) Working Party on Research Tools,* Presented to the Advisory Committee to the Director, June 4, 1998, Washington.
[704] *Ibid.*

research tools or end products varies therefore with the interests of the parties. Inevitably, each minimises the value of the discoveries it borrows from others, while seeing great existing or future value in its own discoveries.[705]

With increased use of the patent system to obtain proprietary rights in research tools across the public and private sectors, there has also been a move toward the use of *licences and material transfer agreements* (MTAs) for the dissemination of such tools, as a means of delineating the terms and conditions under which they can be used. Despite a certain amount of withholding of discoveries from their professional rivals, past practice among scientists allowed for relatively free exchange, typically without formal agreements and without explicit consideration of commercial rights or potential financial benefits.[706] The use of licenses and MTAs, which has long been standard practice for private firms, has now however become fairly standard practice for universities and government laboratories as well.[707] Although such agreements may be used effectively to disseminate patented or unpatented materials, the terms of these agreements can also interfere with the widespread dissemination of resources, either because owners and users are unable to reach agreement on fair terms, or because the negotiations are difficult and cause protracted delays.[708]

The problems of access to resources look quite different from the perspectives of different types of actors: scientists, universities and private firms, with considerable variation within each category.[709] Those who seek advantage in the competitive market from their proprietary research tools are not generally in a position to make them freely available, and may attempt to limit who has access to the tools, restrict how they are used, and delay disclosure of research results.[710] Moreover, corporations that have invested in the development of valuable research tools have a fiduciary duty to use them in a manner that returns value to their shareholders.

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[705] *Ibid.*
[706] *Ibid.*
[707] *Ibid.*
[708] *Ibid.*
[709] *Ibid.*
[710] *Ibid.*

Potential users who have limited ability to pay up-front fees, may enter into licensing mechanisms whereby providers seek to profit from potential discoveries arising from the use of tools, on the basis of future royalty obligations or rights to future intellectual property. Such arrangements are capable of constraining future opportunities for research funding and technology transfer. Other users may be capable of paying fees to obtain biomedical research tools, but are reluctant to share profits in potential future discoveries with institutions that do not share the risks and costs of product development.

As a result, many scientists and institutions involved in biomedical research may be frustrated by difficulties and delays in the negotiation of permission to use tools and materials on a case by case basis. The recommended solution is often to standardise terms of license and MTAs, but given the differences in the nature and value of research tools and in the objectives and constraints of owners and users it is difficult and may be undesirable to standardise terms of access across the broad spectrum of biomedical research. A multi-pronged approach would entail: dissemination of resources without legal agreements whenever possible, especially when the prospect of commercial gain is remote; use of standard agreements such as the 'Uniform Biological Materials Transfer Agreement' ('UBMTA') to reduce the need for individual negotiations; development of guidelines for recipients of public funds regarding reasonable terms for use in licenses and MTAs.[711]

Institutions

Finally, the literature recognises that all of these changes - scientific and technological integration and the expansion of the role of patents in legal doctrine, government policy, and in the practice of both public and private researchers – have consequences for the organisation of research. Universities and public laboratories have become actors in the patent arena.[712] In the field of biotechnology,

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[711] *Ibid.*

[712] Van Pottelsberghe B, 'An insight into the academic patent debate', European Patent Office, available at http://www.zis.gov.rs/upload/documents/pdf_en/pdf/seminari/8nov2007_insight.pdf, accessed 6 December 2012.

collaboration has increased since the 1970s between publicly funded researchers and proprietary firms. With the realisation by scientists and investors of the potential benefits for human health of the advances and products that could be generated in fields such as molecular biology, biomedical researchers increasingly chose to collaborate with *entrepreneurial companies* that understood and valued basic science. Others decided to leave academia and join these firms as founders or employees. As a result many biotechnology companies emerged with strong ties to the academic world.[713]

U.S. venture capitalists suggest that in 2008 there were about 1000 companies in over ten countries involved in the pursuit of cell therapies and regenerative medicine, and while over half of these are mid-sized to large pharma companies with multifold interests, '300 to 400 are focused solely on regenerative medicine.'[714] These fall into four main categories. *Cell therapy companies* pursue therapeutic treatments involving human embryonic stem cells (Geron and Advanced Cell Technology) as well as those derived from adult stem cells and their precursors (Mesoblast and Cytori). *Tissue engineering* firms develop replacement tissues (such as the Tengion product NeoBladder made from bladder epithelial cells of the patient). A third category comprises *tool companies* that produce cells for drug discovery and toxicity testing (VistaGen) and instruments and devices (such as the Novathera bioreactor that enables three-dimensional cell culture) used in the manufacture of cell therapies. Fourthly, other companies focus on bioaesthetics, including skin rejuvenation and repair products (Organogenesis) and hair regeneration procedure involving cultivation of cells from human hair follicles (Intercytex).

Such firms may have a greater role than previously recognised in the shaping of the new 'mode of science'. In the U.S. pharmaceutical sector, *contract research organisations* (CROs), which were largely nonexistent before 1980, now reportedly

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[713] NIH (1998) Report of the National Institutes of Health.
[714] Parson A (2008) 'Stem Cell Biotech: Seeking a Piece of the Action' 132 *Cell* 511, quoting Gregory Bonfiglio, managing partner of U.S. venture capital firm Proteus Venture Partners.

carry out a significant part of drug development and clinical trial management.[715] These firms arose out of small specialised boutique providers of narrowly targeted services to pharmaceutical clients,[716] but now range from small, niche specialty groups to large, international full-service organisations. They differ markedly from earlier for-profit toxicology, bioassay, and pharmaceutical testing firms, which they have tended to drive out of business.[717] The role of the CRO, as opposed to that of its main competitor the 'academic health center', has been discussed in the medical literature for more than a decade, but it need not be restricted to the pharmaceutical industry: it has been suggested that the CRO is the essence of the new paradigm of privatised science in the post-1980 era of commercialised research[718] and as such holds potential for other sectors.

To summarise: since the 1970s there has been significant integration of scientific and technological advances, an expansion of patentability of early discoveries and living things, a dramatic change in the attitude of governments in favour of patenting of publicly funded research, increased volumes of patenting overall, mixed patterns as to the roles of universities and corporations (particularly as between the U.S. and Europe) in regard to such patenting, and the emergence of new actors and types of collaborations between the universities, researchers, and private firms.

6.4 Implications

What do these changes mean for the governance of scientific technologies – particularly biotechnologies - and facilitation of stem cell therapies? I have attempted in the previous sections to identify the main changes that have occurred recently in the models of science and of technology, without straying too far into the issues that they raise, partly because many of them cannot be dealt with fully within the scope of this thesis, but also because it is not the purpose of the thesis to solve

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[715] Mirowski and Van Horn R (2005) 'The Contract Research Organization and the Commercialization of Scientific Research' 35 *Social Studies of Science* 503, 514.
[716] For review of the four largest pharmaceutical CROs see: Rettig R (2000) 'Drug Research and Development: The Industrialization of Clinical Research' 19 *Health Affairs* 129.
[717] Mirowski and Van Horn R (2005) The Contract Research Organization, 514.
[718] *Ibid.*

those problems *per se*, but to consider *how* they are or might be addressed. I outline the main issues below. The question that underlies much of the academic debate around these developments is whether the public system of science is under threat and, assuming that it is, how the situation can be remedied. The central threats under discussion are the inhibition of research as a result of the commercial incentives of patenting and, to a lesser extent, the effect of the crossover of scientists from academic institutions to employment within private sector organisations. There *are* other problems in both public and private sectors - with the patent system in general and biotech patents in particular,[719] barriers to translation of knowledge into final industrial products, and other issues specific to the various sectors and actors. The dominant debate however concerns the impact of commercialisation on *publicly funded* or government-supported science.

This 'privatisation' debate, like that surrounding government policy post-WWII, is not so much concerned with the activity of private sector organisations in research and industry but with *academic or government* research and the consequences of the proprietisation of the work of academics through the encouragement to patent and license. It is the move from the old norms of science to proprietary science *within* the system of public science that is of primary concern to scientists. The problem for facilitative governance is that the situation continues to be assessed in relation to the norms of open science, framed by the traditional distinction between science and technology. Given continued *public* support for research, and the fact that in its new mode it is certainly not *industrial* technology, many (perhaps most) scholars continue to treat public research as the 'science' of the Mertonian conceptual framework. The main response to the changes is therefore to attempt to protect and reinforce the

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[719] The rationale for *absolute liability* for infringement of *product* patents, for example, is reasonable in relation to mechanical inventions, which are inert, static and largely immutable, but may be problematic for biological inventions, which are dynamic and active, because the biological activity of the product itself, rather the behaviour of the defendant, may cause the infringement. See *Monsanto v Schmeiser* [2004] 1 SCR 902, 2004 SCC 34 in which absence of intentionality was asserted where the growing of patented plants was an infringing 'use' of the patented product. The *scope* of biotechnology patents, particularly product patents over genes and DNA sequences, may also be an issue, not because it infringes on science, but because its gives the patentee control over *subsequent uses* of the product, even for uses that they did not envisage or know about, creating a potential disincentive to others to look for other uses for the product.

scientific commons, or at least the essential function of disclosure (or its private counterpart, knowledge transfer) in order to ensure public access to new knowledge.

The reality is that the new mode of public research in fields such as biomedicine is neither open science *nor* industrial technology. Public science has not simply metamorphosed into private industrial technology, nor is it clear that it is heading in precisely that direction, but neither does it conform to the norms of open science. It no longer fits either of the 'old' boxes. The proprietisation of *public* science is one aspect of the development of modern scientific technology across the *public and private* sectors and that the facilitation discourse is inhibited if we continue to frame our approach to these changes in terms of an unsustainable distinction between science and technology. Attempts at governance, I suggest, require a more integrated conceptual foundation upon which to move forward. To understand the new landscape we need to recalibrate our thinking, by abstaining from presumptions and generalisations about openness and commercialisation that are rooted in the received doctrines of open science and industrial technology. Before setting out my perception of the new conceptual landscape, however, I outline the implications of the changes that I described above for patent law, public policy and the development of new ideas regarding new paradigms of science and technology.

Patent law

Scholars in the patenting of academic research have identified at least two different situations in which the presence of patents might potentially hinder research. The first is the grant of '*broad*' patents over research tools: *techniques* that are widely used in a field, *materials* that are frequently used as inputs, or key *pathways* for research. The other is the grant of a profusion of patents in a particular field, so that any one piece of new research may be dependent upon access to '*multiple*' patented technologies. The concern in regard to the broad patent is that the holder could either reserve to itself the exclusive right to use the tool, or aggressively prosecute unlicensed use. The allegation in regard to multiple patents is that the burden of time and cost involved in negotiating the licenses necessary to avoid infringement creates

a disincentive to ongoing research in fields characterised by patent congestion. In each of these situations, perspectives regarding the effect of patents on research are informed by a range of doctrinal theory, anecdotal evidence and empirical studies.

Multiple Patents

Concerns about the effect of multiple patents are heavily supported in theory but are not necessarily borne out in practice. In theory, patent congestion occurs where the advance toward a useful product or technique involves transgression on several patents held by different parties. The more patent claims there are to negotiate for a given piece of research, the more time-consuming and costly for the user.[720] Given the cumulative nature of research, and the speed of technological change, the trend to proprietary science has raised fears that access and licensing difficulties[721] may result in a paradoxical *underuse* of new technologies, thus stifling ongoing research. This 'tragedy of the anticommons'[722] is the reverse of the metaphor of the 'tragedy of the commons'[723] used to explain the *overuse* of *commons* property when there is no incentive to conserve. A resource is prone to overuse when too many owners each have a privilege to use it and no one has a right to exclude another.[724] A scarce resource is prone to underuse when multiple owners each have a right to exclude others from it and no one has an effective privilege of use.[725] Proponents of the theory claim that biomedical research is a key area in which competing patent rights could lead to a reduction in innovation: that the unintended consequence of the proliferation of intellectual property rights upstream may stifle life-saving products

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[720] Heller MA and Eisenberg RS (1998) Can Patents Deter Innovation?, 698.
[721] Rai AK (2005) 'Open and Collaborative Research: A New Model for Biomedicine', in Hahn RW (ed) *Intellectual Property Rights in Frontier Industries: Software and Biotechnology*, AEI-Brookings Press, Washington DC 131, 132.
[722] Heller MA (2008) *The Gridlock Economy: How Too Much Ownership Wrecks Markets, Stops Innovation, and Costs Lives*, Basic Books, New York; Heller MA (1998) 'The Tragedy of the Anticommons: Property in Transition from Marx to Markets' 111:3 *Harvard Law Review,* 621; also May C (2009) 'On the border: biotechnology, the scope of intellectual property and the disseimination of scientific benefits, in Castle D (ed) (2009) *The Role of Intellectual Property Rights in Biotechnological Invention*, Edward Elgar Publishing 252, 262.
[723] Hardin G (1968) 'Tragedy of the Commons' 162 *Science* 1243.
[724] Heller MA and Eisenberg RS (1998) 'Can Patents Deter Innovation? The Anticommons in Biomedical Research' 280 *Science* 698.
[725] *Ibid.*

further downstream in the course of R&D. Too many property rights can arguably block innovation, and prevent useful and affordable products from reaching the marketplace.[726] They assert that 'privatisation of biomedical research must be more carefully deployed to sustain both upstream research and downstream product development'.[727]

Empirical studies in the field of biomedical research however suggest that the need to assemble a large number of permissions or licenses before being able to go forward, is not particularly problematic. The Walsh results[728] demonstrate that although commercial activity is widespread among academic researchers, patenting does not significantly restrict access to *intangible* knowledge inputs essential to research. From a random sample of interviewees, no researcher reported that a project had been stopped as a result of external patents on research inputs necessary to their work, and only 1% reported delays of more than a month.[729] Regarding research tools, a number of the more important general purpose ones are available to all who will pay the price, and while in some cases there were complaints about the price, at least they were available.[730] The studies did not however measure the number of patents impinging on any given piece of research, and researchers indicated a lack of awareness by the interviewees with regard to the existence of the relevant patents.[731] They did however indicate that obtaining access to *tangible* research inputs of others was more problematic than knowledge inputs, and more likely to impede research. Further analysis suggested a distinction between legal and practical excludability in academic research and the need to look beyond patents to understand the restrictions on the flow of information across biomedical research.[732] It was concluded that

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[726] *Ibid.*
[727] *Ibid.*
[728] Walsh JP, Arora A and Cohen WM (2003) 'Effects of Research Tool Patenting and Licensing on Biomedical Innovation' in Cohen WM and Merrill S (eds) (2003) *Patents in the Knowledge-Based Economy*. National Academies Press, Washington DC, 285; Walsh JP, Arora A and Cohen WM (2006) 'Roadblocks to accessing biomedical research tools'. Paper presented at the CSIC/OECD/OEPM Conference, 'Research use of patented inventions', Madrid, Spain, 18-19 May 2006.
[729] Walsh JP et al (2003) Effects of Research Tool Patenting, 285; Walsh JP et al (2006) Roadblocks.
[730] Walsh JP et al (2003) Effects of Research Tool Patenting, 285;
[731] *Ibid,* 285; Walsh JP et al (2006) Roadblocks.
[732] Cohen WM and Walsh JP (2008) 'Real Impediments to Academic Biomedical Research' in Jaffe AB, Lerner J and Stern S (eds) *Volume 8: Innovation Policy and the Economy*, National Bureau of Economic Research, University of Chicago Press, Chicago.

patents are not apparently determinative, and what matters is a combination of academic and commercial incentives and effective excludability.[733]

These results are largely supported by an international analysis[734] and a study of the Canadian stem cell research community.[735] The former found that IP protected technologies 'remain relatively accessible to the broad scientific community'. The Canadian study indicated that although many researchers believe that patents may have adverse effects on research, very few have encountered any in practice. Researchers, while admitting to withholding data to protect patenting opportunities, maintained that patents did not contribute to publication delays, and felt that the pressure to commercialise their research was reasonable.[736]

Broad Patents

Another problem associated with changes in patent law and practice is that of 'broad' or 'blocking' patents.[737] This is a central difficulty in a rapidly changing field of technology, where the thing that is innovative at the time of patenting may quickly become standard practice; the significance of the patent criterion of novelty is soon diminished and the patent becomes a limitation on standard practice rather than an encouragement for invention.[738] Such patents may be problematic if the patent holder aggressively prosecutes unauthorised (unlicensed) use of the technology or refuses to license, reserving exclusive rights to further research using the tool. The empirical studies cited above[739] identified a number of such situations, in which the holder of a patent on a key input or pathway did not widely license, and in some

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733 Cohen WM and Walsh JP (2008) Real Impediments.
734 American Association for the Advancement of Science (2007) *International Intellectual Property Experiences: A Report of Four Countries Project on Science and Intellectual Property in the Public Interest,* Directorate for Science and Policy Programs, American Association for the Advancement of Science, Washington DC.
735 Caulfield T, Ogbogu U, Murdoch C and Einsiedel E (2008) 'Patents, Commercialisation and the Canadian stem cell research community', 3:4 *Regenerative Medicine*, 483.
736 AAAS (2007) International Intellectual Property Experiences.
737 Merges R, Nelson RR (1990) 'On the Complex Economics of Patent Scope' 90 *Columbia Law Review* 839.
738 May C (2009) On the border, 265.
739 Walsh JP et al (2003) Effects of Research Tool Patenting 285; Walsh JP et al (2006) Roadblocks.

cases sought to preserve an exclusive monopoly over use of the technology.[740] These were not limited to the private sector, but arose in relation to patented work that had benefited from some degree of government funding.

The foundational U.S. patents obtained by Wisconsin Alumni Research Foundation (WARF)[741] over human embryonic stem cells are a case in point. Shortly after James Thomson reported that he had developed the first line of hESC cells[742] (which he mildly suggested 'should be useful in human developmental biology, drug discovery and transplantation medicine), three patents ensued. These were issued to Thomson by the United States Patent and Trademark Office (USPTO), assigned to WARF as his sponsoring non-profit organisation, and applied throughout the United States. WARF did not file for patents in Asia, but did file at the European Patent Office and in individual European member states. The three patents claim, respectively: the general class of primate embryonic stem cells; human embryonic stem cells; and the proliferating hES cells maintained without the growth factor LIF, a protein normally expressed in the developing embryo.[743] The third of these, which is 'stunning in its breadth'[744] covers:

'A replicating *in vitro* cell culture of human embryonic stem cells comprising cells which (i) are capable of proliferation in in vitro culture for over one year without the application of exogenous leukemia inhibitory factor, (ii) maintain a karyotype in which the chromosomes are euploid through prolonged culture, (iii) maintain the potential to differentiate to derivatives of endoderm, mesoderm, and ectoderm tissues throughout the culture, and (iv) are inhibited from differentiation when cultured on a fibroblast feeder layer.'[745]

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[740] For an overview of the mixed anecdotal and empirical evidence on the effects of withholding or secrecy on research see: Rodriguez V (2009) 'Access to Data and Material for Research: Putting Empirical Evidence into Perspective' 28:1 *New Genetics and Society* 67.

[741] Sterckx S (2008) 'The European Patent Convention and the (Non-)Patentability of Human Embryonic Stem Cells – The WARF Case' 4 *Intellectual Property Quarterly* 478; Plomer A, Taymor KS and Scott TC (2008) 'Challenges to Human Embryonic Stem Cell Patents' 2 *Cell Stem Cell* 13.

[742] Thomson JA, Itskovitz-Eldor J, Shapiro SS, Waknitz MA, Swiergiel JJ, Marshall VS and Jones JM (1998) 282 *Science* 1145.

[743] Plomer A et al (2008) Challenges 13.

[744] Conley J, Dobson AW, Vorhaus D (2010) 'WARF Reexamination Takes Another Bite Out of Biotech Patents', *Genomic Law Report*, a publication of the law firm Robinson Bradshaw and Hinson, available at http://www.genomicslawreport.com/index.php/2010/05/19/warf-biotech-patents/, accessed 7 December 2012.

[745] Conley J et al D (2010) WARF Reexamination.

With the exception of the reference to exogenous 'leukemia inhibitory factor' (LIF), this is a definition of a stable human embryonic cell line. Thus, any cell line with these characteristics, maintained without applying LIF, would infringe the patent. Although the patents also cover the process by which the cell lines are made, it is the product or 'composition of matter' claim that gives them teeth. It means that not only can WARF exploit the lines it produces, but wherever the patent is in force the company can extract a royalty-bearing licence from anyone who wishes to make *hES* cell lines *by any method*, or to use or sell them. The licensing strategies of WARF are central to the controversy over the patents. Having already taken what was considered an unusually aggressive policy toward educational and scientific institutions,[746] WARF focused its commercial strategy on a prominent exclusive licensing arrangement with Geron for the development of therapeutic and diagnostic products using hESC-based neural, pancreatic, and cardiac cells.[747] Other WARF licensees were able to conduct research in these fields, but any commercial potential was subject to approval by, and payments to, Geron.

The WARF patents were challenged in the U.S on technical grounds, and in Europe on moral grounds. Critics said the patents were too broad, failed to meet the basic requirement of novelty or 'nonobviousness', and that the aggressive approach of the holders would stifle[748] innovation.[749] In Europe, the Biotechnology Directive was interpreted to preclude patents on inventions that required the destruction of human embryos,[750] resulting in further uncertainty for Member states. Upon reexamination in the U.S., the USPTO Board of Patent Appeals invalidated the third (2006) WARF patent on grounds that it had been 'anticipated' by a 1992 patent and was obvious rather than novel, in light of 'significant guideposts' in the prior art.[751] The two related (1986 and 2001) WARF patents survived reexamination. While there are some specific differences in the wording of the claims, the three patents are very

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[746] Plomer A et al (2008) Challenges 13, 13.
[747] *Ibid.*
[748] Murray F (2007) 'The Stem Cell Market – Patents and the Pursuit of Scientific Progress' 356 *New England Journal of Medicine* 2341.
[749] Plomer A et al (2008) Challenges 13.
[750] *Ibid.*
[751] Conley J et al (2010) WARF Reexamination.

close in their structure and scope, and it is not clear why only one failed.[752] The significance of the WARF reexamination ruling for biotechnology patent law is not in the ruling on anticipation, which is dependent upon the factual circumstances of the prior disclosure. The decision may be of greater general significance for the finding of obviousness as a 'collateral attack'[753] on broad patents, particularly in relation to biotechnological inventions – the (retrospective) finding that the invention is obvious to a person skilled in the art.

Responses

All of these potential problems related to patents raise questions for governance that can be dealt with in a variety of ways. For the purposes of protecting the regime of science from encroachment, it is not clear that problems of broad or multiple patents can be adequately addressed by changes to patent law. This is primarily because the patenting of research tools as opposed to final products or processes, questions of subject matter patentability (discoveries versus inventions) and the appropriate scope of patents will always be difficult to discern. 'One can urge several things of the patent office and the courts, but the problem of innately blurry lines will remain.'[754] Arguments can be made in favour of *restricting the patenting of discoveries* of natural phenomenon by requiring that the subject matter be demonstrably 'artificial' or a 'substantial transformation', and limiting the scope of patents to 'artificial' outputs or elements. The *breadth of patents* could be limited by ensuring that claims do not exceed what has been achieved in practice. In the case of a process for purification of natural substances, patentability could be *limited to the process*, excluding the purified product *per se*. The meaning of 'utility' or 'usefulness' could also be given a more restrictive interpretation that requires a more compelling

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[752] *Ibid.*

[753] Compare this with a 'frontal attack' on the patentability of genes in the *Myriad* case, for example: Conley J (2009) 'The ACLU v Myriad Genetics Suit: Legitimate Challenge or Publicity Stunt?' *Genomic Law Report*, a publication of the law firm Robinson Bradshaw and Hinson, available at http://www.genomicslawreport.com/index.php/2009/06/04/aclu-v-myriad-genetics-suit-legitimate-challenge-or-publicity-stunt/ accessed 7 December 2012.

[754] Nelson RR (2004) The market economy, 466.

demonstration of significant progress towards a particular practical solution.[755]

Public policy

The implications of the major shift in government policies toward patenting and licensing of public research are by now apparent. It is evident that the attitude of the patent holder plays a strong role in the effect that patents have upon scientific research, as exemplified in the WARF patent scenario, where the holder controls access to research tools which are key to future avenues of research as well as the solutions to practical problems.[756] The Royal Society in the UK asserts that '[T]he problems associated with intellectual property rights are not primarily due to its format, nor to ideas about how best to deploy it. The problems lie with those who use it.'[757] The claim is supported by the 'Hargreaves Review'[758] in the UK, which found no evidence that intellectual property causes harm to the research community that cannot be remedied by better local practices.

Attempts to influence government and university policy is therefore the objective of other strategies, apart from patent law amendment, for protecting the scientific commons. These focus on promotion of an explicit research exemption, and attempts to persuade universities from harmful patenting practises.

Research Exemption

The point of disclosure as a *quid pro quo* for a grant of patent is to ensure that technical information about an invention is available for use by researchers for ongoing innovation – though not its exploitation - during the patent period. It is not always clear however what constitutes permissible research activity and what infringes the patent, even though many jurisdictions include research exemption provisions in their patent legislation.

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[755] *Ibid.*
[756] *Ibid.*
[757] The Royal Society, *Science as an Open Enterprise*, 46.
[758] UK Intellectual Property Office (2011) *Digital Opportunity: A Review of Intellectual Property and Growth*, Supporting Document U: Universities, Research and Access to IP, available at: http://www.ipo.gov.uk/ipreview-documents.htm

In the U.S., universities until recently relied on judicial statements in support of a 'experimental use' exemption - to the effect that use of a patented product for pure research purposes does not infringe a patent - coupled with the fact that in practice industrial firms were likely to give academic researchers a *de facto* exemption. With university patenting, however, industrial firms are now more likely to see university researchers as direct competitors for practical patentable results - and to require universities to obtain licences to access their patented resources, just as universities require licences from firms prior to use of *their* patented results. In 2002 this position was upheld in *Madey v Duke,*[759] which defined the exemption narrowly and said that universities did not benefit from it, on grounds that research is a core business of universities and it is therefore reasonable for an external patent holder to require them to obtain a licence in order to use patented material in research. The court found that:

'…regardless of whether a particular institution or entity is engaged in an endeavor for commercial gain, so long as the act [research] is in furtherance of the alleged infringer's legitimate business and is not solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry, the act does not qualify for the very narrow and strictly limited experimental use defense. Moreover, the profit or non-profit status of the user is not determinative.' [760]

The decision also undermines potential for wider exemption of basic research by way of new legislation, given the difficulty of distinguishing 'basic research' from other university research, much of which falls within 'Pasteur's quadrant', as previously discussed.

In Europe there is no harmonised approach to research exemptions. Serious uncertainties about the boundaries of the UK exemption[761] has led to the launch of a consultation by the UK IPO in an attempt to obtain some clarification. At present, the defence is limited to acts that are carried out *on* or *into* the invention rather than *with* or *using* the invention. Acts to test a hypothesis about the invention, or to

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[759] *Madey* v *Duke University* (2002) 307 F.3d 1351; 64 U.S.P.Q.2d (BNA) 1737; United States Court of Appeals for the Federal Circuit.
[760] *Ibid.*
[761] *UK Patents Act 1977*, s. 60(5).

develop and improve the invention would generally be safe, but the use of a patented 'research tool' in an experiment unrelated to the subject matter of the invention would not come under the exemption. The exemption does not permit collection of information in regard to regulatory approval of a product;[762] nor does it apply when the preponderant purpose of the defendant is to generate revenue, and conduct of experimental investigation into the invention is secondary.[763] In relation to pharmaceuticals, a specific exemption (the 'EU Bolar' provision[764]) has been adopted to permit pre-clinical studies and trials of medicinal products.

Modification of *Bayh-Dole*

A second strategy for influencing university policies in favour of patenting would be to attack or amend the existing *Bayh-Dole* style laws. The argument for limiting commercial incentives is that as long as public sector work remains publicly funded, proprietary control of its resources is not essential to the survival of universities in the same way that it is to private corporations. While the ability of *private sector* researchers to control their use of results and tools is an important incentive for the research that creates them, this is not usually the case in regard to research funded by *government* grant.[765] It is irrelevant that universities are now conducting 'applied' research, because they have been doing so for years prior to the move toward patenting. Whether or not to patent arguably remains at the discretion of the researcher, institution or government sponsor and a large part of the problems of commercialisation therefore falls on the shoulders of government and university policies.

Further, *Bayh-Dole* legislation could be amended to discourage potential for exclusive or narrow licensing, and to counter rhetoric suggesting that release of research results into the public domain does not encourage use. Non-exclusive

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[762] *Monsanto Co v Stauffer Chemical Co* (1985) Reports of Patent Cases 515, Court of Appeal.
[763] *Corevalve Inc v Edwards Lifesciences AG* [2009] EWHC 6 (Pat).
[764] EU *Directive 2004/27/EC*, *Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004* amending Directive 2001/83/EC on the Community code relating to medicinal products for human use (2004) OJ L136/34, Article 10(6).
[765] Nelson RR (2004) The market economy, 466.

licensing arrangements are not necessarily an impediment to the advance of research, especially where the patented research tools are of wide application, or where successful development would find a large market.[766] The Cohen-Boyer patents provide an example of non-exclusive licensing of university patents that attracted many users. There is also evidence to suggest that private pharmaceutical companies may be willing to work on the basis of non-exclusive arrangements with university patented findings if there is sufficient foreseeable potential for development of treatments.[767] The point is that if universities want to patent their results as a means of generating university income, they should undertake to license the results to all who want to use them, at reasonable fees. The licensing fee is not, within reason, an issue as long as results are made widely available.

The huge increase in patenting and licensing of research that has occurred since the 1970s, both in and out of the academic sector, thus appears to be as much a result of economic and institutional changes, patent laws and policies, as of technological breakthroughs.[768] The debate, as I have said, has focused on the effect of proprietisation of research in the *public* realm of science and the universities in particular[769] even though a patenting boom has occurred simultaneously in the industrial sector. Many scholars have either 'sounded the alarm',[770] sought to define and protect an optimal sphere of pure science, or attempt to minimise the impact of patenting and licensing policies on the research commons. These approaches seek to prevent commercialisation of science in the public arena or, failing that, to ensure that the proprietary science that happens in the public sphere is as open as possible. In the next chapter, I demonstrate that many of the collective approaches to the use of research resources employ innovative structural arrangements to achieve particular goals, but are similarly oriented toward protection of the scientific commons.

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[766] *Ibid.*
[767] Colyvas J, Crow M, Gelijns A, Mazzoleni R, Nelson R, Sampat B (2002) 'How Do University Inventions Get Into Practice?' 48:1 *Management Science* 61.
[768] Asheim et al (2009) Intellectual property rights and innovation systems, 66.
[769] Brown JR (2000) 'Privatizing the University' 290 *Science* 1701.
[770] Mirowski and Van Horn (2005) 'The Contract Research Organisation and the Commercialization of Science, 35:4 *Social Studies of Science* 503, 503.

New paradigm?

The changes to science and technology as described have implications not only for patent law and public policy, but also scientific theory, giving rise to growing speculation about the emergence of a 'new paradigm' or 'paradigms' of science.

Technological Science

The idea of a new paradigm of technological science is articulated in various ways, but there is a prevalent sense among scholars, public authorities and others, that the increasing characterisation of science as technical and proprietary is not only a massive trend but irrevocable, given its embeddedness in a wider set of technological changes and economic and political circumstances. Everyone concerned is beginning to look for patterns to emerge from the disruption of the traditional system of open science. A new *technological* paradigm of science is seen in its orientation toward the solution of technical or practical problems, in its integration with multiple technologies, and in the new technological tools that it applies: particularly the power of modern computers and informatics, which are capable of not only supporting traditional scientific enquiry but fundamentally changing the development of a discipline.[771]

Proprietary Science

The accommodation of the commercial incentives of patenting and licensing within the scientific ethos has generated a new paradigm of *proprietary* science, as discussed above, which nevertheless pertains primarily to science in the public sphere.[772]

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[771] The Royal Society, *Science as an Open Enterprise*, 31.

[772] For a re-examination of the effect of modern developments in relation to the postwar Bush regime in the U.S., see *Science the Endless Frontier: Learning from the Past, Designing the Future*, Highlights of the Conference Series held 1994-1996 at Columbia University, Consortium for Science, Policy and Outcomes, Arizona State University.

Privatised Science

An even wider shift is envisioned by proponents of a paradigm of *privatised* science. These suggest that the focus on commercialisation within the universities obscures the full extent of the privatisation of science on other fronts, and that the restructuring of scientific research since the 1980s is a subset of larger political and economic trends in the privatisation of science, to which universities are relative latecomers.[773] They assert that the development of the services of the 'contract research organisation' and the migration of scientists away from academia, to start up their own businesses or as employees of existing corporations, should not be viewed as 'the dubious behaviors of a few misguided individuals or transgressions of the terminally greedy',[774] but as structural changes in the organisation of science that are 'harbingers of the future of privatized science'.[775]

The advocates of science undertaken in a 'for-profit modality' insist that privatisation has had no adverse effects upon the conduct of research. As a major spokesperson for the industry put it:

'Those of us who choose to pursue clinical science within the CRO industry reject the assumption that wisdom and ethical behavior are solely the province of the academy or the government. We reject also the presumption that the pursuit of profit along with the progress of science and medicine is inherently in conflict. In fact, in our experience the marketplace accurately reflects the public's hopes and expectations for science, and is a powerful guardian of behavior. It has little tolerance for shoddy performance or misapplied energies. It is a powerful mechanism for progress, for which no apologies are needed.'[776]

The 'regime of industrialised research', they argue, implies a necessary reordering of the goals of scientific research, the conduct of research on human subjects, the controls applied to disclosure and confidentiality, the management of intellectual property (especially 'research tools'), and the role and functions of publication, all of

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[773] Mirowski and Van Horn (2005) The Contract Research Organisation, 503.
[774] *Ibid.*
[775] *Ibid.*
[776] Mirowski and Van Horn R (2005) The Contract Research Organization, 507 quoting Helen Davies speaking at a presentation delivered to the Institute of Medicine on 21 August 2001 on 'The Role of the Private Sector in Protecting Human Research Subjects: A CRO perspective'.

which are under discussion in the legal and medical literatures.[777]

Post-academic Science

The 'privatised science' paradigm merges into the *post-academic* paradigm[778] of science, which emphasises both continuity and discontinuity between academic and industrial research. It is based on observation of the 'radical, irreversible, worldwide transformation in the way that science is organised, managed and performed'[779] and reiterates that the new mode of science is driven by 'counter-Mertonian norms' that have 'subverted the idealised social order of academia'. Rather than communal, universal, disinterested, original and sceptical, industrial science is now construed as characteristically 'proprietary, local, authoritarian, commissioned and expert'.[780] *Discontinuity* is identified in the pressure upon scientists to deliver obvious value for money, and the norm of utility that pervades modern research culture. Competition for research funding transforms the forum of scientific opinion into an actual market in research services in which commercial evaluation of scientific discoveries may take priority over scientific validation; as scientists are not well-equipped to assess the utility of their work, expert peer review expands into 'merit review' by non-specialist 'users.' Further, post-academic research is no longer independent of the influence of other actors in the market with similar material interests, with respect to everything from the formulation of projects to the interpretation of outcomes. This has direct repercussions for disclosure, because although scientists may tell 'nothing but the truth', they may be prevented, in the interests of their employers, clients or patrons, from revealing the 'whole truth', including negative results or doubts that would put a very different complexion on their testimony. What is *not said* may corrupt the meaning of what is communicated, with potentially damaging impact on the credibility of scientists and their institutions.

Continuity, on the other hand, is also found here in the development of much closer

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[777] Mirowski and Van Horn (2005) The Contract Research Organisation, 507.
[778] Ziman J (2000) *Real Science: what it is and what it means,* Cambridge University Press, Cambridge; Ziman J (1996) 'Postacademic science: constructing knowledge with networks and norms' 9:1 *Science Studies* 67.
[779] Ziman J (2000) *Real Science.*
[780] Rodriguez V (2009) Access to Data 67.

relationships between academia and industry, and comparable conditions and results in regard to the research conducted in each. Members of this camp argue that with the proprietisation of academic science, industrial scientists now experience little difference in autonomy or openness than their academic colleagues:[781] *both* want to work in environments in which they can do *interesting work* and enjoy a degree of freedom in doing so.[782] There is no clear difference, they suggest, in the quality of the results of university and industrial science,[783] and any presumption to the effect that industrial R&D requires less intelligence than 'pure' research is unsustainable.[784]

To conclude this section, what emerges from all of these changes and the various types of responses to them is a diverse and rapidly evolving landscape in which research, innovation and production are carried out by a variety of different types of actors in many different organisational arrangements across the public and private sectors. Much of the literature is oriented toward the defence of the scientific or research commons, rather than industrial technology, even as it recognises that the changes to science may be representative of a wider paradigm of privatisation.

At this point, I want to remind the reader of the purpose of my analysis of openness in science, technology and the present realities of scientific technology. I recall from Chapter 2 that the policy goal is not merely the advancement of knowledge, but the delivery of cell-based therapeutic products for clinical use or 'improvements in public health'.[785] In Chapter 3, I said that 'a public good is not a single good, but an *effect* involving complex antecedents: complementary goods (private and public) and the activities of different types of social actors'.[786] I also suggested that modern 'scientific technology' - the synergy of science and technology - is the means to production of public goods such as stem cell therapies, and that 'facilitative'

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[781] Shapin S (2008) *The Scientific Life: A Moral History of a Late Modern Vocation*, University of Chicago Press, Chicago, from interview with author, available at http://www.press.uchicago.edu/Misc/Chicago/750248in.html, accessed 10 December 2012.
[782] *Ibid.*
[783] *Ibid.*
[784] *Ibid.*
[785] UK Stem Cell Bank, Research Use Licence, annexed to the Code of Practice for the Use of Human Stem Cell Lines, s. 2.17.
[786] Drahos P (2004) The Regulation of Public Goods 321.

governance is able to address complexity, fragmentation, interdependencies and overlaps between public and private, in order to ease the way.

The way to such facilitation, I suggest, is through development of an integrated conceptualisation of modern scientific technology that accurately observes and describes its real objectives, functions and operations. In the next section, I 'stand back from the landscape' and construe 'scientific technology' as an overarching 'system' rather than a set of isolated components in order to identify the unifying concepts, connections and complementarities among its actors and activities. It is the construction of existing features and functions as an integral whole that provides a sound conceptual foundation upon which to develop effective approaches to facilitative governance; it is not necessary to define the system as a new model or 'paradigm'. Theories of 'technological science' and 'proprietary science' each observe changes in specific components of the system, without defining the factors that connect the whole. The Mirowksi and Van Horn proposition of a new paradigm of 'privatised science'[787] is, in my view, an overstatement of the extent to which the private sector does and will for the foreseeable future dominate scientific technology. Similarly, the Ziman 'post-academic' paradigm[788] overreaches in its attempt to contrive a predominantly proprietary model of science, rather than recognising the variety and diversity of organisations and actors, resources and types of exchange, that presently characterise the realm of scientific technology.

Finally, my conceptualisation of scientific technology in this chapter is not undertaken in an attempt to determine whether and how it might be possible to ensure that publicly funded 'science' remains 'open'. I am primarily interested in understanding the conceptual bridges between basic science and technological research in the public sector, *and* technical research in the private sector *and* private industrial research and development and production, *so that* all of these energies might be brought ultimately to fruition in the production of public goods. One of the

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[787] Mirowski and Van Horn (2005) The Contract Research Organisation, 507.
[788] Ziman J (2000) *Real Science: what it is and what it means,* Cambridge University Press, Cambridge; Ziman J (1996) 'Postacademic science: constructing knowledge with networks and norms' 9:1 *Science Studies* 67.

contributions of my thesis is the identification of certain features that integrate 'scientific technology' across the public and private sectors.

6.5 Integrational concepts

Synergy

The primary factor integrating the modern complex of scientific technology is the synergy or synergies that exist between science and technology, and between different fields or disciplines of science and technology. While some suggest that modern research constitutes a complete merger or *unification* of science and technology, I hold to the view that close association between them does not negate their different orientations and objectives, any more than it negates the different types of expertise contributed by different disciplines. A conceptual, if not very practical, distinction between science and technology still holds, because although the window of opportunity may be small – scientific enquiry can still be conducted without any utilitarian aim; similarly, technical research could still, in theory, proceed with little scientific understanding of its own utilitarian advances. The fact that in modern practice research occurs *least* at these two ends of the spectrum is not, I suggest, an indication that most research entirely obliterates the distinction between science and technology.

That scientific technology is defined by research between these two poles - in which science is inspired by and directed toward practical ends and technology is informed by the explanatory power of science - indicates rather that science and technology are *interdependent*, or *symbiotic*, in that they are drawn to, rely upon and contribute to one another from their respective strengths and capabilities. The rapidity and intensity of the co-evolution of understanding and practice[789] in sophisticated research makes it difficult and pointless to try to discern individual contributions, but it is their very *differences* that create complementarity between them, and their

[789] Nelson RR (2003) The advance of technology, 1691.

complementarities that when combined are capable of outcomes that neither science nor technology is able to produce on its own.

The same is true of the contributions made by different disciplines. Fields such as regenerative medicine integrate a variety of technologies that have themselves reached a certain stage of maturity, opening the way for the exploration of new frontiers in the *combination* of once apparently disparate fields. It is the combination of a variety of tools that stimulates innovation which, as I discuss below, involves the reconfiguration of fundamental elements in pursuit of complementarities and fruitful conjunctions. Such synergies are therefore a basic integrational rather than divisive feature of modern scientific technologies.

Research

The second integral feature of scientific technology is *research*. The literature is full of references to different types of research: basic, pure, scientific, applied, technical, developmental, translational, commercial, non-commercial, upstream, downstream etc.[790] However useful these labels may be to describe what is happening in a given context, for the purposes of facilitation all research is equal. The aim of strategies for the advancement of both knowledge and the production of goods is to create environments that are conducive to all types of research, without distinction.

The bifurcation between 'public' science and 'private' technology results in distinctions, such as those between *basic and applied*, and *commercial and non-commercial* research, that are problematic in the current research environment. Despite their common useage, these distinctions are not clear, and attempts to define and use them in a regulatory capacity are fraught with difficulty. 'Basic' research for example could mean 'early' or 'exploratory' scientific or technical research in relation to a question, subject area, problem or field, but given the cumulative knowledge upon which new enquiry rests and the pace at which it advances, it is

[790] For a categorisation of types of research in health, see Cooksey D (2006) *A review of UK health research funding*, HMS Treasury.

difficult to distinguish 'basic' from that which is the application of something else.[791] Further, basic and applied research have merged in the academic setting, so that the 'application' of knowledge to practical problems now falls under the auspices of scientific research as well as by private firms for purposes of development of products. 'Basic' might refer to 'pure' research, as in scientific enquiry that is not externally 'directed' toward a utilitarian aim, which eliminates most modern research, as previously discussed. Or it might be used to mean 'upstream' in the innovation process, without clarity as to the point at which 'upstream' becomes 'downstream' research.

The distinction between commercial and non-commercial in modern research is equally difficult. Licensing arrangements and material transfer agreements may employ it in various ways: to define the scope of permissible (non-commercial research) use of resources; or to trigger a mechanism (upon determination of a foreseeable commercial potential for licensed research) for negotiation of a separate commercial agreement, or allocation of intellectual property rights. The latter is the situation in the 'Research Use Licence' of the UK Stem Cell Bank. The problem is that in 'Pasteur's quadrant', where the whole field is oriented toward a practical outcome with a potential for commercialisation, there is no point at which research can be characterised as 'non-commercial'. From an industry perspective, determination of actual commercial interest, in a stem cell line, for example, is determined by the existence of a potentially marketable and profitable product or service, on the basis of a satisfactory *commercial risk assessment*. A stem cell line, and the research that it is involved in, could be of commercial interest, therefore, whether it is earmarked for use as a research tool, or for potential clinical application. Equally, potential clinical products may be of no commercial interest if the assessed risks cannot be overcome. In principle, however, all types of research are conducted for a commercial purpose and hold commercial potential.

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[791] Eisenberg RS (1987) Proprietary Rights and the Norms of Science.

The U.S. case of *Madey v Duke*[792] which I referred to earlier, made this point quite clearly when it found that as research was the '*legitimate business'* of the university the research exemption did not apply, regardless as to the 'for profit' or 'not-for-profit' status of the organisation. In effect, all research is of a commercial nature; there is no such thing as 'non-commercial' research in the context of modern scientific technology.

For purposes of facilitative governance this is the preferable approach, because the goal is to encourage people to use resources for all types of research, and to find practical and *commercial* as well as research uses for them. The creation of distinctions between basic and applied, commercial and non-commercial research, arguably discourages potential users from accessing and using resources in ways that will maximise research and produce new innovations. Research is the second consistent feature of scientific technology.

'Innovation'

The third integrational concept in the regime of scientific technology is *innovation*. The pursuit of 'innovation' is the common aspiration - the *raison d'etre* - of both science and technology, in academia and industry. In the previous two chapters I described the perception and process of innovation in science and in technology: science as intellectual discovery, and in industry the intellectual property embodying a new useful method or product, as well as the whole process of development, wrapped up with exploitation, that gave birth to it. I also pointed out that the failure of the literature of industrial technology to articulate the distinction between the *creative event* and the industrial process is a potential source of confusion, and that innovation in technology, as well as science, is rooted in the pursuit of new knowledge. Here I expand slightly on the nature of innovation, in order to demonstrate both its integrative function in scientific technology, and how it might be facilitated.

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[792] *Madey* v *Duke University* (2002).

'Innovation' in the broadest sense is the emergence of something new, unique, or different than what has gone before. It is not necessarily the result of human initiative, but is the source of novelty and diversity that occurs throughout the natural world and in human society. In nature, for example, innovation occurs in the biological processes that generate new species and genetically unique individuals. In social relations, negotiation may result in new understanding of the respective interests of the parties, bringing accord where none was possible before. In product design and manufacture, basic materials are transformed into complex goods that are essentially different than the sum of their component parts.

Recombinatory Process

What is common to all of these situations, and which I suggest is the essence of innovation in science and technology, is that novelty and diversity are the result of new configurations or 'recombinations' of some set of essential 'elements'. This notion comes from the literature of industrial innovation, in which it has been said that innovation is an interactive process that does not happen in isolation,[793] which 'combines factors in a new way', resulting in 'new combinations'.[794] Scholars in the economics and sociology of science also refer to fruitful 'conjunctions'[795] in the generation of knowledge.

The concept of fundamental reconfigurations as the basis of radical innovation is best illustrated by the natural biological process of sexual reproduction. The innovation in sexual reproduction is in the new combination of genetic material that occurs at fertilisation, and in the process of meiosis that precedes it. Not only does fertilisation combine the two sets of chromosomes from the parental gametes, but the single set of chromosomes contained in each of those gametes – egg and sperm – is a scrambled version of the genome of the parent that produced it. The genome of that

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[793] Woolthuis RK et al (2005) A system failure framework, 609.
[794] Schumpeter (1939) *Business Cycles*, 87-88; Lundvall BA (ed) (1992), *National Systems of Innovation: Towards a Theory of Innovation and Interactive Learning*, London: Pinter, 8; Elam M (1992) *National systems of innovation in social and political theory.* Paper presented at the EASST/4S Conference, Gothenburg, Sweden, 12-15 August, 3.
[795] David P (2003) SIEPR, 4.

parent is itself a combination of two sets of chromosomes, each of which derives from a gamete that contains a mixed up version of the genome of the grandparent, and so on.

The scrambling, or 'homologous recombination' of genes, takes place in *meiosis*, the type of cell division particular to the production of gametes. The two sets of chromosomes present in an ordinary diploid cell are duplicated, and an exchange or crossover of pieces of genetic material occurs between the duplicate pairs before the cell undergoes two further divisions. The result is four haploid gametes, each of which is genetically distinct from the individual that produced them. Fertilisation then combines the haploid egg and sperm, reinstating a duploid chromosomal complement in the zygote to produce genetically unique offspring.

In this natural system of innovation, the basic elements that are being reconfigured are tangible genetic materials. Fertilisation is the crucial *engagement* of the elements that facilitates the recombination and thus unique offspring: the introduction or *accessibility* of the gametes to one another, even within a conducive environment, cannot guarantee that it will occur. The result is genetic diversity in sexually reproducing populations, as well as the 'phenotypic' variation in physical and behavioural attributes, upon which natural selection can act.

The enterprise of scientific technology for the production of new knowledge, by contrast, involves the engagement of human minds in the reconfiguration of intellectual elements including data, information, ideas, theories, design[796] and existing knowledge. How 'newness' and 'knowledge' are to be defined, and the nature of the inscrutable process of intellectual creativity are epistemological questions that I do not address here. The message is that however methodological the *pursuit* of innovation may be, however diligent (or mechanised) the *process* of recombining the elements, and however radical or incremental the resulting change, innovation involves *recognition* of something novel and potentially meaningful in

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[796] See Walsh V, Roy R, Bruce M and Potter S (1992) *Winning by Design: Technology, product design and international competitiveness*, Blackwell Publishing, Oxford.

the results. The essence of 'innovation', I suggest, is in this *recognition* of novelty that occurs in the creative process, which may range in effect from the mere compilation of new data, to a greater illumination of understanding of the patterns that they present.

Novelty

I am not however concerned with precise definitions of 'novelty', as various systems, including industry and patent law, define it in different ways for their specific purposes. In patent law, the inventor, by exercising choice in the research process and active involvement in the shaping of the end product, *engages with* nature to create something new.[797] In industrial technology, certain commentators view 'novelty' as the mere creation of new artefacts within the domain of the known, as distinguished from 'variation' (changes in the features and components of an artefact, without affecting its core functions or capabilities), 'improvisation' (to meet urgent demands for creative time-critical responses to crisis situations)[798] and 'innovation' which represents a more *radical* change than the others by expanding the capabilities at the edges of new technologies.[799] These scholars seek a more nuanced understanding of 'innovation' which they argue is being overused by being lumped together with the others.

The point I make is simply that it is a recognition of newness in the dynamics of creativity that is behind both discovery and invention, and which integrates scientific technology. Construed in this way, the *essence* of 'innovation' is an intellectual process and not, as often perceived in the industrial literature, the economic goods that emerge from a process of industrial technology. The new artefact or tangible product is, I suggest, a *realisation* of the innovation that occurs more fundamentally in the minds of the innovators.

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[797] Bently and Sherman (2004), 480.
[798] Scranton P (2006) 'Technology, Science and American Innovation' 48:3 *Business History* 311.
[799] *Ibid.*

Unpredictability

As a creative process, although research may be active, methodological and diligent, innovation is never entirely predictable: the identification of novel and meaningful outcomes cannot be taken for granted. The technology literature refers to 'stochastic' events that occur outside the realm of recognised cause and effect relations,[800] having a 'random probability distribution or pattern that may be analysed statistically, but not predicted with precision.[801] Innovation is construed as non-rational, 'serendipitous' and incapable of being systematised to generate predictable results, or reduced to orderly logics for purposes of effective planning. The 'pursuit' of innovation as discussed earlier may operate on the basis of a belief that the more research that is undertaken, and the more targeted it is toward particular questions, the more likely that radical innovation will occur. Funding cannot 'purchase' innovation, but it can support the search for fruitful combinations among all available resources, and though research will not always produce groundbreaking results it produces *results*, which are new intellectual elements for access and use by others in ongoing research. Nevertheless, there is always some degree of uncertainty or unpredictability in the *nature* of the results, which is a critical consideration for policymakers, funders, industrial strategists and others interested in involvement in the enterprise.

Facilitation: Access and Exchange

For governance of scientific technologies, facilitation of innovation therefore entails the enhancement of *research*, the forum for the recombinatory process. Production of new knowledge is promoted by the engagement of as many users with as many resources as possible, without regard to the domain (public or private, industrial or academic, commercial or non-profit) in which resources are held or in which the interaction occurs. The goal is wide dissemination, accessibility and exchange, and

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[800] *Ibid.*

[801] Oxford Dictionaries on-line (2012) Oxford University Press, Oxford, available at http://oxforddictionaries.com/definition/english/stochastic?q=stochastic, accessed 14 December 2012.

extensive manipulation, use and reuse of resources: a static collection of intellectual resources cannot give rise to innovation.

This notion of facilitation implies the attempt to maximise *accessibility* of intellectual and material resources held in various types of property regimes in the public and private spheres. Availability, '*access*' or authorisation to use resources does not necessarily facilitate 'accessibility' to the full extent. As I have already indicated, there is no such thing as absolute accessibility to any type of resource, whether the common property of the public domain of science, which is limited by practical barriers and public interests[802] or the private resources of industrial firms from which others may be excluded, in whole or in part, in aid of the production of commercial goods. The capacity for engagement with and manipulation of resources is a function of legal structures, the technical properties and 'packaging' of the resources in question, and the capacities of the user. The terms of a license or materials use agreement might, for example, impose legal restrictions on uses to which a licensed technology may be put. Purchase of a proprietary good may permit the consumer to 'consume' the service that it was created to provide, but not transfer the embedded technology for ongoing use. Technical barriers to access - such as the source code for computer software – may bar the type of access that enables manipulation or modification of the resource. Facilitation therefore promotes delivery and dissemination of resources for all sorts of purposes, by all types of vehicles, which provide varying degrees of technical 'accessibility'. Secondly facilitation will attempt to identify potential barriers to innovation imposed by terms and conditions of access that might impair full accessibility and (with special reference to *proprietary* products) promote accessibility that permits fundamental manipulation of the embodied intellectual resources.

Innovation is also promoted through *networks* of intellectual exchange between individuals, groups of individuals and organisations. The potential for innovation is enhanced through exchange of resources among a wide audience of potential users organised in every conceivable way, on commercial or non-commercial terms. This

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[802] The Royal Society (2012) Science as an open enterprise.

notion is supported by prevalent academic references to 'exchange', 'sharing' or 'transfer' of knowledge or technology among some set of actors or elements. In open science disclosure or publication facilitates exchange of intellectual elements through the public domain. Others draw a necessary connection between social interaction and science, suggesting that acquisition of knowledge is impossible without the interaction of social life, which is itself a form of acquiring, preserving and transmitting knowledge.[803] In industry, innovation systems theory defines a technological system as 'a network or networks of agents interacting in a specific technology area under a particular institutional infrastructure to generate, diffuse and utilise technology'.[804] The cumulative effect of the exchange of resources among all actors, and by all means, is knowledge networks that integrate pure science, 'proprietary science' and industrial technology within a '*domain of exchange'*, as discussed below.

Outside of the field of publicly funded pure academic science, the term 'openness' is therefore of limited use in describing the mechanisms, arrangements or types of social organisation that might enhance innovation through the dynamic utilisation of resources. Innovation in modern scientific technology is not facilitated solely by public disclosure, but by dissemination of knowledge through public and private vehicles and environments that enable - to varying degrees - the capacity for interaction and engagement with intellectual resources.

'Utilisation'

The fourth concept that integrates scientific technology is the notion of '*use'* or *'utilisation'* of resources. Utilisation is the flip side of innovation: if innovation is the *generation* of new knowledge, *utilisation* is the manipulation or exploitation of resources in the process. I hesitate to refer to 'use' as 'exploitation' because the traditional dichotomy between open science and private technology associates

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803 Popper K (1989) The Logic of Scientific Discovery.
804 Carlsson B and Jacobsson S (1997) 'Diversity Creation and Technological Systems: A Technology Policy Perspective' in Edquist C (ed) (1997) *Systems of Innovation, Technologies, Institutions and Organizations*, Pinter, London and Washington, 266.

'exploitation' with the commercial function that takes practical value and transforms it into economic value in the development of goods. In fact, intellectual resources are 'used' in the generation of new scientific knowledge just as they are in technology. The difference lies not only in the process but in the objectives of the utilisation. Whereas the 'use' by science or 'research' produces more knowledge for ongoing use, innovation and reuse in continual cycle, industry 'uses' knowledge to generate more knowledge, for ongoing use, but also to generate commercialisable goods. So both science and technology have always each exploited intellectual resources, but for different purposes.

'Use' of resources may seem an obvious concept, and part and parcel of innovation, but it requires different treatment in order to emphasise the need for more attention to it in every aspect of scientific technology. Literature in the governance of science and technology contains enthusiasm for the promotion of *innovation* by protecting openness in the science commons and reducing exclusion to the extent possible in the realm of proprietary research; there is less excitement about the concomitant facilitation of the 'use' of resources across public and private sectors, at least insofar as use implies commercial 'exploitation'. The mission of the scientists, as I point out in regard to commons strategies in the next chapter, is to promote *research* use, rather than *commercial* use even though, as mentioned above, the distinction is a difficult one to make in the current context of proprietary public science. To the extent that mechanisms for the promotion of research also happen to overcome barriers to commercial use, such use finds favour, but it is not pursued in equal measure. The attitude is predominantly defensive of the science commons, and antagonistic toward the background environment of the market.

This focus on facilitation of innovative uses of resources in research, and the relative neglect of industrial exploitation might seem reasonable, given that private industry is inherently motivated toward efficient production, and should be capable of looking after its own commercial interests, but this is not necessarily the case. General concern over patenting and the potential anticommons effect in public sector research may overshadow the identification of the specific problems in any given field of scientific technology. In the stem cell arena for example, it is not a given that there

are problems with encroachment of patents on research and innovation; the more apparent barriers occur further downstream, involving the huge upfront costs of development of products including clinical trials of therapeutic products, and in the EU in particular an almost certain *un*patentability of products – techniques as well as therapies - derived from embryonic stem cell lines. Accessibility to expensive cell-based resources that may not be subject to intellectual property, appropriate frameworks for assessment of commercial potential of cell-based tools and resources, and the need for incentives that might *induce* industry to take and use intellectual and material resources for *commercial* ends are the main issues that need to be addressed. The utilisation of resources for a diverse range of purposes, intellectual and practical, is therefore an integrating feature of scientific technology.

Domain of exchange

A further integrative concept of scientific technology is that of a single public *domain of exchange.* Like the term 'openness', references to a 'public domain of knowledge' have limited usefulness outside of a narrowly defined public system of science. At the end of the previous two chapters I concluded that science and technology presented as two separate systems, pulling in the same direction, one delivering its products into the public domain of knowledge for immediate access, and the other releasing its products, after a period of productive exclusion, into a public domain of commerce. In light of the current proprietisation, which fits research results for exchange in the public domain of commerce rather than the 'public domain' of knowledge, *and* the fact that the freedom of the 'public domain' has always been about freedom of access to knowledge resources rather than freedom from financial charge *per se*, it is not much of a stretch to propose that in reality there is a *single domain of exchange*, in which all types of resources are available on a variety of bases, commercial and non-commercial. *Availability* of resources in this domain does not differ from availability in the public domain of knowledge or the commercial domain of the market: as in the traditional systems of science and technology, the withholding or release of resources into the domain of exchange is a matter of choice of the holder. That the public domain of commerce should be somehow separated from the public domain of knowledge by the payment

of a fee for access seems unsustainable. That the terms of access should vary according to different arrangements for different resources, within a single domain of exchange, does not. The domain of exchange, I suggest, is neither the 'public domain' as previously conceived, nor synonymous with the commercial market. It accommodates commons and contracts, collaboration and competition.

This open domain of exchange is thus the domain of *networks,* in which actors with all sorts of interests can interact with one another in various types of relationship and organisation across different disciplines and regimes for the communication and exchange of resources, intellectual, material and monetary, in the pursuit of any number of objectives. The domain encompasses entirely private commercial transactions between proprietary actors as well as the pooling of resources held in common and shared by a community of users. It permits public-private collaborations, as well as collective arrangements that establish terms of access to common or private property for the optimal use of resources. The 'commons' strategies that I discuss in the next chapter do not fill this domain, as they sometimes suggest; they sit together with exclusively proprietary activity. *Networks of interactivity* are the cumulative result of all sorts of exchange, from individual contracts constituting narrow 'modules' of accessibility to the 'pools' of openness created by the commons.

Further, the domain of exchange is a *global* domain[805] in which international organisations and open trade regimes have a role in the worldwide dissemination of knowledge and transfer of technology,[806] permitting innovation, learning and diffusion to flourish.[807] Access to an extended commercial domain is in principle beneficial for interaction with information and technology, as well as economic development, but the ability to take advantage of global opportunities may itself be dependent upon the existence of competitive technological markets. Some level of technological proficiency by developing countries is arguably therefore a prerequisite

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[805] Maskus KE and Reichman JH (2004) 'The Globalization of Private Knowledge Goods and the Privatization of Global Public Goods' 7:2 *Journal of International Economic Law* 279, 281.
[806] Feldman R and Nelson K (2008) 'Open Source, Open Access, and Open Transfer: Market Approaches to Research Bottlenecks' 7 *Northwestern Journal of Technology & Intellectual Property* 14.
[807] *Ibid.*

to the ability to access the benefits of globalisation: an inability to absorb and implement new technologies could risk increased fragmentation and divergence from the technology-driven world economy rather than growing integration and convergence.[808]

More generally, *accessibility* of resources within this domain of exchange, for purposes of engagement, manipulability and innovation is whatever actors determine it to be. The use of specific arrangements, whether legal instruments, property regimes or social organisation, does not necessarily restrict accessibility to resources, but it means that accessibility is managed, and tailored or devised to meet particular needs. As much of the property created in scientific technology is essentially 'non-rival' intellectual property, there is great capacity for dissemination on a non-exclusive licensing basis for access by multiple users at the discretion of the holder. The precise terms of access to resources available for exchange - will depend on the nature of the resource, the objectives for its *use*, the economic, legal and social frameworks, regimes and circumstances that govern the resources, and the interests of all parties involved.

The domain of exchange is therefore the domain of *facilitative governance*. The domain of exchange provides the scope for strategies that mix and match commons and proprietary devices in pursuit of mutually beneficial solutions to complex problems in a technological system or systems. Those charged with designing such arrangements should ask, among other things, *what* resources need to be made accessible to *whom*, to what *end*, on what *terms*, and by what *means*. What are the interests involved and what is at stake? The capacity for negotiation of facilitative arrangements among all interested actors in the system, as discussed in Chapter 3, also permits *reflexivity* for reassessment and adaptation of modes of governance over time.

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[808] *Ibid.*

Ethos

Finally, the *ethos* of scientific technology is characterised by *institutional values*. With the use of commercial incentives in science and the devolution of some science to the private sector, the question arises as to the source of the social and moral norms that govern the 'post-academic' paradigm. Rather than a shift from communal values to the self-interestedness of the marketplace, what is indicated is the paradoxical notion that the integrity of science now resides *not* in the virtues of the individual but in the institution.[809] The modern *ethos of scientific technology* is arguably no less an inculcation of individual scientists with the cultural values of the organisation than it was in the Mertonian community of science, yet whereas moral responsibility for the scientific mission in that environment rested with the scientists, in the modern ethos it is the institutions in which scientists work that are considered the 'sites of virtue'.[810]

This conceptual shift from the individual to the institution as the moral agent of science is attributed largely to *secularisation* during the late nineteenth and early twentieth centuries, rather than proprietisation *per se*. At a time when all of society construed nature as divine, scientists were made virtuous by its study, and held a place of moral *superiority* in societal perception. *Genius* could be viewed as inspired, as opposed to *method* which was available for mechanical application by anyone who could master and employ it.[811] Professors were not well paid and science could be identified with the cloistered academic life. By the early 20th century, with industrialisation and the employment of scientists in remunerated positions, science was very authoritative, but this no longer rested on the special status of individuals.[812]

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[809] Shapin S (2008) The Scientific Life.
[810] *Ibid.*
[811] *Ibid.*
[812] *Ibid.*

This shift toward institutional values has implications for academic science, for the research firm in the private sector, and for the ethos of capitalism which, as I discussed in the previous chapter, is sustained by additional social values that differentiate the economic market from a market society. First, if universities and public institutes intend to move into the 'business' of practical innovation they should consider how high-tech firms and biotech businesses seek to manage and motivate creative people rather than relying solely on an administrative perception of pertinent business realities.[813] Secondly, contract research firms or biotechnology start-ups are likely to have a more entrepreneurial approach and a different view of risk than large established corporations. Thirdly, some types of modern industry may be able to offer better conditions[814] for scientific inquiry than some universities and institutes. Lastly, the emphasis on institutional values implies a need for more consideration of the 'additional social values' that are required in order to ensure that the power of the market serves rather than undermines society. The prioritisation of values in life science technologies, and support for corporate responsibility in relation to the outcomes of economic productivity, for example, are key to good relationships between science, industry and society. It is easy to assert however that social direction is necessary to ensure that the market serves the public purpose,[815] but how this might be undertaken through a process of deliberative democracy in a particular political economy is a question for another thesis.

6. Conclusions

In this chapter, I have presented my conception of scientific technology, which is informed by an examination of the potential concerns and approaches related to recent changes in law, policy and practices regarding the patenting of research results, as well as the natural interconnectedness of science and technology. I draw the following conclusions.

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[813] *Ibid.*
[814] *Ibid.*
[815] May C (2009) On the border, 256.

1. The current state of 'scientific technology' is rooted in the *integration* of science and technologies across academia and industry in pursuit of outcomes with practical and social benefits that neither is capable of achieving on its own. Most of the 'scientific' research conducted in universities has for some time been in fields that are directed toward practical outcomes. In keeping with these technological developments, changes in patent law doctrine and public policy have resulted in increased patenting and licensing practises that raise fears about privatisation of public sector research, patent congestion and the prevention of ongoing research.

2. There are mixed views and varied sources of evidence with regard to the impact of this shift toward convergence and the proprietisation of public sector research. While it seems clear that these changes give rise to significant *potential* for problems, and that in certain cases such difficulty has transpired, there is sufficient empirical evidence going the other way to suggest that no presumptions can or should be made about the use and effect of commercial incentives in a given field of technology.

3. The focus on changes in university policy for commercialisation of academic science has obscured the process of privatisation of science outside of the public sector. Movement of scientists from academia into biotechnology start-up companies, contract research organisations and employment with established industrial corporations has led to prophecies of wider paradigms of technological, proprietary, fully privatised, or 'post-academic' science. My conception of 'scientific technology' does not conform to these supposed paradigms, which overstate the extent to which science has been dominated by proprietisation, and paints a more accurate picture of its integrative features.

4. The landscape of scientific technology is characterised by *diversity*: of resources, actors and types of organisation and interaction among them, across public and private sectors, and academic and industry divisions. I have no reason to believe that this will change, or any basis for predicting that it is just a matter of time before science will be entirely privatised. I would welcome more empirical research in particular fields to determine the lay of the land: to clarify who the actors are, their

objectives, modes of operation, activities and relationships with others, results and their dissemination.

5. Modern scientific technology, to the extent that I can observe it, is defined by six integrational concepts: synergy, research, innovation, utilisation, a domain of exchange and an institutional ethos. This conception reflects the current state of integration and diversity across academia and industry, without regard to a dichotomy between public and private sectors. It envisions advances at the interface of science and technology through research, innovation and utilisation of resources, for the production of all types of intellectual and tangible products. It contemplates one *domain for exchange* of resources among all types of actors, in all types of organisational structures, for all purposes.

6. The domain of exchange encompasses the interchange of intellectual and material resources among actors by all *means* or *vehicles*, from commons to contracts. These vehicles deliver varying types and degrees of accessibility to resources according to the legal, economic and social norms and regimes that govern them. 'Openness' in both individual and collective exchange of resources is determined by the actors involved, within the limitations of the applicable normative frameworks. Dissemination of, and access to, materials and information can occur through any *combination* of individual 'modules' of transfer and collective 'pools' of sharing that supports the activities and advances the interests of the actors in the system. The cumulative effect of these interchanges is *networks* of interactivity.

7. Scientific technology thus conceived is receptive to 'decentred' governance that includes, but is not limited to, government legislation. Governance occurs within the networks of interactivity, through which a variety of actors impact upon and shape the actions of one another. Every type of individual transaction and collective mechanism for the generation and use of resources in relation to a technology, or field of technology, constitutes 'governance'. Attempts to facilitate include *purposive* attempts by policymakers or parties to construct mechanisms for achieving certain mutually beneficial objectives, such as overcoming hurdles that impair the

production of knowledge and products. This conceptualisation of scientific technology therefore provides a strong foundation for the design and implementation of a variety of vehicles for facilitative governance.

PART III: APPLICATION

Introduction to Part III

In Part II, I analysed the interplay between openness and exclusion in traditional narratives of science and technology. In the last chapter I developed a conceptualisation of scientific technology in which the degrees of accessibility rather than 'openness' are achieved through vehicles of exchange and networks of interactivity across the public and private sectors. Referring back to my research questions, I suggest that I have answered the first two: 'what is the relevance of appealing to openness?' and 'how might the concept and functions of openness be reconceived?' It is now left to address the consequences of my reconceptualisation. How does it make a difference?

In the concluding Part of this thesis, I consider that, as in the concept of governance that I proposed in Chapter 3, the significance of the conceptualisation is not so much in what it means[816] but in what it can do, or what we can do with it.[817] How we think about things makes a difference. The function of my conceptualisation of scientific technology is to encourage networks of interactivity - the construction of all types of creative arrangements and mechanisms - unburdened of the biases of public and private, open and proprietary - in which actors across the board are able to participate and contribute their strengths and capacities to the negotiation of solutions to problems that would otherwise inhibit activity essential to the provision of public goods. To this end, I use it to assess certain examples of the growing number of collective strategies, lumped together under the heading of 'commons approaches', that might be useful for the governance of biotechnologies. Finally I identify the relevant features of the conceptualisation for the UK Stem Cell Bank.

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[816] Black J (2002) *Critical Reflections on Regulation*, ESRC Centre for Analysis of Risk and Regulation, London School of Economics and Political Science, 16, citing Rose N (1999) *Powers of Freedom: Reframing Political Thought*, Cambridge University Press, Cambridge, 9.
[817] *Ibid,* 19.

Chapter 7. STRATEGIES

7.1 Introduction

The growing proprietisation of scientific research in fields directed toward technical goals has given rise to attempts to protect or reinstitute openness through collective arrangements for the sharing of resources. During the 1980s, separate initiatives in different disciplines began to develop collective strategies involving the *common or shared use of resources* to meet a wide range of objectives. These started as largely bottom up initiatives by actors in the field who identified specific needs and the capability to address them through the sharing of resources.

7.2 Common pool resources

Much of the current work in relation to intellectual resources flows from social theory in regard to the sustainable use of commonly held natural resources - in which property rights are not well-defined.[818] Contrary to the traditional notion that the problems of over-consumption of common resources can only be overcome by privatisation or external enforcement,[819] the common pool solution suggests the establishment of self-governing institutions that define terms of community use of the resource.[820] The theory has led to structures for a wide variety of specific uses, and to the top down institutionalisation of some of them by policy organisations and legislatures.

The relevance of these common pool principles for my thesis is that they are now being applied to knowledge[821] or 'cultural' resources[822] and scientific research more

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[818] Ostrom E (1990) *Governing the Commons: The Evolution of Institutions for Collective Action*, Cambridge University Press, Cambridge.
[819] *Ibid.*
[820] *Ibid.*
[821] Hess C and Ostrom E (2003) 'Ideas Artifacts, and Facilities: Information as a Common-Pool Resource' 66 *Law and Contemporary Problems* 111; Boyle J (1996) *Shamans, Software and Spleens: Law and the Construction of the Information Society*, Harvard University Press, Cambridge Mass and London UK; Benkler Y (1999) 'Free as the Air to Common Use: First Amendment Constraints on Enclosure of the Public Domain' 74 *New York University Law Review* 354; David P (2000) 'A Tragedy of the Public Knowledge "Commons"? Global Science, Intellectual Property and the Digital Technology Boomerang' SIEPR Discussion Paper no. 00-02, Stanford Institute for Economic Policy Research; Merges RP (1996)

broadly. The 'commons' is not a new phenomenon,[823] but has found new relevance in constructed 'cultural commons' in which knowledge is the shared resource, and 'research commons or semi-commons' that straddle public and private sectors in the context of modern integration and diversity. Under the auspices of 'building institutions for sustainable scientific, cultural and genetic resource commons', presenters at a conference of the *International Association for the Study of the Commons* (IASC) in 2012 addressed problems related to: global climate change, agrobiodiversity, drug discovery and affordable healthcare, developing country food security, life sciences research collaborations, microbial and genetic research materials, digital information, protected cultural resources, urban spaces and human capital. Manifestations are so diverse that a systematic framework is necessary in order 'to develop an inventory of structural similarities and differences among cultural commons in different industries, disciplines and knowledge domains'.[824]

From my perspective on scientific technology, this is an indication that the 'commons', like 'openness' has outgrown its usefulness as a way of describing the multifarious arrangements that the domain of exchange is capable of supporting. 'Commons approaches' are more accurately 'collective strategies' for the governance of all types of activities and untangling of complex problems. They draw upon all the tools in the toolbox. They may include a 'common' element, but the mutual benefits of sharing resources may equally be achieved without creation of a pool of commonly held resources and may instead build new structures around existing property rights, using legal frameworks for contractual construction, licensing regimes and the like.

'Property Rights Theory and the Commons: The Case of Scientific Research' 13:2 *Social Philosophy and Policy* 145.

[822] Madison MJ, Frischmann BM and Strandburg KJ (2010) 'Constructing Commons in the Cultural Environment' 95 *Cornell Law Review* 657.

[823] Merges RP (2004) 'From Medieval Guilds to Open Source Software: Informal Norms, Appropriability Institutions, and Innovation', Conference on the Legal History of Intellectual Property, Working Paper 204, available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=661543 accessed 16 December 2012.

[824] *Ibid*, 658.

I view these collective arrangements, like individual transactions, as vehicles that are specifically tailored for the exchange of resources, which facilitate the activities and interests of all actors equally, through particular structures devised by the parties to meet their mutual objectives. There is no 'background environment' because the public and proprietary environments are integrated in the domain of exchange. This view overcomes the traditional distinctions reiterated in contemporary perspectives on the 'cultural commons' in which the public domain is characterised as the 'natural' environment of knowledge and the proprietary environment is the 'default' setting, from which the knowledge commons deviates. The collective strategy is simply 'facilitative governance', which is not only capable of finding ways of making resources accessible by breaking down barriers between actors, but also *facilitates facilitation*, by welcoming interested actors to participate in the negotiations.

7.3 Patent pools

In other arrangements, such as patent pools, holders do not relinquish their private property rights, but aggregate and share them by way of mutual agreement to cross-license to other participants in the scheme.[825] The purpose is to facilitate innovation by streamlining the licensing of a number of complementary technologies among the members. Patent pools can act as a means of unblocking or preventing patent congestion, but may create further problems under anti-trust or competition law if the members of the pool are corporations that do compete or might compete directly with each other.[826]

7.4 Open access

I have already touched upon open access arrangements in relation to publication and the public domain at the end of Chapter 4. In these arrangements, voluntary

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[825] Shapiro C (2000) 'Navigating the Patent Thicket: Cross Licenses, Patent Pools and Standard Setting' in Jaffe AB, Lerner J and Scott S (eds) (2000) *Innovation Policy and the Economy 1,* National Bureau of Economic Research, MIT Press, Cambridge MA USA and London UK, 119.

[826] *Ibid*, 129; also Van Overwalle G (2012) 'Individualism, Collectivism and Openness in Patent Law. Promoting Access Through Exclusion' in Rosen J (ed) *Individualism and Collectiveness in Intellectual Property Law*, Edward Elgar, Cheltenham, 71.

participants establish licensing schemes for the sharing of copyright rather than patent rights. In the case of publications, the objective is delivery free to the user, thus avoiding user subscription costs, while the author typically pays to publish.

Attempts to maximise access to publications should be a component of any integrated regime for facilitation of research, in order to overcome barriers to the mining of data and information in the public domain. Moves in this direction will impact on the role of publishers who limit circulation by requiring rights to control access to journals through subscription. Open access and digital journals are a way of 'cutting out the middle man' in order to avoid the limitations they impose on promotion of wider dissemination. In light of the option of on-line publication, there may also be potential to negotiate direct payment for publication services, without provision of additional rights to control circulation.

7.5 Open source

In the open source software strategy, computer scientists share 'code' embedded in software by providing, along with the software, the 'source code', the key that permits access to and manipulation of the programme internal to the software. The Linux operating system for example, was developed on an open source basis as an alternative to proprietary software such as Windows and the Mac OS, by a volunteer collaborative of programmers. The participants in the project contributed pieces of code for common access under the terms of the Linux General Public License, which allowed them to take and modify any of the accumulated code as long as they returned their modifications to the central project. The argument is that open source produces more innovative and stable software as a result of the contributions of a wider community of contributors.

Open source is itself rooted in the concept of 'free software' that arose in the 1980s with the institution of the first computers at the Artificial Intelligence laboratory at Massachusetts Institute of Technology (MIT). The notion of free software is attributable to Richard Stallman, whose immediate objective was to re-create, in the face of the practices of emerging proprietary software companies, a collaborative

community of computer programmers. Early computer users were mainly scientists and engineers, working in corporate and academic laboratories, who did their own programming and exchanged code freely, with few restrictions. As the market for software developed, software companies began spinning off, and the old community of laboratory 'hackers' dissipated as individuals went to work for corporate software developers. In response to commercial pressures, these companies relied on their copyright by withholding the source code to their software, which effectively prevented programmers like Stallman from using and modifying it to suit their own purposes. Without the code it was virtually impossible for hackers to figure out how a programme worked, adapt it to specific technical needs, improve it and circulate the changes. Over time, collaboration among programmers became increasingly contained within in-house communities.

Stallman was perturbed by these changes and envisioned the hacker community being rebuilt around the development of a free operating system. This would run independently of existing operating systems and act as a platform on which other free software could be built. To this end, the 'GNU'[827] project was launched in 1984 with the publication of a Manifesto asking other programmers for their participation and support. The Free Software Foundation (FSF), established a year later as the main organisational support for GNU, describes itself as 'a nonprofit with a worldwide mission to promote computer user freedom and to defend the rights of all free software users'.

Social movement

The free software concept was not just a means of developing better software, but a movement espousing specific ethical and social values.[828] Stallman found it unacceptable that proprietary companies should exert what he considered to be excessive control over software development. The basis of this ethic was a fear of proprietary domination of computer technologies in an increasingly digitised world.

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[827] The acronym GNU refers to 'Gnu's Not Unix', Unix being a popular proprietary operating system.
[828] R Stallmann, *Why Open Source Misses the Point of Free Software,* 52:6 Communications of the ACM, 2009, 31.

Stallman felt that corporate control over the modification of software, through their ownership of sources, would erode human autonomy and enable companies to monitor the technologies used in homes, schools and businesses. The free software movement was defined by four freedoms:

- 'the freedom to run the program, for any purpose;
- the freedom to study how the program works, and adapt it to your needs;
- the freedom to redistribute copies so you can help your neighbor; and
- the freedom to improve the program, and release your improvements to the public, so that the whole community benefits.'[829]

The 'freedom to run, for any purpose' meant that no restrictions should be imposed on the use of free software in terms of time, purpose or geographic area. Specification that a licence applies for only a predetermined trial period, or until a stated expiry date, limits the use of free software. Similarly, specification of *permissible* types of use, such as research or non-commercial, or *prohibited* uses, or *places of use*, would encroach on the freedom of the user.

Secondly, if users are unable to understand and modify software to suit their specific needs their work will be restricted by versions supplied by the sole proprietor who is controlling the changes. Failure to release the source code - the preferred representation of a programming language – prevents a user from comprehending and thus editing a programme. Mandatory conditions of use, such as special licensing terms or a non-disclosure agreement are also forms of proprietary control that the philosophy of free software seeks to avoid.

The notion that modified software should be *freely distributable* for the benefit of others affirms the collaborative approach to problem solving on which the early programmers operated. Freedom here means permissible, not free of charge. Software can be disseminated at will, but it is not necessarily transferred without financial charge. Stallman was not opposed to the imposition of a fee, despite the fact that software can be copied and distributed at virtually no cost. The freedom to

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[829] GNU's Bulletin, Vol 1 No. 1, February 1986.

distribute was not limited to the assistance of other programmers, but includes the possibility of releasing improved software to the public, many of whom do not have the time or skills to solve problems. In this way, the community as a whole might benefit indirectly from the freedom to modify software. This distribution may also be done for a charge.

These freedoms were espoused not simply for the sake of the individual user, but to promote social solidarity in the form of sharing and cooperation. He envisioned a different society in which computers 'work for the benefit of the individual and the community', not for proprietary software companies or governments who might seek to restrict and monitor use. The open source explosion that came out of the free software movement did not entirely embrace these social values,[830] but picked up on the value of the copyleft licensing regime for communal building of software as a huge boon for innovation. Whether it is essential to embrace these values as a basis for the development of free software is a question that has divided computer programmers. From the perspective of my model of scientific technology this is a good example of an 'ethos' defined by an institution, which might be a local phenomenon or an attempt to influence a wider body of actors in the system.

Open source biotechnology

The success of open source was widely advertised and attempts to apply its principles in a variety of other disciplines have met with varied success. Of particular interest are the attempts to apply it to the field of biotechnology in the hope that the capacity to foster innovation encountered in the information technologies would rub off on the life sciences.[831] Attempts to apply open source licensing schemes, in any direct way to biotechnological research have however been largely

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[830] Stallmann R (2009) 'Why Open Source Misses the Point of Free Software' 52:6 *Communications of the ACM* 31.

[831] See for example Hope J (2008) *Biobazaar: The Open Source Revolution and Biotechnology*, Harvard University Press, Harvard; Oye KA & Wellhausen R (2007) 'The Intellectual Commons and Property in Synthetic Biology' 1 *Science, Technology and Innovation Policy;* Nicol D and Hope J (2006) 'Cooperative Strategies for Facilitating Use of Patented Inventions in Biotechnology' 24:1 *Law in Context* 85; Guadamuz-González A (2006) 'Open Science: Open Source Licenses in Scientific Research' 7 *North Carolina Journal of Law & Technology* 321.

unsuccessful, primarily because of the different intellectual property regimes on which they are reliant: the automatic copyright of open source versus the patent system of biotechnology. Further, the physical material component of biotechnology which impacts dramatically on both costs and transferability and dissemination of resources is not a factor in the open source system of information technologies.

7.6 Research commons

Of collective arrangements that I have encountered the most relevant for stem cell technology is the contractually constructed[832] research commons for the sharing of knowledge assets and physical materials. An example is the microbial research commons[833] which enables the sharing of upstream research inputs in the life sciences based on the formation of digitally integrated research networks that afford willing participants greater reciprocity benefits than those that are likely to accrue from hoarding materials, data and information. The microbial research commons seeks to overcome the hoarding of microbial resources that have accumulated in hundreds of culture collections around the world and the propertisation of these resources through the use by culture collections such as the American Type Culture Collection, which have devised MTAs that progressively restrict access to use and re-use, even for research. A fundamental difficulty to be overcome is that everyone treats each unit of microbial genetic material as if it were potentially valuable, when in reality the bulk of all the microbial materials in collections have no known or likely high pay off commercial applications, but are only valuable as inputs of basic scientific research.

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832 Reichman JH and Franklin JA (1999) 'Privately Legislated Intellectual Property Rights: Reconciling Freedom of Contract with Public Good Uses of Information' 147 *Univeristy of Pennsylvania Law Review* 875.
833 Reichman JH, Dedeurwaerdere T and Uhlir PF (forthcoming 2013) *Designing the Microbial Research Commons: Global intellectual property strategies for accessing and using essential knowledge assets,* Cambridge University Press, Cambridge; Rai AK, Reichman JH, Uhlir PF and Crossman C (2008) 'Pathways Across the Valley of Death: Novel Intellectual Property Strategies for Accelerated Drug Discovery' VIII:1 *Yale Journal of Health Policy, Law, and Ethics* 53; Reichman JH and Uhlir PF (2003) 'A Contractually Reconstructed Research Commons for Scientific Data in a Highly Protectionist Intellectual Property Environment' 66 *Law and Contemporary Problems* 315; Reichman JH (2000) 'Of Green Tulips and Legal Kudzu: Repackaging Rights in Subpatentable Innovation' 53:6 *Vanderbilt Law Review* 1743.

The microbial research 'commons' is a virtual pool, rather than a physical repository; it only receives deposits of materials that have no known or likely high value commercial uses at the time of deposit; individual collections must maintain the highest quality standards; and within the semi-commons there are virtually no restrictions on upstream public research functions with respect to all the deposited material. The intention is that participants should invoke a ('take and pay' or 'liability') rule[834] by which original depositors would be compensated by way of an pre-determined royalty payment in the event of the development of downstream commercial applications of the pooled materials. The 'liability rule' is not an exclusive property right that says 'you cannot use my property unless you have my permission', but an entitlement to take: 'please use my property, do something, make it valuable, just give me equitable compensation for the commercially valuable uses that you have put it to.'

The model is structured by the use of an standardised MTA, that regulates all willing participants. The scheme requires a governing body or a trusted intermediary to deal with the governance of knowledge and international legal aspects which are important and complicated, as well as a set of governance rules related to mediation and *dispute resolution.* The culture collections from which the microbes were taken would manage any resulting income streams from downstream applications. The proposed model would require external funding most likely from the public sector, but might also be attractive to the private sector.

The *key premise* is that the depositor of material in the research semi-commons does not forfeit all rights to benefit from downstream commercial applications that emerge. The objective is to strengthen the potential reciprocity gains from participation in the collective arrangement by addressing the fear that the original depositor will lose out if someone else makes money from his materials. The sub-premise is that participants will not normally, nor would they be expected, to

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[834] Calabresi G & Melamed AD (1972) 'Property Rules, Liability Rules and Inalienability: One View of the Cathedral' 85:6 *Harvard Law Review* 1089.

contribute materials having a known or likely potential for high commercial pay off. The model establishes a global research exemption within the controlled commons that communicates to researchers that they can take materials and do whatever they want with them, as opposed to the message 'do what you want if its non-commercial'. The economic logic is that depositors should obtain more potential reciprocity benefits from access to vast upstream research opportunities through the semi-commons than would accrue from operating in isolation.

The model accords with my conception of the domain of exchange in that it overcomes the inhibitions of public and private, open and proprietary, and in particular commercial and non-commercial *research.* It illustrates the construction of facilitative strategies grounded in the identification of real rather than perceived, problems.

7.7 Conclusions

Collective strategies for facilitative governance provide endless opportunity for the advance of scientific technologies. In my conception of scientific technology their strength is both in the interactivity with resources that they promote, and in the interactivity of the process, which is the inclusion of all receptive actors for the negotiation of mutual benefits.

The difficulty that I have with analytical approach of many of the collective strategies is that they are conceived in terms of the old unhelpful contradictions between proprietary and public domains. I see no benefit in framing mutually beneficial collective arrangements as means of capturing a particular kind of 'openness', defined in terms of a deviation[835] from a default or background environment, which generally implies that one approach to achievement of accessibility and exchange is preferable to another.

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[835] *Ibid*, 686.

In my conception of the domain of exchange, there is no 'background' environment and therefore no need to catalogue in these divisive ways the various means by which resources might be accessed and exchanged. The point is that the combination of public and private, commons and property in the exchange domain provides the widest selection of tools and devices for designing architecture that contain rooms and corridors for various types of interchange and transmission, all of which are necessary in the enterprise of facilitation of the production of knowledge and goods. My conceptualisation does not eliminate the extremes: sometimes pure commons and purely proprietary approaches are necessary to achieve certain objectives. The domain of exchange however invites every possibility by enhancing the opportunities for collaboration and exchange among parties from across the spectrum of social organisation in the public and private sectors.

Chapter 8. UK STEM CELL BANK

Finally, I come back to the UK Stem Cell Bank, to flag up the implications of my ideas about scientific technology for the Bank, and for a future research project. First I remind the reader that the UKSCB is one illustration of the much broader set of issues that I have addressed in my thesis surrounding the sharing of resources for the facilitative governance of scientific technology. It is one governance structure in the field of stem cell technology, and constitutes one set of arrangements that impact on the behaviour of actors in the system. I view it therefore as one of the actors in the overarching enterprise of the delivery of stem cell-based public goods.

Secondly, the UKSCB cannot be construed as a 'collective' arrangement for the use of resources (even though the public supporters of the Bank might be considered one of the actors in such a scheme or a neutral holder of pooled resources) because the depositors are at present not all voluntary participants. The Bank is neither the product of statutory authority *per se,* nor a self-organised arrangement. It comprises both voluntary and non-voluntary participants. The terms of use established by the Code of Practice and the Material Transfer Agreements are not negotiated among the participants, but externally imposed, however receptive the Bank may be to their adaptation over time.

The rationale for this structure is rooted in the origins of the Bank as an informal regulatory mechanism for the ethical oversight of embryonic stem cells, and is unlikely to change as long as human stem cells are construed as products of embryos rather than 'ordinary' human tissue such as blood or transplantable organs. To the extent that the oversight functions of monitoring compliance of ongoing research could be severed from the functions of the Bank as a vehicle for sharing of cell lines, a structure more in line with a controlled common might be contemplated. I think that such a separation is conceivable, primarily because apart from the records of the Bank, which provide the traceability that supports guarantees of both ethical and technical provenance, the functions of the Bank (custody and qualification of cells) and those of the Stem Cell Steering Committee (monitoring of applications for access and ongoing use among other things) are already distinguishable.

Thirdly, in its own terms, a main objective of the Bank is to provide support for 'research', yet the Code of Practice and the MTAs attempt to create a distinction between research use and commercial use that is not and cannot be properly defined and is therefore a source of confusion and inhibition to upstream as well as downstream activities. There is no apparent reason for the distinction, except for the notion that the embryonic origins of the cell line makes them special in a way that requires that they should not be 'commodified'. The more relevant distinction is the technical one, between cells that are cultivated for clinical use, according to EUTCD standards, and those that are laboratory grade cell lines, which is relatively clear and subject to different types of MTAs. The use of laboratory grade cells and clinical grade cells could in each case result in some type of 'commercial' outcome as research tools or tangible therapies, so any attempt to create a commercial/non-commercial distinction remains problematic.

Subject to the ethical monitoring function of the Steering Committee, it might be possible to consider modifications to the Bank to create a mechanism more along the lines of a contractually constructed global research commons. The Bank lends itself to such a scheme because its resources (stem cell lines) are 'upstream' products, likely to be unpatented, and therefore amenable to transfer by MTAs rather than patent licensing. As a centralised repository with strong expertise in biological standards, the Bank would not have to address the issue as to how to regulate quality standards in the individual facilities of the participants. Necessary changes would include the willing participation of all depositors, standard MTAs negotiated among the participants, alterations to governance to reflect the collective nature of the project, and terms of access and use that encourage all types of research, without distinction as to 'commercial' and 'non-commercial'. It is feasible that a liability rule for compensation of depositors in the event of downstream success could act as an incentive to encourage buy-in by cell developers who are wary of sharing their cell lines. Finally, the role of the Bank as a biological resource could be greatly enhanced by linking its current functions to a global digitally-integrated network for dissemination of data and information related to particular stem cell lines.

Potential difficulties to be addressed include first, the fact that stem cell lines, unlike microbes, never have nominal economic value - given the investment in their creation - even if they are considered useful only for research purposes. Whether they are ever 'pre-competitive' is also questionable. Still, if cell developers are not obliged to deposit all of their cell lines, as they are at present, giving them the option of selectively retaining those with greatest likelihood of commercial payoff, then they might be willing to contribute some research grade cells for common use.

Secondly, a more technical consideration is whether it is possible to devise a 'chain of title' for stem cell lines, such as a genetic biomarkers to track research uses of all stem cell lines. This is important for living resources that are continually replicating, divisible and subject to modification into multiple derivatives because when downstream developments become potentially patentable by the user, it is necessary to be able to link the patent back to the original depositor.

Thirdly, the use of a liability rule may act as an incentive to deposition by publicly funded cell developers, but the more important consideration is whether it would provide sufficient incentive to the private sector to attract participation by the corporations that are most capable of taking and developing the cell lines on offer. Opening the semi-commons to use by non-members creates the potential for a 'free rider problem', but might nevertheless be considered. The UKSCB is in a good position to advocate such a system if it should choose to do so, given its international profile as a leader of stem cell banking initiatives.

Such collective regimes are not however the whole answer in relation to stem cell technology. A big issue for the translation of stem cell research into therapeutic treatments is the high cost of clinical trials. The matter requires either adequate incentives for large private investment or treatment of the clinical process as a public good, whereby government reimbursement is provided to private companies if they get to third stage trials.

These are the ways in which I see my conceptualisation as applicable to the organisation of the UK Stem Cell Bank. Further research might take an empirical

approach to the attitudes of public and private sector cell developers, and biotechnology companies who might be interested in participation in a global stem cell semi-commons.

CONCLUSIONS

In this thesis I have sought to demonstrate the significance of appealing to 'openness' in attempts to promote facilitative governance for the equal enhancement of all aspects of scientific technology. The origins, institutions and practices of science and technology suggest that the two systems are not intrinsically incompatible, but constitute complementary modes of innovation, capable of powerful conjunctions of understanding and utility across different fields and disciplines. The associations of science with public and 'open', and technology with private and proprietary are nevertheless deeply embedded in the discourses related to governance of life sciences technologies. Although this bifurcation may at one time have constituted an accurate reflection of the social organisation of science and technology, it is clear that it no longer does so, and that attempts to hold to it prevent a move toward a more realistic conception of modern scientific technology. I argue that, in an environment in which public sector as well as private industrial science is increasingly proprietised and directed toward technological objectives, the perpetuation of value-laden caricatures of science and technology is inappropriate. These invest open science with a status superior to that of utilitarian and commercial technology and inhibit dialogue about the construction of effective governance by undermining equal handed policy treatment of all aspects of modern scientific technology.

The main contribution of my thesis is the proposition of an integrated conceptualisation of 'scientific technology' which bridges oppositional perceptions of science and technology that inhibit the discourse about facilitative governance. My conception of the modern context neutralises these biased perceptions of science and technology and provides an integrated way of thinking about modern scientific technology that facilitates not only technologies but the negotiation, by actors in the system, of types of governance that would welcome all participants and advance equally their interests and outcomes across the public and private sectors. My view does not *eradicate* the distinction between public and private and its implication for avenues of funding, business operations and dissemination of research, but asserts that public and private are elements of the *same* environment, are equally valuable to

society and require the same policy considerations and access to reflexive governance processes. The domain of exchange encompasses the whole gamut of public science, and public proprietary science, and private proprietary science, and private industrial scientific research, and private industrial production etc. The domain is populated by all types of resources, available for access by users on various terms, according to applicable social as well as legal and economic norms or regimes. Such regimes, whether property rights, public interests or ethical considerations are the 'gatekeepers' to access and use of resources.

In my conceptualisation, the 'proprietisation' of research by increased patenting in the public sector, although it gives rise to much noise in the literature, does not constitute the complete 'privatisation' of science nor the demise of public support for science. It reflects greater integration of science with technologies, and the fact that although science has long been supported as a public good, it has practical value for technology that is capable of holding its own in the commercial market. The implication I suggest is that the domain of scientific technology, public policies and private choices matter more than ever. Greater public support for university research, and the support of universities for publication rather than patenting, are still options that can be promoted and defended. I have no firm agenda for what specific policies and choices *ought* to be made in relation to problems such as the scope of patentability, or patent blockages. Any system will be subject to implementation difficulties but my thesis addresses the broader picture. I suggest that in the current environment, the accessibility of knowledge resources may depend upon terms and conditions negotiated collectively or individually among the actors in the system. In my conceptualisation of this environment, 'degrees of openness' may be instituted through a variety of arrangements, from contracts to commons, among actors in the system, in various types of organisation and affiliation. It is in the plethora of commercial and non-commercial relationships and public and private choices that the accessibility and use of resources is defined.

I submit that my conception of scientific technology and the public domain of exchange is preferable to the current appeals to a concept of openness that is of limited use outside of the particular institutional construct of open science. In the

realm of collective strategies for example, my conceptualisation provides an appropriate basis for assessment of various tools and mechanisms of governance that might be employed to advance scientific technologies. The potential for establishment of creative collective mechanisms across public and private sectors, for the expansion of accessibility to resources and enhancement of activities is welcome, and in principle aligned with my conception of a domain of exchange. The caveat to this is that in my domain of interactivity, collective strategies do not constitute a 'deviation' from a background environment, but a modification of behaviour by agreement among the willing participants in the arrangement.

If there is a normative aspect to my thesis it is that for the purposes of equal facilitation of all aspects of scientific technologies, more attention ought to be paid to consideration of the issues and means of facilitation that affect industrial and commercial sectors. The governance of biotechnology literature is weighted heavily toward resolution of problems in relation to the public system of science and pays too little attention to the real difficulties, including barriers to entry, confronted by private research and industry for the development of commercial goods.

In terms of its implication of my thesis for various audiences, I suggest that the public sector can consider much of what is generally referred to as 'science' as 'scientific technology'. Whether patented, or simply directed toward technological goals, research in most fields of publicly funded research is tied up with the pursuit of answers to complex problems of practical and utilitarian significance. In my view these alliances between science and technologies are positive, despite the fact that we now have to work harder to ensure that materials and knowledge are available, accessible and utilisable across the spectrum of actors.

For the private sector, my conceptualisation implies a wider range of relationships with a wider variety of actors across public and private sectors. I suggest that my conceptualisation of the domain of exchange facilitates receptiveness to public-private partnerships and involvement between private industry and researchers in both academia and the private sector. An undivided domain in which the strengths of

all actors are sought and valued creates a level playing field that should enhance relationships and facilitate rather than inhibit mutually agreeable outcomes.

For the UKSCB, by disregarding the ethical debate over the use of embryos, I have been able to clarify what is happening in regard to other issues, and construe the Bank as only one part of the bigger undertaking of stem cell technology and of its governance. What my thesis reveals is that the failure to see the bigger picture – science and technology as co-existing and a need to take into account commercial as well as scientific aspects of scientific technology – leaves room for expansion of the support of the Bank for all kinds of research. The creation of unsupportable distinctions between research and commercial use, even if they do not prohibit commercialisation *per se,* send a message to the user that some thought needs to be given to what type of research is being undertaken, which creates uncertainty and potential inhibition. Further, subject to social reasons for using this particular existing architecture as a means of maintaining surveillance over the ongoing uses of human embryonic stem cells, consideration could be given to adapting the Bank to create a global stem cell research commons.

Finally, my thesis points to several areas of further research. First my basic conceptualisation of scientific technology would benefit from further elaboration and development in relation to existing concepts, such as that of the public domain, with which it interfaces. Secondly, there is room for more empirical research in regard to specific barriers, particularly in relation to the private sector translation of research into therapies, and patenting practices. Thirdly, in regard to the governance of stem cell technology, the obvious follow-on project to my thesis is a comprehensive analysis of the operations of the UK Stem Cell Bank, with a view to determining whether a global research commons is feasible and desirable. Thirdly, at the date of finalisation of this thesis, there is pending a further EU project in relation to the establishment of an EU Bank for induced Pluriopotent Stem Cells (EBiSC). In the absence of social sensitivity related to embryonic derivation of the cells, the new pan-European bank for stem cells of adult origin will provide a prime opportunity for application of the conceptual foundations developed in this thesis to the design of mechanisms of governance that will optimise the use of such a resource.

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