

**THE EMERGENCE OF A MEDICAL EXCEPTION FROM PATENTABILITY
IN THE 20TH CENTURY**

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ABSTRACT

Many patent law dilemmas arise from a failure to understand technologies as embedded in broader social, economic and political realities and to contextually analyze these legal phenomena. This narrowness leads to poor legal development, of which the modern medical exception from patentability is one example. Judges have difficulty interpreting it, patentees do not understand its purpose and it does not protect the important medical technologies to which the public would like access. This thesis applies a legal pluralist analysis to examine the emergence of the medical methods exception in order to understand why it was created and legislated. It starts by examining the origins of the exception in the caselaw, and the informal, concurrent norm established by the emerging medical profession in the early 20th century. It then proceeds to examine why the medical profession might have sought and enforced a norm prohibiting its members from patenting, and concludes that this arose from the need of the medical profession to distance itself from the patent law. As a result, professionalizing physicians established an internal normative order that mimicked and in many cases replaced the effect of the formal law. The thesis then proceeds to examine how the form of the informal norm evolved in the period between WWI and WWII, finding that the profession's norm transformed and broke down concurrently with its efforts to achieve external legitimacy through legislation. That breakdown arose from factors which included growing labour mobility, greater understanding of the benefits of patents, and a growing role of science and industry in medicine that threatened the profession's access to valuable medical innovation. The thesis concludes with a study of a current case (Myriad Genetics) that applies the thesis' theoretical framework to a present dispute over the role the law should play in regulating genetic diagnostic tests.

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TABLE OF ABBREVIATIONS

ABCM	Association of British Chemical Manufacturers
ABPI	Association of the British Pharmaceutical Industry
ALRC	Australian Law Reform Commission
AMA	American Medical Association
BMA	British Medical Association
BMJ	British Medical Journal
BOT	Board of Trade
BSG	British Science Guild
BTG	British Technology Group
CEC	Central Ethical Committee
CNIPA	Committee of National Institutes of Patent Agents
DH	Department of Health
DOIA	Development of Inventions Act
EPC	European Patent Convention
GMC	General Medical Council
ICI	Imperial Chemical Industries
IIC	International Review of Industrial Property and Copyright Law
JCC	Joint Chemical Committee
MDD	Medical Devices Directorate
MME	Medical Methods Exception
MRC	Medical Research Council
MRI	Magnetic Resonance Imaging
NEB	National Enterprise Board
NHI	National Health Insurance
NHS	National Health Service
NRC	National Research Council
NRDC	National Research and Development Corporation
OECD	Organization for Economic Cooperation and Development
PBC	Parliamentary Bills Committee
PO	Patent Office
PRO	Public Records Office
R&D	Research and Development
RCP	Royal College of Physicians
RCS	Royal College of Surgeons
SASF	Semi-Autonomous Social Field
SOM	Statute of Monopolies
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
TSA	Therapeutic Substances Act
UKPA	United Kingdom Patents Act
UKPO	United Kingdom Patent Office
UNEPA	Union of European Patent Attorneys and Other Representatives Before the European Patent Office
UNICE	Union of Industrial and Employers' Confederations of Europe
USSC	United States Supreme Court
VPRS	Voluntary Price Regulation Scheme

WWI	World War One
WWII	World War Two

1. THE DILEMMA

1 Introduction to the Thesis

The goal of this thesis is to establish a framework to better analyse and understand current dilemmas in patent law. I argue that by considering technology development and concomitant patenting activity as embedded in a broader social, professional, cultural, economic and practical context we are better able to conduct accurate and effective analyses of legal phenomena. The thesis focuses on an area that poses particular problems for patent law: the patentability of medical technologies as manifested by the modern legislative medical exception from patentability.

Patent law poses many dilemmas for policy-makers and, as such, has been at the front of international¹ and domestic² policy-making agendas in recent years. Much of this development seeks to address perceived problems created by the patenting of medical technologies, including substances and processes. Debates over the impact of patents on access to medical treatment generally,³ exploitation of traditional knowledge for Northern pharmaceutical production⁴ and research into the

¹ World Health Organization, 'Public Health, Innovation and Intellectual Property' (Inter-Governmental Working Group homepage) <<http://www.who.int/phi/en/>> accessed 15 December 2007; World Trade Organization, 'TRIPS' (WTO TRIPS homepage) <http://www.wto.org/english/tratop_e/trips_e/trips_e.htm> accessed 15 December 2007; Organization for Economic Cooperation and Development, 'Guidelines for the Licensing of Genetic Inventions' (OECD homepage) <www.oecd.org/sti/biotechnology/licensing> accessed 15 December 2007; World Intellectual Property Organization, 'Patentscope' (homepage) <<http://www.wipo.int/patentscope/en/>> accessed 15 December 2007.

² Eg, US: 'Patent Reform Act of 2007' SR 1145; HR 1908; US Doha Declaration SR 241; HR 525. Canada: An Act to amend the Patent Act and the Food and Drugs Act (The Jean Chrétien Pledge to Africa) Bill C-9 SC c 23 (Bill C-9).

³ Knowledge Ecology International, 'Access to Medical Technology' (homepage) <http://www.keionline.org/index.php?option=com_content&task=view&id=18> accessed 15 December 2007; Médecins sans frontières, 'Campaign for Access to Essential Medicines' <<http://www.accessmed-msf.org/>> accessed 15 December 2007; Global Treatment Access Group (homepage) <<http://www.aidslaw.ca/EN/issues/GTAG.htm>> accessed 15 December 2007; Essential Action (homepage) <<http://www.essentialaction.org/access/>> accessed 15 December 2007.

⁴ South Centre (publications) <http://www.southcentre.org/publications/publist_issue_area.htm> accessed 15 December 2007.

effect of the patent system on healthcare by a range of stakeholders⁵ all testify to this interest and activity. These have led to policy-making initiatives to enhance access to essential medicines to treat HIV/Aids and other diseases⁶ and to biotechnology for research, public and commercial purposes through regulating licensing,⁷ among other areas of active policy review.

These debates and policy-making initiatives concerning regulating medical technologies through the patent law are not new, although the international scope and drive to harmonization are unprecedented. Historically, countries that share a legal link with the UK (e.g. Canada, US, Australia, New Zealand) practised an exception for patenting medical technologies, known as the ‘medical methods exception’ (MME). While the MME seems like a promising tool to regulate medical technologies in the patent law, in practice it provides limited regulation of the patentability of medical technologies and plays almost no present role in international debates about regulating medical technologies through the patent law. This chapter explores why this is the case, by examining the present contours of the MME, particularly as applied to diagnostics, and its limitations.

Chapter 2 lays the theoretical foundation to explore how the MME developed to acquire its present legal form and limited effect. The MME developed from a norm of the medical community that aided in the profession’s quest for professional status, into a formal legislated exception. The historical analysis and investigation of the

⁵ Eg, MA Heller and RS Eisenberg, ‘Can Patents Deter Innovation? The Anticommons in Biomedical Research’ (1998) 280 Science 698; JP Walsh and others, ‘View from the Bench: Patents and Material Transfers’ (2005) 309 Science 2002.

⁶ Bill C-9 (n 2); US Doha Declaration (n 2).

⁷ National Institutes of Health, ‘Best Practices for the Licensing of Genomic Inventions’ (2005) <<http://ott.od.nih.gov/pdfs/70FR18413.pdf>> accessed 11 July 2007; OECD, ‘Guidelines for the

articulation of a group norm of practice requires drawing on legal sources outside formal documents such as caselaw and legislation. In so doing the historical research is inspired and guided by legal pluralist scholarship that studies rule-following based on the creation of formal and informal norms. Chapter 2 justifies a broad consideration of the roots of the MME, building the analytical framework by relying on other legal pluralist studies of creative communities.

Chapters 3 to 5 study the history of formal law-making and informal rule-creating activities leading eventually to the legislated MME in the 1970s. Chapter 3 moves from a close consideration of the formal legal norm principally in caselaw in the pre-WWI period, to an exploration of the developing informal norm against patenting by members of the medical profession during the same period.

Chapter 4 considers *why* the medical profession was so opposed to patents that it developed and enforced an informal norm against patenting by its members. This requires taking a step back to consider the roots of the modern patent system in 15th century England, the growing economic and social problem of so-called ‘patent medicines’ in the 1700s and 1800s, and the drive to professionalize medicine starting in the early 19th century. Chapter 4 will demonstrate that the professionalizing medical corps sought to distance itself from the market and industry, from associations with dangerous ‘patent medicines’ that damaged its credibility, and from regulation by the profession of lawyers. The development of an informal norm against patenting helped the medical profession to control, standardise and improve the quality of medical practice, measures that were needed to support its claims to

Licensing of Genetic Inventions’ (2006) <<http://www.oecd.org/dataoecd/39/38/36198812.pdf>> accessed 11 July 2007 (OECD Guidelines).

self-regulation and the secure income arising from an effective monopoly.

Chapter 5 reprises Chapter 3's discussion, although now considering first, the transformation of the informal norm during the period between WWI and WWII, and then the formal regime that emerged after WWII. The analysis of the informal norm during this 'inter-war' period considers how the norm responded to changed circumstances after WWI and parallel developments abroad, principally in the US. Chapter 5 illustrates that as the political economy of medical innovators changed, science evolved, international trade and comity grew, and legislative regimes and agencies took on greater regulatory roles regarding medical technologies, the internal norm against patenting began to break down. As the informal norm became increasingly irrelevant to a successfully professionalised medicine, its advocates sought formal legislative recognition of the norm arguing that a rule against patenting would preserve (the medical profession's, in particular) access to the valuable medical innovations of the growing industrial medical sciences. The medical profession's proposals for a formally legislated exception or system of public patents dedication were ultimately unsuccessful and stopped after WWII. The formal law had also been chipping away at the common law medical methods exception, although the passage of the European Patent Convention 1973 (EPC)⁸ and UK Patents Act 1977 (UKPA)⁹ ended this erosion by formally legislating a medical methods exception that exists in UK patent law to the present.

In Chapter 6, I apply the theoretical approach and observations developed in

⁸ Convention on the Grant of a European Patent (adopted 5 October 1973, entered into force 7 October 1977) 1065 UNTS 255 as revised by the Act revising the EPC (adopted 29 November 2000 entered into force 13 December 2007).

⁹ Patents Act 1977 (UK) c 37.

the previous chapters to analyze the role and effect of the patent law in a current controversy over medical technologies, the case-study of Myriad Genetics' breast cancer gene patents. I conclude that a contextual, ground-up approach to understanding innovation in scientific communities supplying medical technologies provides important guidance to how or whether the patent law¹⁰ should intervene in these disputes.

The thesis also explores cross-cutting theoretical, practical and methodological themes. At the level of theory, the thesis argues that existing justifications of patent law, such as utilitarianism and labour, poorly represent the complex social and relational network reality of the innovation process and the complex nature of technologies. I build on the work of legal scholars in challenging and reformulating justifications for intellectual property (particularly patent) law through grounded empirical consideration of the MME in patent law.¹¹

Two practical themes this thesis explores are first, how a formal and ineffective exclusion from patentability became entrenched in the patent law and second, how innovative communities frequently create internal normative order to govern their innovation. Addressing the first, exempting technologies in order to protect access to valuable technologies remains an attractive option to policy-makers.¹² This thesis explores the pitfalls and advantages of excluding controversial

¹⁰ I leave consideration of competition law, drug safety legislation, trade protection and international IP treaties to others.

¹¹ Including P Drahos, *A Philosophy of Intellectual Property* (Dartmouth, Hanover 1996); R Gold, *Body Parts: Property Rights and the Ownership of Human Biological Materials* (Georgetown, Washington DC 1996); T Fisher 'Theories of Intellectual Property' in S Munzer (ed) *New Essays in the Legal and Political Theory of Property* (CUP, Cambridge 2001); J Boyle *Shamans, Software and Spleens: Law and the Construction of the Information Society* (HUP, Cambridge 1996).

¹² Eg ALRC 'Gene Patenting and Human Health' ALRC
<<http://www.alrc.gov.au/inquiries/current/patenting/index.htm>> accessed 15 December 2007; Nuffield

technologies from patentability. It concludes that evidence from the MME suggests exclusions rarely have the desired effect. Second, through detailing the informal rules that governed innovation in the medical profession in the early 20th century, this thesis concludes that formal patent law may be inconsequential or irrelevant to innovation in some tightly knit communities that develop their own patent-like norms. Patent law may thus have its greatest effect amongst strangers.

Finally, a transversal methodological theme of this thesis is that many studies of patent law caricature the process of innovation and simplify complex social processes. This may be due to the limited caselaw and legislative sources used by patent commentators. Patent law scholarship is ripe for inter-disciplinary studies of legal and extra-legal phenomena to paint a richer picture of its processes. In epistemic terms I propose, and conduct in this thesis, a ‘thicker’, external analysis to enhance existing ‘thin’, internal analyses of patent law.¹³ Features intrinsic to patent law, however, retard this project. Patents, as compared with copyrights and trade marks are often isolated from broader debate, perhaps due to their complex subject-matter, the difficult process to obtain a patent, notoriously obscure patent disclosures and claims,¹⁴ and the application of complex criteria to determine validity. Commentary amongst patent law experts is often a self-referential technocratic discourse that fails to consider the external rationality of the patent system, ignoring broader political, social and economic effects as externalities and focusing instead on accuracy,

Council on Bioethics ‘The Ethics of Patenting DNA’
<<http://www.nuffieldbioethics.org/patentingdna/index.asp>> accessed 15 December 2007 (Nuffield Report).

¹³ DH Flaherty, ‘Writing Canadian Legal History: An Introduction’ in DH Flaherty (ed), *Essays in the History of Canadian Law* (Osgoode Society, Toronto 1981) 3-19.

¹⁴ Accessibility to a member skilled in the relevant art is a far cry from accessibility to the general public.

compliance, and ‘getting the job done’.¹⁵ Thus we tend to judge the patent system as a ‘technique’ whose efficacy is assessed by highly-trained experts and internal markers such as the number of patents granted, not by more relevant and accessible indicia such as whether patents incentivise or appropriately reward innovation or contribute to society. As patents granted on some technologies (eg business method patents) become more unjustifiable, the flaw in these technocratic judgments becomes apparent. A broader, contextual, inter-disciplinary analysis is needed that considers a range of formal and informal sources. Such analysis allows a more accurate representation of the role of patent law in innovation, attracts positive and negative input from broader constituencies and ultimately increases its social relevance and legitimacy by providing more robust justifications for patent allocations.

2 Introduction to the Dilemma

This chapter will now introduce the patent law controversy that underpins the contextual analysis of the role of patent law in medical innovation: the international and domestic patent laws that exclude from patentability therapeutic, surgical and diagnostic methods applied to the human body. The exception ostensibly fulfils public health objectives by ensuring that valuable medical technologies are not patented and remain accessible and affordable. However, the rest of this chapter will argue that the exception fails to live up to its promise in various ways.

First, its protection has been hollowed out, so that few technologies fall within

¹⁵ J Ellul, *The Technological Society* (Vintage, NY 1967); W Vanderburg, *The Growth of Minds and Cultures: A Unified Theory of the Structure of Human Experience* (University of Toronto Press,

its ambit. Secondly, the criteria for determining which technologies fall within or outside the exception seem arbitrary, unprincipled and riven with contradiction. Thirdly, the exception enjoys little support and legitimacy with the judiciary, which has difficulty interpreting its terms to allow it to fulfil its stated purpose. Fourthly, not patenting a technology does not necessarily make it accessible.

In order to focus the analysis, this thesis initially concentrates on modern diagnostic methods as the paradigmatic example of the emaciated general medical exceptions that will be elaborated later. Concentrating on diagnostic exceptions is also useful as it contributes to the final case-study which considers current challenges posed by the patentability of genetic diagnostic tests. As we will see, to many, the diagnostic exception from patentability is a confusing, vestigial and largely irrelevant provision the potential of which to resolve pressing issues of access to medical technologies remains unmet.

3 Introducing the Patents Regime

A patent, as currently understood, is a right, granted to an inventor or her successor patentee by the state to exclude others from the manufacture, use, sale or other commercialization of a new, non-obvious, industrially applicable invention.¹⁶ The patentee can, however, consent to any of these activities by a third party. This right to exclude, often referred to as a legal monopoly, may not necessarily result in an economic monopoly. The patent holder's right may be circumscribed by health and

Toronto 1985).

safety regulations, criminal law, human rights law or competition law, among other possible rights or claims. Further use of the patent may also be limited by prior (and subsequent) rights: eg a patent that improves a prior patented innovation may only be used subject to the rights of the earlier patent holder.

The patented invention can be a product (a physical entity or thing), a process (an activity or action such as a method, process or use), or even a hybrid entity. The decision to seek a patent is often made with the assistance of professional patent agents, skilled in the administrative, substantive and scientific aspects of patents. A patentee may seek a patent granted by a national patent office, or by the European Patent Office (EPO) in Munich¹⁷ or via the initial application system under the Patent Cooperation Treaty.¹⁸ The grant is secured through application and payment of a fee (and periodic renewal fees), registration, examination and prima facie validation of the novelty, non-obviousness and industrial applicability of the invention by the relevant Patent Office (PO). In the UK examination was first introduced in 1905¹⁹ to increase the likelihood of validity and to deter weak applications that might chill research and development in certain fields.²⁰ Novelty ensures that patents are not granted for inventions in the public domain and that are part of the state of the art, to prevent enclosing prior knowledge available to the public that needs no incentive for

¹⁶ EPC Arts 52-57; Trade Related Agreement on Intellectual Property Rights (adopted 15 April 1994) 33 ILM 81 Art 27 (TRIPS); UKPA ss 1-4A (UKPA).

¹⁷ The EPO awards a standard bundle of national patents from the EPO, which grants a patent in each of the designated countries that is governed by national law.

¹⁸ These mechanisms are outlined in great detail in L Bently and B Sherman *Intellectual Property Law* (2nd edn OUP, Oxford 2004) 344.

¹⁹ Fry Committee (1901) 23 Parliamentary Papers which discovered that over 40 percent of patents registered at that time were for inventions already described in other patents

²⁰ W Cornish, M Llewelyn and M Adcock, *Intellectual Property Rights (IPRs) and Genetics: A Study into the Impact and Management of Intellectual Property Rights within the Healthcare Sector* (Cambridge Public Health Genetics Unit 2003) 16 (PHGU Report).

its disclosure.²¹ Non-obviousness assesses whether an invention is inventive enough to be granted a patent²² to ensure that only real contributions (not minor improvements) are granted exclusive exploitation rights.²³ Further, non-obviousness is said to incentivise more adventurous research and also ensures the public is not barred from doing something that is merely an obvious extension of what already exists.²⁴

Importantly, for the purposes of this thesis, the PO also ensures that the patent application is not for a prohibited subject-matter. Once obtained by the inventor or her assignee, the patent becomes a proprietary, territorially circumscribed asset that can be bought, sold or licensed to third parties.²⁵ Patents can be pooled (subject to competition law) or otherwise managed strategically as assets between and within businesses.²⁶ In the UK, the patent will be granted to the first inventor to file a patent application, rather than to the demonstrated first inventor (as in the US).

The patent's written scope and claims are disclosed to the public by the PO in return, it is argued, for the grant of a monopoly of exploitation to the patentee. Determining adequate disclosure remains a challenging exercise.²⁷ The invention will enter the stock of publicly available knowledge that can be built upon through research by other inventors. The inventor's monopoly is enforced by the state, secured through statutory recognition, processed by administrative agencies of the

²¹ Bently & Sherman (n 18) 443.

²² Bently & Sherman (n 18) 470.

²³ *Harwood v Great Northern Railway Co* (1964-5) 11 HLC 654, 682 (Lord Westbury).

²⁴ *PLG Research v Ardon International* [1999] FSR 116, 136.

²⁵ To be discussed further in Chapter 2.

²⁶ Eg PH Sullivan, *Profiting from Intellectual Capital: Extracting Value from Innovation* (Wiley, Toronto 1998).

²⁷ See eg PHGU Report (n 20) [3-50]; *Valensi v British Radio* [1973] RPC 337 (CA).

state, and enforceable in court. The monopoly lasts 20 years from the filing date,²⁸ after which time it expires.²⁹ This term applies to all types of inventions³⁰ and was thought to be the fairest balance between sufficient reward to innovators and the public detriment of high monopoly costs.³¹ The ‘ideal term’ of patent protection remains an unresolved and controversial topic of discussion.³²

The remedies for infringing a patent holder’s veto rights have typically included injunctions against defendants, destruction or stopping imports of infringing articles and an account of profits, or damages for lost profits (awarded on a royalty basis to the patentee) or primary and secondary losses.³³ After examination and grant, a European patent can be ‘opposed’, a procedure which can be brought within nine months after grant on the grounds of unpatentable subject-matter, inadequate disclosure or over-breadth.³⁴ A successful opposition will invalidate the patent in all the designated states; outcomes include revoking, maintaining, or maintaining with amendments.³⁵ Oppositions can be filed by anyone, and have been used by non-governmental organizations (NGOs) and other interested parties protesting the grant of patents on public policy or morality grounds.³⁶

²⁸ EPC Art 63.

²⁹ Except for certain goods: Council Regulation (EEC) 1768/92 of 18 June 1992 concerning creation of supplementary protection certificates for medicinal products [1992] OJ L 182.

³⁰ Except for patents subject to patent ‘term restoration’ which has lengthened patent term by up to 5 years for certain products by Regulation to compensate for time consumed by regulatory processes: Council Regulation (n 29). See also S Crespi, ‘The EC’s Draft Regulation on Patent Term Restoration’ (1990) *Intellectual Property in Business* 17; HP Kunz-Halstein, ‘The Compatibility of a Community “Certificate for the Restoration of Protection” with the European Patent Convention’ [1990] *EIPR* 209.

³¹ PHGU Report (n 20) [3-48]; I Ayres and P Klemperer, ‘Limiting Patentees’ Market Power Without Reducing Innovation Incentives: The Perverse Benefits of Uncertainty and Non-Injunctive Remedies’ (1999) 97 *Michigan L Rev* 985.

³² I Rahnasto, *Intellectual Property Rights, External Effects, and Anti-Trust Law: Leveraging IPRs in the Communications Industry* (OUP, Oxford 2003) [2.143].

³³ Bently & Sherman (n 18) c 48.

³⁴ EPC Art 100(a); EPC Art 100(b); Art 83; EPC Art 100(c); Art 123(2).

³⁵ EPC Art 102.

³⁶ The first of the three grounds of opposition described above: s 53(a). Eg Greenpeace opposition resulted in the decision *Plant Genetic Systems/Glutamine synthetase inhibitors* [1993] 24 *Intl Review*

This thesis will be concerned with technologies that are excluded as unpatentable subject-matter because they are medical methods, particularly of diagnosis. In order to frame the later theoretical discussion, the next section will discuss in detail some specific features of the patent law.

4 Further Features of the Patent Right

(a) Limited Subject-Matter

Not everything can be patented. Historically, patentable subject-matter was defined by the Statute of Monopolies (SOM) 1623,³⁷ which prohibited the Crown from granting patents, *inter alia*, where the invention was ‘contrary to law, [or] mischievous to the State, by raising prices of commodities at home, or hurt of trade, or generally inconvenient’.³⁸ ‘General inconvenience’ was often used successfully to deem inventions unpatentable until it was removed from the UKPA.³⁹ As will be discussed further in Chapter 4, ‘general inconvenience’ suggests that an overriding

of Industrial Property and Copyright L 618 (Opp Div); Curie Centre opposition to Myriad Genetics patents on diagnostic tests (text to n 1163 c 6); a collection of 23 European animal rights organizations filed 17 oppositions on animal welfare and environmental grounds which resulted in *Re President and Fellows of Harvard College* [1991] Eur Patent Office Rep 525 (Examining Div) (Harvard Mouse); oppositions filed by the Green Party of the European Parliament led to the decision in *Howard Florey/Relaxin* [1995] OJEPO 388 (Opp Div). See also Nuffield Report (n 12) [3.46].

³⁷ This built on the efforts by King James I who had revoked all previous patents and declared in his Book of Bounty that ‘monopolies are things contrary to our laws’ and ‘we expressly command that no suitor presume to move us’. The exception to the ban on patents was for ‘projects of new invention so they be not contrary to the law, nor mischievous to the State’: HI Dutton *The Patent System and Inventive Activity During the Industrial Revolution 1750-1852* (Manchester U Press, Manchester 1984) 94.

³⁸ (UK) 21 Jac 1 c 3.

³⁹ *Hiller’s Application* [1969] RPC 267 (Pat App Trib); *Rolls-Royce Ltd’s Application* [1963] RPC 251 (Pat App Trib).

test of public interest must be satisfied when granting a patent.⁴⁰

From these roots grew the four types of subject-matter exception to the UKPA and EPC to let the Patent Office operate at the ‘crossroads between science and public policy’.⁴¹ The first exception requires that inventions must be capable of ‘industrial application’,⁴² also referred to popularly as ‘utility’ or ‘usefulness’.⁴³ Importantly, lack of industrial applicability justifies excluding medical and veterinary methods of treatment from patentability.⁴⁴ A public interest exemption⁴⁵ requiring a public benefit,⁴⁶ ‘utility’ has grown into one tool to weed out abstract or intellectual creations or discoveries.⁴⁷

Secondly, patents are not granted for inventions ‘the *commercial exploitation* of which would be contrary to public policy or morality’ or under the EPC ‘inventions the *publication or exploitation* of which would be contrary to “*ordre public*” or morality’.⁴⁸ These provisions are subject to the proviso that contrary to public policy or morality does not mean contrary to national law or regulation⁴⁹ and are subject to the minimum requirements of TRIPs.⁵⁰ Morality and public policy judge the lawfulness of the grant of intellectual property rights (IPRs) and are closely related to

⁴⁰ S Ricketson, ‘Business Method Patents: A Matter of Convenience?’ (2003) 2 IPQ 97, 119.

⁴¹ *Greenpeace v Plant Genetic Systems NV* [1995] OJEP 545 (Tech Bd App) 564-565 (PGS).

⁴² UKPA 1977 s 1(1)(c); EPC Art 52(1)(4).

⁴³ Nuffield Report (n 12) [3.35].

⁴⁴ UKPA 1977 s 4(2).

⁴⁵ PHGU Report (n 20) B.1.

⁴⁶ Harvard Mouse (n 36); M Llewelyn, ‘Industrial Applicability/Utility and Genetic Engineering: Current Practices in Europe and the United States’ (1994) EIPR 473 for more discussion.

⁴⁷ Llewelyn (n 46) 476.

⁴⁸ UKPA 1977 s 1(3); EPC Art 53(a) [emphasis added]: note that this has been modified by Art 6(1) the Biotech Directive to state that ‘Inventions shall be considered unpatentable where their *commercial exploitation would be contrary to ordre public* or morality; however, exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation’ (emphasis added). This will be discussed more fully in the next section.

⁴⁹ UKPA 1977 s 1(4); EPC Art 53(a).

⁵⁰ Specifically TRIPs Art 27.2.

the use or industrial applicability of an invention.⁵¹ Thus the historical industrial inapplicability of medical diagnostic methods in both the UKPA and the EPC (although both recently amended in this regard, as will be discussed below) is closely linked to considerations of morality and public policy. The public policy and morality provisions have arisen more frequently in recent years than in the past due to the ethical questions about patenting the products of genetic engineering.⁵² EPO guidelines stipulate that the purpose of the provisions is ‘to exclude from protection inventions likely to induce riot or public disorder, or to lead to criminal or other generally offensive behaviour.’⁵³

Generally, the EPO has defined the concept of *ordre public* as including the protection of public security and physical integrity of individuals as a part of society, as well as the protection of the environment.⁵⁴ Morality seeks to ascertain and respect society’s views on a particular subject, through such means as opinion polls,⁵⁵ surveys,⁵⁶ the critical cultural morality⁵⁷ and laws and legislation.⁵⁸ Two morality tests have developed in the case-law: the public abhorrence test⁵⁹ and the unacceptability test,⁶⁰ which may be irreconcilable.⁶¹ Ultimately morality often

⁵¹ Some argue ‘inextricably linked’: Harvard Mouse (n 36).

⁵² Bently & Sherman (n 18) 434; D Thomas and G Richards, ‘The Importance of the Morality Exception Under the European Patent Convention: The Oncomouse Case Continues’ (2004) 26(3) EIPR 97.

⁵³ Guidelines for examination in the European Patent Office, as last amended in December 2007, Part C, c IV [4.1].

⁵⁴ Nuffield Report (n 12) [3.45]; Thomas (n 52) 98.

⁵⁵ Rejected in PGS (n 41).

⁵⁶ Rejected in PGS (n 41).

⁵⁷ Thomas (n 52); PGS (n 41).

⁵⁸ *Harvard/Onco-mouse* [1989] OJEPO 451, [10.3] (Exam Board) (Onco-mouse).

⁵⁹ Adopted in *Lubrizol Genetics Inc (Lubrizol II)* [1992] OJEPO 71; by the Examining Division in PGS (n 41); and by the Opposition Division in *Relaxin* (n 36).

⁶⁰ ‘To balance the respective advantages and disadvantages to society of the patent’, which was adopted in Onco-mouse (n 58) and the more specific ‘unacceptability to the moral norms of European culture’ test adopted in PGS (n 41).

⁶¹ A Warren, ‘A Mouse in Sheep’s Clothing: The Challenge to the Patent Morality Criterion Posed by “Dolly”’ (1998) 20(12) EIPR 445, 452. She believes that abhorrence is a much better standard, in part

devolves to a utilitarian benefit/detriment analysis of whether the commercial exploitation of an invention is immoral or not.⁶² Commentators question whether patent offices, as opposed to national legislatures or specialised commissions, are the proper forum for deciding complicated matters of morality and public policy⁶³. The EPO has said that *it* ‘is not the legislature which has to balance conflicting interests and lay down legal rules.’⁶⁴

The third type of subject-matter exception excludes discoveries, scientific theories and presentations of information, among other things.⁶⁵ This exception seeks to preserve certain tools and knowledge in a public domain accessible to all creators.

The fourth type of subject-matter excluded from patentability is ‘any variety of animal or plant or any essentially biological process for the production of animals or plants, not being a microbiological process or the product of such a process.’⁶⁶ Animals are excluded because of public sentiment that they are not proper patentable subject-matter for moral or ethical reasons; the plants exclusion reflects international commitments under the International Convention for the Protection of New Varieties of Plants (UPOV) that ensure that plant varieties are not over-protected.

because it is more fixed and certain; unacceptability is more uncertain and unfixed and may merely reflect personally held views.

⁶² PHGU Report (n 20) C(3)(b).

⁶³ The initial decision by the Examining Board in Harvard Mouse declined to consider Article 53(a) arguing that morality was not the legislative tool to regulate these problems: Onco-mouse (n 58) [10.3]; D Beyleveld and R Brownsword *Mice, Morality and Patents: The Onco-mouse Application and Article 53(a) of the European Patent Convention* (Common Law Institute of Intellectual Property, London 1993).

⁶⁴ S Moore, ‘Challenge to the Biotechnology Directive’ [2002] EIPR 149, 154.

⁶⁵ UKPA 1977 s 1(2); EPC Art 52(2)(3).

⁶⁶ UKPA 1977 [3f] of sch A2; EPC Art 53(b).

(b) Patent Rights Holders can Multiply

The patent law has developed mechanisms to allow patent holders either to consent or to be forced to grant others rights under their patent. The voluntary mechanism, a licence, is negotiated between the patentee and a third party, subject to the general law on contracts.⁶⁷

Practice with respect to licences recognises that obtaining a valid patent is only the first tier of legal regulation of the rights granted. A patent gives its holder the exclusive right to exploit an invention, or to authorise someone else to exploit it. If the patent holder decides to pursue this latter path, she can then authorise third parties to exercise those rights instead or in addition to the patent holder through a formal licence agreement. Further, the licence can cover some or all of the rights she has in the patent. While there are no required terms for a patent licence to be enforceable, licence terms generally include its subject, duration, nature (exclusive, sole or non-exclusive), the territory within which the licensee can exercise her rights, obligations of the licensor and licensee, financial terms that cover licence fees and tax liability, provisions for termination of the licence, ownership of any IPRs (including improvements) that may result from the licensed invention, and confidentiality obligations (including requirements that the terms of the licence be kept confidential). Licences are policed by competition law, which protects the public interest by monitoring the territorial exclusivity of licences as well as prohibiting certain restrictive terms.⁶⁸

⁶⁷ Licences are sometimes created unilaterally without consideration. The distinction between a contract and a licence is significant in US law as it determines which of the federal (licence) or the state (contract) government will regulate the innovation.

⁶⁸ PHGU Report (n 20) [7-32]-[7-40]. These provisions are contained in the Council Regulation (EC) 1996/240 on the block exemption for technology transfer [1996] OJ L31 (Block Exemption).

The commercial development of a patented product is often determined by how it has been licensed (exclusively, solely or non-exclusively). An exclusive licence permits only the licensee (and whoever he authorises) to exploit the patent, barring even the patent-holder from the rights.⁶⁹ A sole licence entitles both the patent holder and the licensee to exploit the patent, but does bar the patent holder from granting rights to others. A non-exclusive licence allows the patent holder to retain rights to exploit the patented invention and also to license the invention to others on any terms it likes. Patent licences are rarely stand-alone documents; they fit into a much broader commercial strategy. Licences are frequently involved in the creation of a spin-off company, a strategic alliance or joint venture, and may be implicated in manufacture and collaboration agreements. Licences may allow companies to exchange information and resources, or provide a company with access to a new market by providing access to manufacturing or distribution networks. The licence may be used to cement future research collaborations or to settle prospective or existing patent litigation.⁷⁰

Despite a light registration requirement mainly for exclusive licences, very little is known about who is licensing what to whom, and under what terms.⁷¹ Licensing practice is rarely documented and publicised. It remains embedded within a regime of private ordering and is treated as a trade secret by some industries. There is no obligation to make the terms of licensing agreements public, even when they cover important technologies such as medicines essential to treating serious diseases

⁶⁹ Exclusive licenses may be limited to a particular country, for a specific period of time or for a specific use, thus allowing potentially several exclusive licences on one patent.

⁷⁰ ALRC (n 12).

⁷¹ OECD, *Genetic Inventions, Intellectual Property Rights and Licensing Practices* (OECD, Geneva 2002) 45, 48 (OECD Report). Noted recently by MA Lemley and N Myhrvold, 'How to Make a Patent Market' (August 2007) Stanford Law and Economics Olin Working Paper No 347 <<http://ssrn.com/abstract=1012726>> accessed 15 December 2007.

and epidemics.⁷² Licensing of patented technologies is widespread. What research exists suggests that in Germany, for example, about 50% of patented inventions held by research institutions and biotechnology companies are licensed.⁷³ The data showed that companies were generally willing to license innovations except some valuable research tools.⁷⁴ Other data suggest that the prevalence of licences on gene patents leads to such problems as royalty stacking (payment of multiple royalties for access to patented technologies) and claims for reach-through royalties on downstream inventions.⁷⁵ These results are consistent with those found in the US.⁷⁶ A further study concluded that licensing was common for new biotechnology firms in order to allow pharmaceutical companies access to innovations.⁷⁷

Exclusive licences, especially their effect on restricting broader access to patented inventions, have led to high profile quasi-regulatory activity in recent years, particularly by the US National Institutes of Health in relation to genomic inventions⁷⁸ and the OECD in respect of genetic inventions.⁷⁹ The OECD Guidelines, for example, set out principles and best practices for licensing agreements, research freedom, commercial development and competition, treating patents and licensing as part of a broader business and research strategy. They particularly encourage limiting the use of exclusive licensing and reducing coordination problems, to ensure that the

⁷² L Peterson, 'More Anti-Virals in the Hands of Politicians' *Embassy* (Ottawa 19 October 2005) 1.

⁷³ The data are unclear, however, as to whether licensing statistics covered multiple licences on a single patent and there is no data available for pharmaceutical companies: OECD Report (n 71) 46.

⁷⁴ OECD Report (n 71) 47.

⁷⁵ OECD Report (n 71) 48. Reach-through generally means the ability of a patent holder to claim entitlements or royalties for further unrelated uses of their patented invention identified by researchers at a later stage: Nuffield Report (n 12) [5.37].

⁷⁶ OECD Report (n 71) 50.

⁷⁷ OECD Report (n 71) 52.

⁷⁸ National Institutes of Health, 'Best Practices for the Licensing of Genomic Inventions' (2005) <<http://ott.od.nih.gov/pdfs/70FR18413.pdf>> accessed 11 July 2007.

⁷⁹ OECD, 'Guidelines for the Licensing of Genetic Inventions' (2006) <<http://www.oecd.org/dataoecd/39/38/36198812.pdf>> accessed 11 July 2007 (OECD Guidelines).

best products and services are brought to market.⁸⁰ These Guidelines provide a window into existing practice by encapsulating and disseminating best practices.⁸¹ Thus patents, through disclosure, provide information about what has been invented and by whom but provide limited information⁸² on the broader ecology of invention, eg how the technology is being developed, by whom, where and how. Thus, truly to understand the effect of a patent, one must at the very least consider the effect of accompanying licensing regimes and their terms.

Governments can also force a patent holder to license patent rights to third parties, through compulsory licences for objectives that include ensuring that valuable patents are worked or that patents are not used to block the exploitation of other technologies.⁸³ The state allows the patentee a royalty or other fee in exchange for the compulsory licence to some or all of the patent rights.⁸⁴ In reality, the threat of compulsory licences is much more often used than the actual mechanism, so their impact is unclear.⁸⁵ Additionally, through ‘Crown use’ the Crown itself can make a patented product or sanction its use (among other rights) without a licence, subject to compensating the patent holder.⁸⁶ It can do this for purposes that include defence and the production or supply of specified drugs or medicines.⁸⁷ Crown use provisions are

⁸⁰ OECD Guidelines (n 79).

⁸¹ M Herder and J Johnston, ‘Licensing for Knowledge Transfer in Human Genetics Research: A Study of Business Models for Licensing and Technology Transfer in Human Genetics Patents’ (2007) Report for Health Canada (on file with the author).

⁸² Except through studies of patent citation statistics.

⁸³ PHGU Report (n 20) [7-44].

⁸⁴ UKPA 1977 s 50(2). The UK compulsory licensing provisions are now amended so as to be subject to TRIPS Art 31 which requires that granting compulsory licences should be subject to an individual assessment, as well as to a range of conditions.

⁸⁵ PHGU Report (n 20) [7-48]; MAL Banks *The British Patent System: Report of the Committee to Examine the Patent System and Patent Law* (HM Stationery Office Cmnd 4407 1970) 65 (Banks Committee). See also UKPA 1977 ss 48, 48A, 48B.

⁸⁶ UKPA 1977 ss 55-58; Bently & Sherman (n 18) 529; PHGU Report (n 20) [7-49-7-50]. This provision was introduced especially because the compulsory licensing procedure would not apply to the Crown: PHGU Report (n 20).

⁸⁷ UKPA 1977 s 56(2)(a), 56(2)(b).

now subject to TRIPs Article 31(a) which restricts the conditions under which uses not authorised by the patentee can occur.⁸⁸

(c) Research Nominally Allowed

Patentees also do not have the right to block many research uses of their patented invention. A research exemption exists in EPC countries as well as in the Community Patent Convention (CPC),⁸⁹ and allows exemptions for experimental use.⁹⁰ It does not encompass using patented tools for experimental research.⁹¹ There is great uncertainty, however, as to the precise scope of the research exception.⁹²

5 Patent Legislation

The UK patents regime, and in particular the exclusion of medical and diagnostic methods, is governed by the terms of the UKPA⁹³ and the EPC.⁹⁴ The UKPA has largely adopted the harmonised patenting standards of the EPC and the CPC.⁹⁵ The legislation is interpreted by caselaw. Both statutes have recently modified these provisions in the Patents Act 2004 (UK)⁹⁶ and EPC 2000⁹⁷ respectively. I shall first outline the original provisions, since the current caselaw developed under those, and

⁸⁸ TRIPs (n 16).

⁸⁹ 89/695/EEC Agreement Relating to Community Patents (adopted 15 December 1989) [1989] OJ L401 (CPC).

⁹⁰ PA 1977 s 60(5)(b); CPC (n 89) Arts 25-28; PHGU Report (n 20).

⁹¹ PHGU Report (n 20).

⁹² PHGU Report (n 20); T Cook 'A European Perspective as to the Extent to which Experimental Use, and Certain Other, Defences to Patent Infringement, Apply to Differing Types of Research' (IPI 2006).

⁹³ UKPA (n 9).

⁹⁴ EPC (n 8).

⁹⁵ PHGU Report (n 20) 16.

⁹⁶ c 16.

⁹⁷ (adopted 28 June 2001) Special Edition No 1 OJ EPO 3.

then discuss the changes. The UKPA provided in section 4(2) under the heading of ‘Industrial Application’ that

An invention of a method of treatment of the human or animal body by surgery or therapy or of diagnosis practiced on the human or animal body shall not be taken to be capable of industrial application.

The EPC similarly provided under the heading ‘Patentable Inventions’:

Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body shall not be regarded as inventions which are susceptible of industrial application...⁹⁸

The Patents Act 2004 moved the MME from under ‘Industrial Application’ to section 4A:

Methods of treatment or diagnosis

- (1) A patent shall not be granted for the invention of
 - (a) a method of treatment of the human or animal body by surgery or therapy, or
 - (b) a method of diagnosis practised on the human or animal body.
- (2) Subsection (1) above does not apply to an invention consisting of a substance or composition for use in any such method.

In much the same way, the EPC 2000 moved the provision to ‘Exceptions to Patentability’ and removed any suggestion that medical methods were unpatentable due to a lack of industrial applicability. The provision now reads:

53. European patents shall not be granted in respect of:

...

- (c) methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body; this provision shall not apply to products, in particular substances or compositions, for use in any of these methods.⁹⁹

The wording of the original EPC and UKPA provisions differs from one other

⁹⁸ Art 52(4).

⁹⁹ Art 53(c).

in four ways¹⁰⁰ that, however, have had no discernible impact on how the exception of diagnostic methods has developed.¹⁰¹

A further note about terminology is needed. The caselaw and literature use many terms for methods that all have essentially the same meaning. A method is synonymous with a process or procedure but is distinct from a product or substance. Thus the method of medical treatment exception does not prohibit the patenting of diagnostic substances, compositions, apparatuses or products. A method patent can be used to achieve the desired results by following the procedure set out in the specification, whereas a product patent's goal is to produce the product from the specification. The distinction between product and process or method is significant, since not until 1842 was it clearly held by a court that the definition of a 'manner of new manufacture' in the Statute of Monopolies (SOM) 1623¹⁰² comprehended both products and processes.¹⁰³ There are legitimate concerns that allowing patenting of methods strays dangerously close to inherently unpatentable subject-matter like discoveries and mathematical methods.

¹⁰⁰ 1) The UKPA presumes the innovation in issue to be an invention that is not capable of industrial application. In the EPC, the technology is not even regarded as an invention.

2) The UKPA refers to a 'method of treatment... or of diagnosis' presumably meaning the conjunction 'method of diagnosis'; the EPC uses the term 'diagnostic methods'.

3) The use of the term 'and' in the EPC between surgery or therapy and diagnostic methods, as compared to the equivalent use of the term 'or' in the UK Act.

4) UK Inventions of methods are not 'capable' of industrial application whereas in the EPC they are not 'susceptible' of industrial application.

¹⁰¹ Although the EPC will prevail: Jacob, J in *Bristol-Myers Squibb Co v Baker Norton Pharmaceuticals Inc* [1999] RPC 253 (Pat Ct) [51], aff'd in part [2001] RPC 1 (CA) [3]-[5].

¹⁰² (UK) 21 Jac 1 c 3.

¹⁰³ *Crane v Price* (1842) 1 WPC 393, 134 ER 239.

6 Caselaw Interpreting the Legislation has Narrowed the Exception

In the UK and Europe, both medical methods of treatment and diagnostic methods are excluded from patentability. The following is a current snapshot of how exclusion has been interpreted, focusing on diagnostic methods.

To determine whether the method in question falls within the exception, one must look to the overall purpose or effect of the invention.¹⁰⁴ In particular, until the recent *Cygnus* case, the medical exception was construed narrowly, which consequently provided minimal protection.¹⁰⁵ The definition of a diagnostic method was established in the foundational *Thomson-Csf/Tomodensitometry (No 2)* case.¹⁰⁶ In *Thomson* the Technical Board of Appeal held that a diagnostic method cannot comprise merely a method of analysis, but must also include a concrete diagnostic result.¹⁰⁷ Thus, as was then held in *Ultrafem*, it must encompass *all* the steps involved in making a medical diagnosis.¹⁰⁸ As was elaborated in *Bruker*, methods that provide interim results are not diagnostic methods even if they can be used in making a diagnosis. Mere data-gathering or examination do not constitute a method of diagnosis, which also requires the further steps of a) comparison with normal values, b) identification of a deviation from normal, and c) attribution to a clinical

¹⁰⁴ *Baxter* [1998] EPOR 363 (Tech Bd App) 367-68.

¹⁰⁵ *Eisai/Second Medical Indication* [1979-85] EPOR B241 (Enlarged Bd App); *Bruker* [1988] EPOR 357 (Tech Bd App) [3.2].

¹⁰⁶ [1979-85] EPOR C917 (Tech Bd App). The patent application was for a method of tomodesitometry.

¹⁰⁷ This was confirmed in *Philips/Diagnostic Method* [1979-85] EPOR C937 (Tech Bd App); *Siemens* [1988] EPOR 365 (Tech Bd App); *Thomson-Csf/Tomodensitometry (No 1)* [1979-85] EPOR C763 (Tech Bd App). Note however, the contrary holding in *Baxter* where the Board found that a method of blood extraction could be unpatentable if it constituted one step of a diagnostic method (note not the final result), eg, blood analysis for determining the cause of disease: *Baxter* [1998] EPOR 363 (Tech Bd App) 367.

¹⁰⁸ Eg *Ultrafem* [2002] EPOR 35 (Tech Bd App) where a female vaginal discharge collector was not considered a method of diagnosis since it did not produce results that made it directly possible to decide on a particular course of treatment.

condition.¹⁰⁹ For example, if the result of the process in issue was a quantitative variable, it would be exempt from patentability only if a course of medical treatment were ‘immediately clear’ from that variable.¹¹⁰ A mere investigation into the state of the body, for example by measuring blood pressure, would not be enough. The condition measured must itself indicate the pathological deviation.¹¹¹

If the device can be used by a technician who has no specialist medical knowledge or skills then it is merely a technical method of measurement, not a ‘diagnostic method’ capable of industrial application.¹¹² However, as held in *Nycomed*, if even one essential stage of the diagnosis requires a skilled medical professional then the diagnostic process is not patentable.¹¹³ A method is more likely to fall within the exception if it must be conducted by or under the supervision of a doctor,¹¹⁴ but this consideration is not definitive.¹¹⁵ Further, a ‘diagnostic method’ must include both examination and determining the symptom that should be performed *on* or *in* the human or animal body, but does not apply to substances removed from the body.¹¹⁶ When this is not the case, the device cannot constitute a diagnostic method.¹¹⁷

¹⁰⁹ *Bruker* (n 105) [3.3].

¹¹⁰ *Bruker* (n 105) [3.4.1].

¹¹¹ *Bruker* (n 105) [4.3.2].

¹¹² *Bruker* (n 105) [3.5.2].

¹¹³ *Nycomed* [1998] EPOR 206 (Tech Bd App). The Board held that to do otherwise would clearly conflict with the spirit of Art 52(4). The Board also found that the doctor who supervised the diagnostic process did not have to be the same doctor responsible for the final diagnosis: 210.

¹¹⁴ *Siemens* [1989] OJEPO 171 (Tech Bd App).

¹¹⁵ *Baxter* (n 107) 366-67.

¹¹⁶ EPO Guidelines ch IV 4.3.

¹¹⁷ *Bruker* (n 105) [4.1]; *R v Cygnus* [2002] EPOR 26 (Tech Bd App) [27]. Examples of tests performed ‘on’ the human body include allergy tests and scarlet-fever spots observed directly.

Apparatus used for diagnosis is patentable like any other apparatus but is not patentable when used in a method of diagnosis. Second medical uses of apparatus are also not patentable.¹¹⁸ The justification is that compositions are expended in use; thus further use requires expansion of manufacture, whereas the same apparatus can be used many times for many different purposes.¹¹⁹

Commentators believed that these holdings by the Technical Board of Appeal, particularly that diagnosis must comprise all steps, effectively dissolved the legislative exclusion of diagnostic methods.¹²⁰ The requirements of the caselaw were fully incorporated into the EPO Guidelines.¹²¹

However, many of the holdings on diagnostic methods to this point were substantially reversed by the 2002 decision in *Cygnus*. In that case, the Board of Appeal held that diagnostic methods were not limited to those methods that comprised *all* the steps necessary to reach a medical diagnosis, as required by *Bruker*; to hold otherwise would create a harsher standard for diagnostic methods than that established for methods of surgery or therapy,¹²² lead to perverse results¹²³ and would be inconsistent with definitional readings of the terms ‘diagnostic’ and ‘diagnosis’ in English, French and German.¹²⁴ Further, the Board of Appeal held that the exception

¹¹⁸ *Expandable Grafts/Surgical Device* [2002] EPOR 24 (Tech Bd App); *Codman/Second Surgical Use* [1995] EPOR 82 (Tech Bd App).

¹¹⁹ *Codman* (n 118) [5.2].

¹²⁰ R Moufang, ‘Methods of Medical Treatment Under Patent Law’ (1993) 24(1) IIC 18, 47. The requirements of the caselaw have been fully incorporated into the EPO Guidelines ch IV 4.3.

¹²¹ Esp EPO Guideline ch IV 4.3.

¹²² *Cygnus* (n 117) [21], see below for further elaboration.

¹²³ A strict interpretation of this requirement would mean that typical diagnostic procedures like percussion, auscultation or palpation would be patentable since they do not provide a complete medical diagnosis. The Board also felt that to create an exception for manual methods of diagnosis would go against the spirit of Art 52(4): *Cygnus* (n 117) [20].

¹²⁴ *Cygnus* (n 117) [26].

should not be interpreted narrowly.¹²⁵ This broader interpretation of the exception has led to dissatisfaction among some of the patent community.¹²⁶ On 8th April 2004 the President of the EPO referred a point of law relating to the interpretation of the term ‘diagnostic methods practised on the human or animal body’ within the meaning of Article 52(4) EPC to the Enlarged Board of Appeal.¹²⁷

The Enlarged Board of Appeal overruled most of the holdings in *Cygnus*, narrowing the scope of the diagnostic exception even further in the interests of legal certainty. It held that *Bruker*’s test for an excludable diagnostic method was still good law,¹²⁸ justifying that narrow interpretation by arguing that the EPO is in the business of granting patents and that diagnostic tests are not generally performed by medical practitioners anyway so they will not be unduly constrained.¹²⁹ Thus a prohibited diagnostic technology must include both the intellectual act of diagnosing and the preceding technical steps.¹³⁰ In this respect, argued the Enlarged Board, a diagnostic method was inherently different from a surgical or therapeutic method as it requires several steps of examination, data gathering and comparison.¹³¹ Thus legal treatment of diagnostic methods was not inconsistent with surgical and therapeutic methods. The Enlarged Board also held, significantly, that a medical or veterinary practitioner did not have to be present, bear responsibility or even be the only one qualified to

¹²⁵ *Cygnus* (n 117) [28]; D Vaver ‘Intellectual Property: The State of the Art’ (2000) 116 LQR 621.

¹²⁶ TW Roberts, ‘Methods of Diagnosis: Request for an Opinion from the Enlarged Board of Appeal’ (2002) Chartered Institute of Patents Agents J 73. Roberts asked for an Enlarged Board of Appeal to provide a decision on the patentability of diagnostic methods resulting from the holding in *Cygnus*. He alleged that the *Cygnus* decision violated EPO Guidelines, overturns a decade of caselaw and contravened the *Vienna Convention on the Law of Treaties*, which requires a narrow interpretation of statutory exceptions.

¹²⁷ EPO (homepage) <http://www.european-patent-office.org/news/info/2004_04_08_e.htm> accessed 2 September 2004.

¹²⁸ *Opinion of the Enlarged Board of Appeal* [2006] OJEP 334, [5] (EBA Decision).

¹²⁹ EBA Decision (n 128) [6].

¹³⁰ EBA Decision (n 128) [6.1].

¹³¹ EBA Decision (n 128) [6.2.2].

carry out the diagnostic steps for it to be unpatentable, on the logic that defining and protecting medical practitioners was a matter for state regulation, not the EPO.¹³² In keeping with a narrow interpretation, the Enlarged Board held that the requirement of ‘on the human body’ requires an interaction with the human body at each step, necessitating the presence of a body.¹³³ Software and *in vitro* methods, for example, would not be excluded.¹³⁴ The Enlarged Board also stated that the EPC 2000 would not alter the interpretation of the provision.¹³⁵

The Enlarged Board of Appeal thus overruled *Cygnus*, while attempting to address some of the core concerns with conflicting caselaw on the diagnostic methods exception. While it adverted at the beginning of the decision to the public health and socio-ethical justifications of the exception, it is interesting that those questions of access or a broader interpretation of the exception’s function played no role in the subsequent decision. A further significant feature is the Enlarged Board’s reluctance to single out medical practitioners for protection, a wise move given the range of individuals who in fact administer these tests.¹³⁶

¹³² EBA Decision (n 128) [6.1].

¹³³ EBA Decision (n 128) [6.4.4].

¹³⁴ EBA Decision (n 128) [6.4.3].

¹³⁵ EBA Decision (n 128) [10-11].

¹³⁶ The impact on the interpretation of medical exclusions of the recent *Aerotel v Telco* ([2006] EWCA Civ 1371) decision in the UK and *Duns Licensing Associates* ([2006] T 0154/04 – 3.5.01 (Enlarged Bd App)) from the EPO on the interpretation of exceptions is unclear, although there is little indication thus far that the approach to the MME will change particularly at the EPO given its rejection of the questions posed in *Aerotel* in *Duns*.

7 **Diagnostic Exception Construed More Narrowly than Surgical and Therapeutic Methods Exceptions**

Surgical and therapeutic methods are also excluded from patentability by Article 52(4) EPC and section 4(2) UKPA, but their patentable scope is broader than that of diagnostic methods.¹³⁷ Surgery is defined as the branch ‘of medicine concerned with the healing of disease, accidental injury or bodily defects by operating on the living body’ and includes invasive procedures using instruments as well as non-invasive ones.¹³⁸ Therapy broadly ‘implies the curing of a disease or malfunction of the body’.¹³⁹ The surgical and therapeutic exception, similar to the diagnostic methods exception, excludes apparatus and substances,¹⁴⁰ and applies to treatment only ‘on or in’ the body.¹⁴¹ A technology is more likely to be excluded where a high level of skill and knowledge for its use is required;¹⁴² this adversely affects the exclusion of diagnostic methods since technicians (of supposedly lower skill and knowledge) disproportionately apply diagnostic methods to patients.

As mentioned above in relation to *Cygnus*, however, methods of surgery and therapy can be excluded from patentability if they constitute only one step of a surgical or therapeutic nature¹⁴³ and therapy can include both prophylactic treatments and also curative treatments of diseases that have already arisen.¹⁴⁴ (It will be recalled that the diagnostic methods exclusion does not apply to prophylactic testing).

¹³⁷ Moufang (n 120); Bently & Sherman (n 18) 367.

¹³⁸ *Shell/Blood Flow* [1994] EPOR 320 (Tech Bd App).

¹³⁹ EPO Guidelines (n 121) 4.2.1.

¹⁴⁰ *Expandable Grafts* (n 118); *Codman* (n 118).

¹⁴¹ *Salminen/Pigs III* [1989] EPOR 125 (Tech Bd App); *Siemens* (n 114).

¹⁴² *Thompson/Cornea* [1995] OJEPO 512 (Tech Bd App).

¹⁴³ *Georgetown University* [2001] EPOR 21 (Tech Bd App); *Telectronics* [1996] EPOR 409 (Tech Bd App) but see comments in EBA Decision (n 128).

¹⁴⁴ *Duphar/Pigs II* [1988] EPOR 241 (Tech Bd App).

The narrowness of the diagnostic exception, as compared to surgery and therapy, further justifies focusing on it in understanding why medical methods were legislatively excluded.

8 International Commitments: TRIPS

The regime excluding medical methods of treatment from patentability in the UK and Europe is supported by an international regime. The UK is a signatory to TRIPS,¹⁴⁵ which in Article 27.3(a) allows members to exclude ‘diagnostic, therapeutic and surgical methods for the treatment of humans or animals’ from patentability. TRIPS is regarded as the international baseline of IP protection required by states and stands as an example of how harmonization through minimum standards has caused patent provisions to propagate. The scope of the permissible exclusion is unknown, especially since TRIPS must be interpreted in light of the national laws existing at the time the treaty was negotiated. In the context of UK and European law, TRIPS may well be as limited as diagnostic methods are by the existing caselaw; these limitations will be explored in the following section.¹⁴⁶

¹⁴⁵ TRIPS (n 16).

¹⁴⁶ *Vienna Convention on the Law of Treaties* [1974] ATS 2 (entered into force 27 January 1980) art 31–32.

9 Questions about the Exception in the Domestic Courts of Other Countries

The international regime envisioned by Art. 27.3(a) of TRIPS is reinforced by a matrix of legislation and caselaw in other countries. Many of those other countries have had similar challenges to those of the UK and Europe in determining the proper scope of the modern MME. I shall consider a sample of countries, in particular those that have recently legislated novel forms of MMEs (the US), and countries that have either imported statutory patent regimes from the UK or whose caselaw is influential in the UK (Australia, New Zealand and Canada). Their varying responses to this common dilemma suggest both the ambiguity and path dependency of MMEs from patentability.

The United States has a limited MME in practice, after creating and then abolishing it through caselaw. Medical and diagnostic processes are not explicitly excluded from or included in patentability in the US Constitution or in any subsequent Patent Act.¹⁴⁷ From 1862 until 1954, medical and surgical procedures were not patentable.¹⁴⁸ They became patentable in the US from 1954 until 1996 after the decision in *ex p Scherer*.¹⁴⁹ Medical and surgical procedure patents were, however, rarely enforced. They were mainly used to assert authorship of a procedure, rather than to reap financial reward.¹⁵⁰

¹⁴⁷ Note that patentable subject-matter under US patent legislation is very broad and includes ‘anything under the sun that is made by man’ ((HR 1923 82nd Congress 2nd Session 6 (1952); *Diamond v Diehr* 450 US 175, 101 S Ct 1048 (1981)) with some clear exceptions, such as laws of nature, physical phenomena, and abstract ideas (*Diamond v Chakrabarty* 447 US 303, 100 S Ct 2204 (1980)).

¹⁴⁸ *Morton v New York Eye Infirmary* 17 F Cas 879 (CCSDNY 1862) 883-84; reinforced by *ex parte Brinkerhoff* in DS Chisum, *Patents: A Treatise on the Law of Patentability, Validity and Infringement* (M Bender New York 1978) s 1.03[3], 1-70.

¹⁴⁹ 103 USPQ 107 (PO App Bd 1954) 110 where the Patent Office Board of Appeals distinguished *Morton* and expressly reversed *Brinkerhoff*.

¹⁵⁰ LR Judge, ‘Issues Surrounding the Patenting of Medical Procedures’ (1997) 13 Santa Clara Computer and High Technology LJ 181,187.

In 1996 the US enacted legislation that excludes medical practitioners from patent infringement liability when medical methods are used in the course of medical treatment.¹⁵¹ This action arose out of a case where a doctor refused to license a patent to another doctor for a procedure that avoided sutures during cataract surgery.¹⁵² Although diagnostic methods were not included in the legislation, a Democrat introduced a Bill entitled the ‘Genomic Research and Diagnostic Accessibility Act of 2002’ into the House of Representatives¹⁵³ to amend section 271 of Title 35 and exempt ‘genetic diagnostic, prognostic, or predictive test[s] or a medical or surgical procedure’ from infringement remedies.¹⁵⁴

An opportunity to consider the patentability of a diagnostic test was recently refused by the United States Supreme Court, when it denied certiorari in *Laboratory Corporation of America Holdings v. Metabolite Laboratories* (‘LabCorp’) thus upholding the lower court’s finding of patent infringement by the petitioner.¹⁵⁵ The patented test in issue claimed a method of detecting Vitamin B12 deficiency by testing for high levels of an amino acid called homocysteine. LabCorp argued the patent was invalid as it claimed a ‘natural phenomenon’. Justice Breyer, in dissent

¹⁵¹ 35 USC § 287(c): ‘Limitation on damages and other remedies; marking and notice’. Note that earlier versions of the legislation would have prevented the PTO from granting a patent for ‘any invention or discovery of a technique, method, or process’ of ‘making a medical diagnosis (defined as the identification of a medical condition or a disease or disorder of a body)’; HR 3814 104th Congress (1996). The medical activity encompassed by s. 287(c) includes ‘the performance of a medical or surgical procedure on a body, but shall not include (i) the use of a patented machine, manufacture, or composition of matter in violation of such patent (ii) the practice of a patented use of a composition of matter in violation of such patent, or (iii) the practice of a process in violation of a biotechnology patent.’

¹⁵² *Pallin v Singer* 36 USPQ 2d 1050 (D Vt 1995).

¹⁵³ HR 3967 107th Congress (2002). For the full text of the Bill see: Democratic Caucus, ‘Committee on Science’ <http://www.house.gov/science_democrats/member/lr031402.htm> accessed 3 June 2003.

¹⁵⁴ S 271(3)(a). The Democratic Representative who introduced the Bill was not re-elected in November 2002 and the present status of this initiative is unclear.

¹⁵⁵ *Laboratory Corporation of America Holdings v Metabolite Laboratories* 548 US __ (2006) [LabCorp].

from the Supreme Court's denial, (Souter and Stevens JJ concurring), agreed with LabCorp holding that the patent claimed a basic scientific relationship. He argued that his reasoning was supported by public interest concerns of legal certainty, leaving medical practitioners' exercise of judgment unrestricted, and ensuring doctors did not have to divert their energies to checking licence agreements before proceeding.¹⁵⁶ The Court's failure to consider *LabCorp* has been widely criticised, in particular as an abdication of responsibility as gate-keepers of subject-matter eligibility in patent law.¹⁵⁷

In Canada, the Patent Act¹⁵⁸ has no statutorily mandated MME.¹⁵⁹ The caselaw has determined that medical methods are excluded from patentability.¹⁶⁰ Medical methods are not perceived as 'inventions' for the purposes of the Patent Act since they are 'essentially non-economic and unrelated to trade, industry or commerce,¹⁶¹ and instead more closely related to the area of professional skills.'¹⁶²

¹⁵⁶ LabCorp (n 155).

¹⁵⁷ DS Olson, 'Patentable Subject Matter: The Problem of the Absent Gatekeeper' (September 27, 2006) <<http://ssrn.com/abstract=933167>> accessed 15 December 2007.

¹⁵⁸ RS 1985 c P-4. It does contain an exception for a 'mere scientific principle or abstract theorem': s 27(8).

¹⁵⁹ While it was suggested at one stage that the Act be amended to contain an exception from patentability of medical treatment procedures, this was never implemented: *Working Paper on Patent Law Revision, Department of Consumer and Corporate Affairs* (Minister of Supply and Services Ottawa 1976) 119.

¹⁶⁰ *Tennessee Eastman v Comr of Patents* [1974] SCR 111; *Re Schering AG's Application* [1971] 3 All ER 177 (Pat App Trib).

¹⁶¹ The invention in issue in *Tennessee* was a surgical method of joining or bonding the surfaces of incisions or wounds in living animal tissue by applying certain compounds. The compounds were old and well-known but the compounds' property of bonding the tissues was a new discovery. The key issue facing the court was whether a new use for surgical purposes of a known substance could be claimed as an invention. The court found that if a process claim for a method of treatment of a substance were patentable then the inventor would have subverted the instructions of s 41 prohibiting the patenting of substances for food and medicine by effectively patenting the substance. However, patents on a specific process for making a substance are valid. The decision in *Tennessee* that medical methods of treatment are not included in the definition of 'invention' was subsequently upheld as a general principle of patent law, independently of the specific provisions of the *Patent Act*: *Imperial Chemical Industries Ltd v Canada (Patent Comr)* [1986] 3 FC 40 (Fed CA). The decision in *Imperial Chemical* held that a leading function of a claim for a method of cleaning dental plaque or stains was medical. See also *Re Senentek* (1997) 77 CPR (3d) 321 where the Patents Appeal Board more recently decided that a claimed method and composition for reversing the effects of ageing was not a method of medical treatment as ageing was not a disease and thus did not relate to medical treatment.

Diagnostic methods, however, are patentable.¹⁶³ Patents for purely diagnostic methods have regularly been granted by the Patent Office.¹⁶⁴ One may question whether the division in Canada between medical and diagnostic methods is sustainable: it is indispensable to medical treatment to diagnose a disease properly, and diagnostic methods play an integral role in the treatment of disease through medical methods.

New Zealand caselaw excludes medical methods from patentability¹⁶⁵ and appears to extend the same treatment to diagnostic methods,¹⁶⁶ although diagnostic testing that does not require surgery may still be patentable.¹⁶⁷ Legally, the unpatentability of medical methods of treatment in New Zealand seems to rest on the notion that they are not a ‘manner of manufacture’ or are ‘generally inconvenient’.¹⁶⁸ A treatment on the human body cannot create a vendible article or one that could directly or indirectly be used in commerce.¹⁶⁹ The normative reason why methods of medical treatment are excluded from patentability is based on morality, ethics and

¹⁶² As interpreted by Wilson J in *Shell Oil Co v Canada (Comr of Patents)* [1982] 2 SCR 536 [41]. This decision was later elaborated upon in *Lawson v Comr of Patents* (1970) 62 CPR 101 (Can Ex Ct) where a patent on a method for describing boundaries of plots of land was rejected on the basis that it was not an ‘art’ as contemplated by the act because it related to the application of professional skills, rather than to trade, industry or commerce: 109.

¹⁶³ Foreshadowed in *Burton Parsons Chem Inc v Hewlett-Packard (Can) Ltd* [1976] 1 SCR 555. Decided in *Re Goldenberg* (1988) 22 CPR (3d) 159.

¹⁶⁴ Eg Patent 3944693 entitled ‘Fluorescent Dyes to Make Visible Disease Causing Matters in Oral Cavity’; Patent # 1087981 entitled ‘Plaque Disclosing Agent’; Patent #1075601 entitled ‘Composition and Method for Determining Size and Location of Myocardial Infarcts’. See also: Patents #1071102, 1075154, 1171952: Canadian Intellectual Property Office, ‘Canadian Patents Database’ <<http://patents1.ic.gc.ca/intro-e.html>> accessed 23 June 2003.

¹⁶⁵ *Wellcome Foundation Ltd v Comr of Patents* [1983] NZLR 385 (CA).

¹⁶⁶ *Pfizer Inc v Commissioner of Patents* (2004) 60 IPR 624 (NZ CA) [95].

¹⁶⁷ *Pharmaceutical Management Agency Ltd v Comr of Patents* [1999] NZCA 330 where the Court of Appeal concluded that allowing ‘diagnostic testing not requiring surgery’ was acceptable: 24.

¹⁶⁸ *Wellcome* (n 165); *Pfizer* (n 166).

¹⁶⁹ *Maeder v ‘Ronda’ Ladies’ Hairdressing Salon* [1943] NZLR 122 (SC). This case, however, was criticized in *Wellcome* by Cooke J who stated that ‘this Court need no longer insist on the *Maeder* limitation’: 389. See also *Swift & Co v Comr of Patents* [1960] NZLR 775 (SC).

public policy.¹⁷⁰ As a result, any change in the established law must rest with the legislature, after consulting with the appropriate interest groups and accounting for concerns that rest outside the realm of strict legal reasoning.¹⁷¹ Note that as a result the Ministry of Economic Development reviewed the medical exception and has made submissions to Parliament on this issue.¹⁷² Meanwhile, the Intellectual Property Office of New Zealand rejects patent claims to methods of medical treatment.¹⁷³

Australia stands out in this list of countries for providing no exception whatsoever from patentability for either medical or diagnostic methods, either by statute or common law.¹⁷⁴ While early Australian cases concurred with the UK position opposing the patentability of medical methods of treatment,¹⁷⁵ Australian law no longer adopts this position. The foundation of the MME from patentability was that a treatment of a part of the human body could not create the required vendible commercial product.¹⁷⁶ However, *National Research Development Corp v Comr of Patents (NRDC)*¹⁷⁷ dispensed with the requirement for a vendible product. While the legislature did not take the opportunity to exclude processes of medical treatment

¹⁷⁰ Or as Hammond J explains in *Pfizer* (n 166) that ‘historically, the exclusion of patents for medical treatment was not (until relatively recently) doubted’ even though the reason why could not be easily juristically pigeon-holed: [107].

¹⁷¹ *Wellcome* (n 165) 404, 398 Somers and McMullin JJ respectively; *Pfizer* (n 166) [83].

¹⁷² NZ Ministry of Economic Development, ‘Intellectual Property Policy’ <http://www.med.govt.nz/buslt/int_prop/patentsreview/discussion/patentsreview-09.html#TopOfPage> accessed 15 December 2007.

¹⁷³ Regulatory and Competition Policy Branch ‘Review of the Patents Act 1953: Boundaries to Patentability, A Discussion Paper’ (2002) New Zealand Ministry of Economic Development <http://www.med.govt.nz/buslt/int_prop/patentsreview/discussion/patentsreview-09.html#P539_128966> accessed 12 July 2003 [213].

¹⁷⁴ *Bristol-Myers Squibb Co v F H Faulding & Co Ltd* (2000) 97 FCR 524; see also Ricketson (n 40) for a discussion of ‘general inconvenience’ and business methods patents in Australia.

¹⁷⁵ *Maeder v Busch* (1938) 59 CLR 684 (HCA) 33.

¹⁷⁶ *ibid* 706-7.

¹⁷⁷ (1959) 102 CLR 252 (HCA) 276; *Joos v Comr of Patents* (1972) 46 ALJR 438 (HCA); *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1994) 50 FCR 1 (NSW Gen Div); *Bristol Myers Squibb Co v FH Faulding & Co Ltd* (2000) 97 FCR 524.

when it enacted the most recent version of the Patent Act in 1990,¹⁷⁸ the recent court decisions refused to pass on issues of ethics and social policy¹⁷⁹ and so the question whether medical methods of treatment should be excluded from patentability is still very much under discussion in Australia.¹⁸⁰

Thus, the international regime is supported by a well-developed national debate in several countries about whether, why and how medical methods of treatment should be excluded from the patent regime.

10 Public Health Justifies the Exclusion from Patentability

Understanding how the legal system justifies the exclusion of medical technologies helps explain the present definition and scope of the exception. The earliest general justification for the exclusion from patentability, initially articulated in 1914 in *Re C&Ws Application*¹⁸¹ and reinforced in many subsequent cases,¹⁸² was that medical methods were not patentable because they did not result in a vendible product, and thus lay outside the sphere of economic activity.¹⁸³ The particular justification is grounded in a desire not to commodify the human body or create a market by commodifying treatments on the body, through patents.¹⁸⁴ This argument has lost

¹⁷⁸ *Rescare* (n 177) 19, 43.

¹⁷⁹ *Rescare* (n 177) 45.

¹⁸⁰ ALRC (n 12).

¹⁸¹ (1914) 31 RPC 235 (S-G).

¹⁸² In New Zealand: *Maeder v Ronda* (n 169); *Wellcome Foundation Ltd v Comr of Patents* [1983] NZLR 385 (CA) (Cooke J); *Swift* (n 169). In Australia: *Maeder v Busch* (n 175).

¹⁸³ *Re C&W's Application* (1914) 31 RPC 235 (S-G).

¹⁸⁴ D Thums, 'Patent Protection for Medical Treatment - A Distinction Between Patent and Medical Law' (1996) 27(4) IIC 423, 430.

favour in legal circles over time for two main reasons.¹⁸⁵ First, the line between what is and is not economic is hard to draw.¹⁸⁶ In particular, it is difficult to argue that medical treatment is a non-commercial activity outside the economic sphere, especially because of the massive economic activity in biotechnology, genetics, pharmaceuticals, medical devices and, increasingly in medical care itself. Secondly, the dispute now is not whether treatments on the body could lead to the commodification of the body, but rather whether parts of the body themselves are the proper subject of property rights.¹⁸⁷ The fall from favour of the perception that medical treatment is non-economic or non-industrial is evidenced by the recent revisions enacted by the EPC 2000 and the UKPA 2004 that have removed the so-called ‘legal fiction’ of the unpatentability of medical methods due to a lack of industrial applicability. Medical diagnostic methods of treatment are now just unpatentable, presumably for public health reasons.¹⁸⁸

This public health justification has grown from the doctrinal soil of section 6 of the SOM.¹⁸⁹ Section 6, as will be discussed in Chapter 4, was the statutory foundation for the grant of patents until the UKPA 1977. Under Section 6, patents would not be granted for inventions deemed ‘generally inconvenient’ (among other grounds). By 1975, some judges were asserting that ‘general inconvenience’ underpinned the MME (which included the diagnostic exception),¹⁹⁰ although neither the EPC nor UKPA has explicitly enacted a ‘generally inconvenient’ provision. The

¹⁸⁵ This justification has been explicitly rejected in *Joos v Comr of Patents* (1972) 126 CLR 611 (HCA) and *Rescare* (n 202), both heavily influenced by *NRDC* (n 1035). See also recent EBA Decision (n 128).

¹⁸⁶ *Joos* (n 185) 617.

¹⁸⁷ *Moore v Regents of the University of California* (1988) 249 Cal Rptr 494 (CA), rev’d (1990) 51 Cal 3d 120 (SC).

¹⁸⁸ *ibid.*

¹⁸⁹ This will be discussed more fully in the next chapter.

¹⁹⁰ *Eli Lilly* (n 1051); *Wellcome* (n 182); *Joos* (n 185); *Rescare* (n 202).

UKPO recently confirmed that the exception has a public health objective,¹⁹¹ as did the EPO when it stated the exception was ‘based on socio-ethical and public health considerations’.¹⁹² Its core concern is generally ensuring access to healthcare. Its promise is that the ‘life-saving’ work of a doctor should not be hampered by the exercise of patent rights,¹⁹³ or as Jacob J noted in relation to medical methods generally: ‘The purpose of the limitation is... merely to keep patent law from interfering directly with what the doctor actually does to the patient.’¹⁹⁴ The EPOs Enlarged Board articulated it as ‘those who carry out diagnostic methods as part of the medical treatment of humans or veterinary treatment of animals are not inhibited by patents’.¹⁹⁵ However, UK and EPO caselaw lacks any more detailed development of this justification.¹⁹⁶

11 The Promise and its Problems

The promise and public health objective of the diagnostic exception on their face suggest that a reformulated exception could play a role in resolving the current conflicts between IPRs and access to health care goods in the ownership of cutting-edge technologies, particularly in the field of genetics.¹⁹⁷ Studies and commentators

¹⁹¹ UKPO, ‘Updates to Patents Bill’ UKPO <

<http://www.patent.gov.uk/about/ippd/issues/patsbill/index.htm>> accessed 4 June 2004.

¹⁹² EBA Decision (n 128) [4].

¹⁹³ *Georgetown* (n 143); *Nycomed* (n 113); *Wellcome/Pigs* [1988] EPOR 1 (Tech Bd App) [3.7]; *Cygnus* (n 117) [13]; *Bruker* (n 105); *Wellcome* (n 182) (Sheppard J).

¹⁹⁴ *Bristol-Myers Squibb Co v Baker Norton Pharmaceuticals Inc* [1999] RPC 253 (Pat Ct) [51], *aff’d* in part [2001] RPC 1 (CA).

¹⁹⁵ EBA Decision (n 128) [4].

¹⁹⁶ See generally D Vaver, ‘Invention in Patent Law: A Review and a Modest Proposal’ 11(3) *Intl JL Info Tech* 286.

¹⁹⁷ W Cornish, M Llewelyn and M Adcock, *Intellectual Property Rights (IPRs) and Genetics: A Study into the Impact and Management of Intellectual Property Rights within the Healthcare Sector* (Cambridge Public Health Genetics Unit 2003) Part 2.C.3(c) (PHGU Report); Ontario Ministry of Health, ‘Genetics, Testing & Gene Patenting: Charting New Territory in Healthcare (2002)’ Ontario

who have considered this issue also note, however, that the use and application of this provision have been widely ignored and rarely discussed. This thesis identifies how the provision originated, analyses its development and considers where it fits in a broader matrix of public health, access and IP law concerns.

Although courts and legislatures promise to protect doctors' valuable life-saving work, the promise has remained unfulfilled in four ways. First, while the medical diagnostics exception exists on paper in caselaw and statute, in practice the substantive legal protection it provides is emaciated or, as some argue, non-existent.¹⁹⁸ As the brief discussion above of UK and European caselaw demonstrates, a method of diagnosis has to encompass all stages of diagnosis and produce a concrete diagnostic result. Few diagnostic methods meet these stringent criteria, which do not reflect the true nature of a medical diagnosis: such a diagnosis is rarely final and is generally aided by data and quantitative results from laboratory testing.

Moreover, the legitimacy of the patent system is undermined when there is limited substantive protection of what a lay citizen would comprehend as a valuable health care good that ought to be covered by the exception and be exempt from the patent monopoly. The medical methods of treatment exception from patentability, described by Cornish as the 'last redoubt against the sweep of the patent system into the territory of health care',¹⁹⁹ is a natural site of contest and interpretation. For

Ministry of Health

<http://www.health.gov.on.ca/english/public/pub/ministry_reports/geneticsrep02/genetics.html> accessed 25 March 2004 89 (Ontario MOH Report); Nuffield Council on Bioethics, 'The Ethics of Patenting DNA' <<http://www.nuffieldbioethics.org/patentingdna/index.asp>> accessed 2 July 2003 xi (Nuffield Report).

¹⁹⁸ This is further elaborated by Moufang (n 120) 47; W Cornish *Intellectual Property: Omnipresent, Distracting, Irrelevant?* (OUP, Oxford 2004) 11.

¹⁹⁹ WR Cornish and D Llewellyn, *Intellectual Property: Patents, Copyright, Trade Marks & Allied Rights* (5 ed, Sweet & Maxwell, Andover 2003) [5-73].

example, lay observers have brought oppositions challenging the patents on genetic diagnostic tests owned by Myriad Genetics over the BRCA1 and BRCA2 genes. These oppositions ask, among other grounds, why the exception has not stepped in to exclude inventions that clearly impede public access to healthcare, ostensibly the reason why the exception exists in the first place.²⁰⁰ The lack of alternative substantive protection for health care in the patent law increases the importance of the MME.

Secondly, what protection of diagnostic methods does exist shows little evidence of a principled legal approach with objectively justifiable outcomes. The distinctions drawn in law seem arbitrary, fruitless and riven with contradiction, as judges since the 1970s have observed.²⁰¹ An example is the requirement that diagnosis must be performed *on or in* the body. This means that a diagnostic method of testing for allergies performed on the skin will be excluded from patentability whereas a blood test of material removed from the body to the same end will be patentable. It is unclear why apparatus and drugs are patentable but medical and diagnostic methods are not, particularly when both can be applied in or on the

²⁰⁰ Institut Curie *European-Wide Opposition Against the Breast Cancer Patents* Press Release (26 September 2002).

²⁰¹ In *Eli Lilly & Co's Application* [1975] RPC 438, 445 the Patents Appeal Tribunal held that it has been long established that the medical exception is based on ethics not logic: 'It is no doubt sensible that a person who is able to produce a substance which, for example, would cure or prevent cancer should, subject to safeguards, be offered a limited monopoly as a reward, and the possibility of such monopoly protection has undoubtedly resulted in an enormous investment in research in the medical field. If this position is accepted, it is a little difficult to see why someone who by research effort devises a new method of using a known substance to achieve equally beneficial results should be denied patent protection.' This was most recently reinforced in a UK by Jacob J in *Bristol-Myers* (n 194): 'The thinking behind the exception is not particularly rational: if one accepts that a patent monopoly is a fair price to pay for the extra research incentive, then there is no reason to suppose that that would not apply also to methods of treatment.' . See also 'Grounds given with regard to the ratification of international patent conventions' where it is stated that the exclusion made by Art 52(4) EPC is ethically motivated: R/1181/74, p 18, [3].

body.²⁰² Further concerns are raised as to why doctors in particular are given blanket protection from patents in the course of their ‘life-saving’ work, while other professions and trades whose work is arguably as important to preserving or bettering life are not treated similarly. Examples are fire fighters and emergency workers, paraprofessional health workers, municipal water suppliers, sanitation and other public authorities. In many cases, diagnostics are not even administered by medical practitioners:²⁰³ so exempting diagnostics from patentability seems like a mismatch between regulation and effect if doctors’ work is the intended target.

Third, judges, lawyers and commentators²⁰⁴ have questioned the legitimacy of the exception since the 1970s.²⁰⁵ In fact, a survey of the literature on this topic has not found a single commentator who supports the continued existence of the exception in its present form. This questioning has been brought to its logical conclusion in Australia, where the exception has been judicially abolished altogether, a result most recently approved by the Australian Law Reform Commission (ALRC).²⁰⁶ Though quelled in Europe by the passage of legislation, this scepticism has led to the progressive hollowing-out of the exception since its purpose, scope and role are not understood.²⁰⁷ This question merits serious attention in the harmonised, globalised intellectual property law world, where a provision excluding medical methods is almost automatic for countries seeking to legislate IP protection at acceptable levels

²⁰² *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1994) 50 FCR 1 (NSW Gen Div) 6; *Bristol-Myers Squibb Co v F H Faulding & Co Ltd* (2000) 97 FCR 524 [15].

²⁰³ As observed in EBA Decision (n 128).

²⁰⁴ O Mitnovetski and D Nicol, ‘Are Patents for Methods of Medical Treatment Contrary to the Ordre Public and Morality or “Generally Inconvenient”?’ (2004) 30(5) J Medical Ethics 470; Thums (n 184).

²⁰⁵ *Eli Lilly* (n 201); *Re Schering AG’s Application* [1971] 3 All ER 177 (Pat App Trib) 181; *Re Dow Corning Corporation (Bennett’s) Applications* [1974] RPC 235 (Pat App Trib).

²⁰⁶ ALRC (n 12).

²⁰⁷ *Eg Bio-Digital Sciences Inc’s Application* [1973] RPC 668 (Pat App Trib).

for compliance with TRIPS.²⁰⁸

Finally, legislating an exception to patentability is not a useful means of maintaining access to valuable medical technologies. Excluding valuable technologies from patent protection means that the innovator will either protect them by some other form of IPR, most likely trade secrecy, which limits disclosure and onward use of the innovation. Or the inventor will place the invention in the public domain, where a later inventor could patent a further technical application distinct from the unpatentable original innovation, limiting access anyway.²⁰⁹ Thus not patenting may be as limiting as patenting. Holding a patent may also sometimes give innovators the power to allow access and control valuable uses of technology. This has increasingly been acknowledged and adopted by some public institutions, including hospitals and universities.²¹⁰

Excluding certain medical technologies entirely from patentability would make sense if medical technology were created and used exclusively by physicians, and its unpatented use were governed by a series of robust norms concerning appropriate use. This is, in fact, the situation that existed when the exception from patentability was first sought, as will be discussed in Chapters 3 to 5. However, that reality no longer exists. Medical innovation now occurs through a vast collaboration of researchers at universities, public and private research institutes and private corporations, governed by a range of heterogeneous normative orders that will be

²⁰⁸ Eg Article 27:3(a) of the *Agreement on Trade-Related Aspects of Intellectual Property Rights* (adopted 15 April 1994) 33 ILM 81 (TRIPS); *North American Free Trade Agreement* Article 1709(3)(a) (opened for signature 17 December 1992) (1994) 32 ILM 289 (NAFTA).

²⁰⁹ S Boettinger and D Burk, 'Open Source Patenting' (2004) 1 J Intl Biotech L 221; A Chander and M Sunder, 'The Romance of the Public Domain' (2004) 92 California LR 597.

²¹⁰ See for eg the British Columbia Cancer Agency with respect to patenting the SARS virus.

discussed in Chapter 6.

This chapter has self-consciously adopted a ‘thin’ formal legal analysis to sketch the current law regarding the MME in a range of jurisdictions and introduce the current dilemma over excluding medical technologies. Two aspects of this analysis thread through the thesis.

First, it is evident that the modern MME excludes few technologies and is ineffective in addressing controversial new medical technologies, particularly diagnostics. The pervasive uncertainty as to why the MME exists and what purposes it serves (or could fulfill) is an international debate. The present state of affairs makes sense once one considers the origins of the formal legislated exclusion and recognises it ultimately as the product of a need to reach consensus in international negotiations (Chapter 5). The present ineffectiveness of the MME also reflects the predictions and experiences of the various parties who either sought, or fought, the enactment of a formal norm (Chapters 4 and 5).

Secondly, the modern MME has evolved from focusing on the non-vendible nature of the medical product created, to a justification concerned with securing access to valuable medical innovation. As will become clear, particularly in Chapters 3 and 5, this closely maps the evolution of the informal norm in the same period, suggesting that formal and informal regimes influence each other although the means by which they do this remain unclear.

2. JUSTIFYING PATENT LAW

1 Introduction

The previous chapter detailed the MME's present legal form and limited effect by analyzing formal legal sources. This chapter will introduce the theoretical framework that will aid in widening our examination of the MME's legal development to broader social, economic and political factors. The theory of legal pluralism underpins this effort. When applied to this study, it posits that informal norms and customs may have significantly contributed to the development through the 20th century of the law excluding medical technologies, in addition to formal law-making activities. This chapter argues that a legal pluralist account of the development of the MME will help explain and justify the eventual form of the MME better than an account drawn from purely formal sources. In fact, an exclusively formal account would be incoherent, as it misses the negotiations, non-legal rule-making and practices that informed and shaped the law.

In order to justify adopting legal insights from formal and informal sources, I first consider the analytical framework, promise and drawbacks of the legal pluralist approach. Then I consider how other classical theories that might be relied on (instead of legal pluralism) to explain the development of the MME either fail to account for patent practice or are a poor fit. Finally, I examine how other legally plural scholarship has studied the interaction between formal and informal IP norms and the resulting lessons that can be applied to this study of the MME. This chapter lays the theoretical groundwork for Chapter 3 which examines group processes and formal law to account for the evolution of an norm against patenting medical

technologies.

2 Introducing Legal Pluralism

Legal pluralism is an approach to studying the law that holds that ‘formal law’²¹¹ cannot be understood without considering custom or informal norms,²¹² and vice versa. Neither formal nor informal sources takes primacy over the other; informal laws (henceforth ‘norms’) are not subordinate to an overarching state law. State law is merely one of several forms of legal regulation. As an overarching theory of law, rather than a normative theory prescribing good or bad laws, the primary use of legal pluralism is in accurately reflecting the origins, scope and effect of laws and accounting for rule-making and following behaviour.²¹³ Legal pluralist analysis arose from the insights of anthropologists and law and development scholars who observed in the field that conduct could not be accurately described or predicted by formal law. For example, anthropologists concluded that British colonial law had a limited effect on African tribes, who were in fact governed by a range of highly developed customary norms more powerful than the legislation imposed.²¹⁴

Legal pluralism makes no assumption about the effects of laws on society and individual behaviour, and is particularly sceptical of the extent to which formal law

²¹¹ Other terms used are ‘lawyer’s law’, ‘state law’ or ‘official law’: S Engle Merry, ‘Legal Pluralism’ (1988) 22(5) *L & Society* R 869.

²¹² Other terms used are ‘tradition’, ‘private government’, ‘folklore’: Merry (n 211).

²¹³ G Teubner, ‘The Two Faces of Janus: Rethinking Legal Pluralism’ (1992) 13 *Cardozo LR* 1443; E Melissaris, ‘The More the Merrier? A New Take on Legal Pluralism’ (2004) 13(1) *Social & L Studies* 58.

²¹⁴ S Falk Moore, ‘Law and Social Change: The Semi-Autonomous Social Field as an Appropriate Subject of Study’ (1973) 7(4) *L & Society* R 719.

can transform either.²¹⁵ By making no initial assumptions, a legally plural analysis judges the true effect of law empirically through practice. Thus a legal pluralist approach commends itself at the outset as a good model for studying the medical exception from patentability which, as discussed in Chapter 1, seems to have limited practical effect on regulating medical technologies and transforming medical practice.

Legal pluralists further reject the role of the state as the sole definer of the normative order. They argue that state power is often symbolic and rhetorical rather than ‘real’ and alive to citizens’ deeper personal commitments.²¹⁶ Thus citizens may be affiliated to different legal narratives based, for example, on tradition (‘this is the way we’ve always done it’) and maintaining or forging new relationships of support and interest (eg foregoing a legal right to sue over a late delivery in order to preserve a long-standing commercial relationship).²¹⁷ These other commitments may more significantly affect normative behaviour than does formal law. If so, then arguably these commitments should be considered as a form of law, even though traditionally they have not been labelled as such.²¹⁸ Situations where no formal law exists, but very complex rule-based activities take place nonetheless, should not be seen as ‘lawless’.²¹⁹

Legal pluralism is studied through examining ‘semi-autonomous social fields’ (SASF) or the activities of a social group or field. One example would be a vertical

²¹⁵ DM Trubek and M Galanter, ‘Scholars in Self-Estrangement: Some Reflections on the Crisis in Law and Development Studies in the United States’ (1974) 4 Wisconsin LR 1062.

²¹⁶ B de Sousa Santos, *Toward a New Common Sense: Law, Science and Politics in the Paradigmatic Transition* (Routledge, London 1995).

²¹⁷ R Cover, ‘Nomos and Narrative’ (1983) 97 Harvard LR 4.

²¹⁸ Moore (n 214); L Fuller, ‘Law and Human Interaction’ (1977) 47(3-4) Sociological Inquiry 59.

²¹⁹ Merry (n 211); Santos (n 216).

analysis of the garment industry, from buyers to retailers to garment-makers,²²⁰ or the norms governing the behaviour of passengers on a cruise ship. SASFs do not, however, correlate to obvious social sub-groups such as ‘the family’, ‘women’ or ‘Chinese-Canadians’ unless these are fields of shared understanding of rules.²²¹ Laws inhabit rather than create or define a rich ecology of continuous social interaction and play a much broader role than as individualistic tools of social control.

Legal pluralist accounts of patent law promise greater theoretical understanding of patent law but may also lead to better law-making. Patent law’s legitimacy has been questioned throughout its existence,²²² debates that continue to the present.²²³ Justifications for entitlements change with social, economic and political circumstances, and the process of discussion and formulation may be more important to the law’s legitimacy than a concrete outcome. A renewed framework for studying patent law may increase patent law’s legitimacy and sustainability, minimizing arbitrariness and legal ossification.

Legal pluralism has weaknesses as well as strengths. It embraces a more ponderous empirical approach that rarely leads to conclusive answers. While this may disrupt rather than help policy-making in the short term, it may, more closely represent reality in the longer term than other legal analytical tools. Further, empirical results may be biased by the observations and affiliations of the investigator, although this can usually be controlled through experimental procedures. More seriously, at its

²²⁰ Moore(n 214).

²²¹ J Griffiths, ‘The Social Working of Legal Rules’ (2003) 48 J Legal Pluralism 1.

²²² Janis (n 351).

²²³ Negative commentary on the patent law has increased to a level some commentators argue parallels patent abolition movements in the mid-nineteenth century: W Cornish *Intellectual Property: Omnipresent, Distracting, Irrelevant?* (OUP, Oxford 2004) 5.

extreme, legal pluralism may become so contextual that everything is law, thus posing a problem for bounding the research and reaching meaningful conclusions.²²⁴ One tool to limit legal pluralism is to define the concept of a ‘norm’.

Norms are structural characteristics of groups that both summarise group behaviours and streamline processes of influence within the group.²²⁵ They are generally developed and applied for behaviours that the group finds important.²²⁶ Norms are distinguished from other behaviours in specific situations as people engage in them out of a sense of obligation.²²⁷ Norms-based systems operate on principles that are generally not written down or made explicit, but that are often complex.²²⁸ The group subject to those norms is educated in their terms through apprenticeships, social indoctrination events, and long-term involvement within the group. Often, the best evidence of a norm is observing if departures from it are punished by the group.²²⁹ Means of punishment include gossip, total or partial exclusion from the group or its activities, lack of trust and a reduced reputation within that group, but the means are as varied as the groups themselves.²³⁰

Norms can be developed through a decentralised or centralised process, such as through the practice of individuals (eg doctors) or centralised organizations (eg medical associations), respectively.²³¹ Further, norms do not relate only to behaviour

²²⁴ Merry (n 211).

²²⁵ E Fauchart and E von Hippel, ‘Norms-Based Intellectual Property Systems: The Case of French Chefs’ (2006) MIT Sloan Research Paper No 4576-06 <<http://ssrn.com/abstract=881781>> accessed 15 December 2007, 5.

²²⁶ Fauchart (n 225) 5.

²²⁷ Melissaris (n 213).

²²⁸ Fauchart (n 225) 3.

²²⁹ J Bendor and P Swistak, ‘The Evolution of Norms’ (2001) 106(6) *Am J of Sociology* 1493.

²³⁰ AK Rai, ‘Regulating Scientific Research: Intellectual Property Rights and the Norms of Science’ (1999) <<http://ssrn.com/abstract=172032>> accessed 15 December 2007, 6.

²³¹ *ibid* 7.

with economic consequences²³² but also to purely social rewards provided by the group. The more a group member needs the social rewards provided by group membership, the more likely she is to conform to the norm. Individuals of very high or low social status within the group are least likely to conform.²³³ Further, and importantly, many norms co-exist with and interdepend on the formal law.²³⁴

Legal pluralist methods and the study of the norms detailed above have played a limited role in the study of IP law to the present.²³⁵ IP scholarship has traditionally concentrated instead on the role of legislation and caselaw as a locus for understanding IP and its reform.²³⁶ A limited body of IP scholarship (to be discussed at the end of this chapter) explicitly integrates formal law and the informal norms of innovative communities to discover plural IP legal orders.²³⁷ Other familiar IP scholarship has integrated plural, empirical or inter-disciplinary insights that provide limited insights for this study. Two examples will be considered. First, scholars in law and economics have performed quantitative research in ‘new institutional economics’²³⁸ and have used economic analysis to speculate about the effect of legal rules on market or individual behaviour.²³⁹ Law and economics, however, is more

²³² Fauchart (n 225) 5.

²³³ Fauchart (n 225) 6.

²³⁴ Rai (n 230).

²³⁵ But a growing role if considers a number of new research groups including, for eg, the work of the Intellectual Property Modelling Group (homepage) <www.cipp.mcgill.ca/en/projects> accessed 15 December 2007; Duke University’s Center for Genome Ethics, Law & Policy (homepage) <<http://www.genome.duke.edu/>> accessed 15 December 2007; the University of Oxford’s E-Research Centre (homepage) <<http://www.oerc.ox.ac.uk/>> accessed 15 December 2007; and the University of Alberta’s Health Law Institute (homepage) <<http://www.law.ualberta.ca/centres/hli/research.html>> accessed 15 December 2007.

²³⁶ Nuffield Report (n 197); ALRC (n 12); but see OECD Guidelines (n 79) and the Commission for Intellectual Property Rights (homepage) <<http://www.iprcommission.org/>> accessed 18 July 2007.

²³⁷ One notable endeavour has been the effort to explore the role of the informal research exemption: MR Henry and others, ‘A Pilot Survey on the Licensing of DNA Inventions’ (2002) 279 Science 1279.

²³⁸ R Merges, ‘Contracting into Liability Rules: Intellectual Property Rights and Collective Rights Organizations’ (1996) 84 Cal LR 1293.

²³⁹ JM Grushcow, ‘Measuring Secrecy: A Cost of the Patent System Revealed’ (2004) 33 J Legal Studies 59.

concerned with avoiding unexpected or unwanted inefficiencies than with the discursive role of law and norms and the social ecology of rule-following behaviour. Secondly, IP law has engaged with the inherently pluralist tensions arising from the debate over traditional knowledge. Northern researchers are characterised as imposing their liberal, individualistic understanding of property rights and laws on knowledge that is traditionally accessible to the Southern community through local custom. While IPRs prioritise individual commercialization, Southern communities are characterised as being more concerned with the traditional, religious or group functions of a technological artifact developed by a community of innovators rather than by one individual.²⁴⁰ This debate is thus a conflict between the ‘informal’ indigenous legal order and formal, harmonised IP law. The relevance of these studies is limited, however, by the economic or development focus of their analysis.

Before considering studies that have considered the development of IP laws through the lens of legal pluralism, I shall consider in the next section why other ways of theorizing IP law are not appropriate or are ill-suited to this study.

3 How Existing Justifications Fall Flat

Existing justificatory theories do not provide a coherent account of how patent law actually operates. Utilitarian theory fails to account for the actual operation of patent law by caricaturing its application as narrow, atomistic and economic in focus with an unspecified notion of the greatest good. Labour and social contract theory similarly simplify the patent as a strong right with duties to a diffuse and unspecified public

²⁴⁰ Chander & Sunder (n 209).

interest, ignoring the nature of a patent as a regulatory privilege.²⁴¹ Far from harmless, these limitations of proprietorism have been identified as leading to access and distribution problems.²⁴² I shall demonstrate that, at a broad level, patents and the complex technologies they represent are negotiated within a network of relationships. Those networks of communities of creation (be they professional, occupational or even improvisational) have a complex social understanding of motivation, incentive and reward, poorly represented by the formal law. Open source licensing practice and informal research exemptions have provided windows into that world of informal normativity. The historical examination of the MME in the rest of this thesis continues that discussion.

The failure to conceive of innovation and the social good as being achieved by groups or lineages of innovators, communicating and interacting through formal and informal channels, for rewards much more complex than economic ones, has impoverished patent theory and practice. The reasons for this, including the desire to create a manageable, objective, 'scientific' discourse about innovation and the convenience of using existing property and economic frameworks to rationalise the messiness of innovation, will not be explored in this thesis.

²⁴¹ Although an emerging body of so-called relational proprietorism philosophy emphasizes reliance interests and virtue ethics as analytical frameworks: JW Singer, 'Sovereignty and Property' (1991) 86 *Northwestern U LR* 1; D Lametti, 'The (Virtue) Ethics of Private Property: A Framework & Implications' in A Hudson (ed), *New Perspectives on Property Law, Obligations and Restitution* (Cavendish, London 2003) 39.

²⁴² *ER Gold and others, 'The Unexamined Assumptions of Intellectual Property': Adopting an Evaluative Approach to Patenting Biotechnological Innovation* (2004) 18(4) *Public Affairs Q* 299.

The traditional patent vision of innovation sees the inventor as a member of a liberal society maximizing his economic interest as a rational market player using a patent as a right to pursue its commercialization and development. This enriches both the inventor and society. The standard liberal patents discourse has caricatured the process of innovation, generally ignoring subjective, localised investigations into why people, and people as part of groups, innovate and their complex relationships of interdependence, authority, reputation and reward. This section will chart that debate, starting by considering theoretical justifications for patent law, then moving to evidence from practice to evaluate those justifications, and finally by developing a legal pluralist methodology for exploring the broader rules governing innovation. That contextual approach focuses on groups rather than inventors; norms in addition to law; innovation processes rather than patents on invention; and broadly diffuse benefits in addition to economic markers. That approach will then be adopted in subsequent chapters of this thesis.

4 Justifications

Innovation is a complex, dialectical process that involves individuals, groups and communities in particular social and economic settings, negotiating rights to innovation. Traditional theory does not adequately represent the dynamics of innovation. This section explores the traditional justifications for patent law starting with property theory (which argues that patents should be treated and protected like full property rights), then addressing other popular justifications for patent law such as utilitarianism, labour theory (which argues that individuals may have a natural right to

their innovation), and finally social contract theory (which rests the entitlement of the patent holder in a contract with the state). This section argues that while various traditional justifications drawn from political theory may represent important perspectives on the justifiability of patents, they are limited in their explanatory power. A broader premise for patents will be sought.

I do not address personhood²⁴³ and first occupancy²⁴⁴ theory as neither has played a significant role in the development of Anglo-American patent law. Despite its limited role historically,²⁴⁵ personhood theory's core insights into the need for a richer conception of social welfare than economic efficiency and the broader personal or social reasons why creators create do inform this chapter's conclusions.²⁴⁶ First occupancy is, at best, a weak claim of entitlement, not a robust justification²⁴⁷ and is not supported by UK or other European patent law.²⁴⁸

²⁴³ Eg T Fisher 'Theories of Intellectual Property' in S Munzer (ed), *New Essays in the Legal and Political Theory of Property* (CUP, Cambridge 2001).

²⁴⁴ P Drahos, *A Philosophy of Intellectual Property* (Dartmouth, Hanover 1996) 202.

²⁴⁵ Particularly as many patents are held by corporations or employers, and there is no obvious patent 'moral right'.

²⁴⁶ J Hughes, 'Philosophy of Intellectual Property' (1988) 77 Geo LJ 287.

²⁴⁷ JW Harris, *Property and Justice* (OUP, Oxford 1996).

²⁴⁸ Patents in the UK and elsewhere (except the US) are granted on a first to file basis, rather than first to invent. Thus the patent law envisages independent simultaneous invention and negotiates between the two inventors.

(a) Distracting Property Discourses

An initial account of IPRs uses terms and norms from property law. Property grounds the use of, for example, both Locke and social contract theory, which justify IPR entitlements through allocating property rights. IP law has a close relationship with traditional property theory. IP is similar to traditional property in name as it is limited a right to exclude labeled 'property'. IPRs framed through property discourse are predicated on the rational and autonomous liberal subject linked to others through relationships based on property and contract,²⁴⁹ ideally to maximise his economic benefit.²⁵⁰ The IP holder has a right to exclude others that the state will enforce; the IPR gives its holder a negotiable token the benefit of which the holder tries to maximise. The property framework allows the certainty of a ready-made set of justifications and regularises expectations based on a history of practice and normative development. Justifying IPRs on the basis of traditional property rights, however, misses much of the richness and flexibility inherent in IP and its regulatory form,²⁵¹ and the use of the term 'property' is actively avoided by some.²⁵²

At a fundamental level, collapsing IP and property justifications ignores the

²⁴⁹ M Minow and ML Shanley, 'Relational Rights and Responsibilities: Revisioning the Family in Liberal Political Theory and Law' (1996) 11(1) *Hypatia* 4,12.

²⁵⁰ Some scholars have challenged this perspective although they remain on the margins of the debate: (n 241).

²⁵¹ J Boyle, *Shamans, Software and Spleens: Law and the Construction of the Information Society* (HUP, Cambridge 1996); W Cornish *Intellectual Property: Omnipresent, Distracting, Irrelevant?* (Oxford OUP 2004) at 2; Harris (n 247) 348; Nuffield Report (n 197) 22. Not to say that those who use the term 'intellectual property' are misguided. Their interest in communicating their ideas about IP likely trumps their desire to use a different label.

²⁵² Renaming IP courses as 'The Regulation of Information Production and Exchange: An Introduction to Patents, Copyrights and Similar Exclusive Rights Regimes': Professor Benkler at Yale University Law School. Renaming the World Intellectual Property Organization (WIPO) as the 'World Intellectual Wealth Organization': Free Software Foundation Europe, 'Towards a "World Intellectual Wealth Organisation"' <<http://www.fsfeurope.org/documents/wiwo.html>> accessed 5 July 2007. Other light-hearted names for intellectual property have included 'IMPs' (Imposed Monopoly Privileges) and 'GOLEMs' (Government-Originated Legally Enforced Monopolies).

very different nature of physical and intellectual property. Their differences are well-documented in the literature and will be reviewed here only briefly. First, while physical exclusivity of tangible property can be real and enforced by material fact (eg one person's use of a pencil will deprive another), IP exclusivity is manufactured through legal (eg patent infringement) and technical (eg copy protection) restrictions. Secondly, IP in most cases is costless to reproduce and its use by one person does not deprive another. Thus legal regulation enforces artificial scarcity to support economic rewards for the creator (or assignee) but ignores the power of IP that lies in its inherent reproducibility and availability. Further, in most instances IP builds on the insights and creations of those who came before in a way unparalleled by tangible property. Thus analogizing physical and intellectual property misses some of the strengths and the transformative potential of IP. Using the broad term 'intellectual property' also misses the distinct effects, history and purposes of the main different types of IPR, ie patents, copyrights and trade marks.

Not only does the attempted analogy between physical and intellectual property miss the distinctive features of IP, but it also encourages the notion that the object of patent protection is an easily definable and commodifiable 'thing'. Essentializing innovation may profoundly misrepresent the nature of the technology. For eg, patents granted over genes increasingly mischaracterise advances in the field of biochemistry which regards genes as much more complicated biochemical mediators than as carriers of the information to build one protein.²⁵³ However, patents are routinely granted over gene mutations known to cause disease, the use of proteins as medicines for specific conditions, and the ability to test for a particular

genetic mutation associated with a disease. The vision of the industrial genome as a ‘tidy collection of individual genes’ each linked to a specific condition like breast cancer is no longer accurate.²⁵⁴ Genes overlap and interact with one another in complex networks that are not yet understood.²⁵⁵ This reality challenges the validity of the liberal, atomised gene, leading to ambiguity over the scope and validity of these types of patents and casts doubt on how the patent law characterises the technologies it represents.

The patent system also simplifies and commodifies the relationships that create patented technologies. Theorists outside law perceive technological development as dialogic,²⁵⁶ implicitly countering the primacy within patent law of the heroic inventor and the inventor-user dichotomy.²⁵⁷ There is some acknowledgement in practice that the patented technology is embedded in broader relations with other things and people, and this is reflected in the development of physical technological ecosystems like business clusters.²⁵⁸ Scientific inventions are in fact the product of a sociology of science which acknowledges that discoveries often happen in several

²⁵³ Each protein has a specific cell function as diverse as regulating metabolism, muscle movement and nerve generation. Disruption of protein function is generally thought to lead to disease: Nuffield Report (n 197) at 12.

²⁵⁴ The ENCODE Project Consortium, ‘Identification and analysis of functional elements in 1% of the human genome by the ENCODE pilot project’ (2007) 447 Nature 799. For more information see National Human Genome Research Institute, ‘First Major Results from The ENCODE Project’ <<http://www.genome.gov/25521622>> accessed 13 July 2007.

²⁵⁵ ENCODE (n 254) at 254.

²⁵⁶ F Williams and DV Gibson, ‘Technology Transfer: A Communication Perspective’ (1992) 17(3) Canadian J Communication 113.

²⁵⁷ L Suchman, ‘Working Relations of Technology Production and Use’ (1994) 2 Computer Supported Cooperative Work 21 at 22; S Trosow, ‘The Illusive Search for Justificatory Theories: Copyright, Commodification and Capital’ (2003) 16(2) Can JL & Jurisprudence 217.

²⁵⁸ Department of Trade and Industry UK, *Our Competitive Future: Building the Knowledge Driven Economy* (HMSO 1998). Research substantiates the importance of business clusters to the innovation process: AN Link and JT Scott, ‘Opening the Ivory Tower’s Door: An Analysis of the Determinants of the Formation of US University Spin-Off Companies’ (2005) 34(3) Research Policy 1106.

places at the same time, as a field reaches a certain stage of maturity²⁵⁹ ideally governed by norms of communitarianism and organised scepticism (among others).²⁶⁰ While patent law reflects these realities to some extent by recognizing claims from multiple inventors, negotiating the conflict between first-to-file and first-to-invent by granting the patent to the first innovator, and using novelty and inventiveness to separate genuine contributions from replications of existing art, it does still caricature the innovation process by granting named inventor(s) exclusive rights to important aspects of the technology. As more patents are granted over a greater range of subject-matter, patent law becomes increasingly confounded by the interstitial nature of technological development, suggested by growing patent thickets, overlapping claims and concerns about inventorship.²⁶¹ Patent law fails to reflect the unavoidable complexity of technology by commodifying its objects and relationships, leading to distortions and inaccuracies.

In addition to the problems that arise from the propertization of innovation and its social ecology, the ‘property right’ label carries centuries of historical, social and political meaning that has the potential to distort our understanding of relatively less-developed IPRs.²⁶² Characterizing IPRs as property rights leads to assumptions that IPRs should be regulated as though they are exclusive and subject to limited exceptions like tangible property and that the individual property right trumps

²⁵⁹ T Kuhn, *The Structure of Scientific Revolutions* (University of Chicago Press, Chicago 1962); DE Stokes, *Pasteur’s Quadrant* (Brookings Institution Press, NY 1997).

²⁶⁰ R Merton, *The Sociology of Science: Theoretical and Empirical Investigations* (University of Chicago Press, Chicago 1973).

²⁶¹ MA Heller and RS Eisenberg, ‘Can Patents Deter Innovation? The Anticommons in Biomedical Research’ (1998) 280 *Science* 698.

²⁶² For the purposes of this discussion I am not going to delve into the more theoretical questions of whether IP by its nature is characterisable as property. This perspective argues that IP is capable of non-exclusive use, no dispossession results if it is taken, it is not consumed through use like real property, there is close to zero cost to make it available, or not, and it is easily transmissible: E Hettinger, ‘Justifying Intellectual Property’ (1989) 18(1) *Philosophy & Public Affairs* 31.

particularly as against the public interest.²⁶³ Rights constrain decision-making and limit what is morally permissible, without regard for what might be a better outcome.²⁶⁴ Absolute property rights are difficult to revoke, regulate or limit. Thus the term ‘property’ may obscure the nature of IPRs as a limited legislative privilege rather than as a fundamental right to own property.²⁶⁵ Some have argued that characterizing IP as a property right is only useful to the extent that it describes the rights that exist as part of IP, but not as a prescriptive argument as to what those rights should or ought to entail.²⁶⁶

Optimists argue that calling IPRs ‘property rights’ imports correlative social, moral and ethical obligations that can be avoided for so long as patents are characterised as limited regulatory negative rights to exclude.²⁶⁷ Hence the full-blooded owner becomes more susceptible to regulation because of her excess of control or monopoly. The history of property law, however, suggests that responsible stewardship does not increase proportionately with power. In fact, the force of ‘property’ in shielding the target of its rights from scrutiny will be much stronger than exposing the rights which it purports to protect to external regulation.²⁶⁸ ‘Property’ is unlikely to respect the notion of balance and the inherent, accepted limits of the patent right (eg its finite term, criteria for novelty and obviousness, and significant government powers to control patents). Finally, relying too closely on property theory risks caricaturing the ‘certainty’ of its terms and rules. As a growing body of property theorists has observed, the term ‘property’ has no easily definable

²⁶³ Boyle (n 251).

²⁶⁴ Drahos (n 244) 201.

²⁶⁵ TG Palmer, ‘Are Patents and Copyrights Morally Justified? The Philosophy of Property Rights and Ideal Objects’ (1990) 13 *Harvard J L & Public Policy* 817.

²⁶⁶ Cornish (n 198) 2; Harris (n 247) 348.

meaning.²⁶⁹

(b) Utilitarianism

The most popular justification for patent law is utilitarian, but the precise contours of that justification are unclear.²⁷⁰ Utilitarian philosophy justifies an ethical course of action and thus suggests the best way to proceed as between several options. The basic formulation of utilitarianism is that ‘the good’ is whatever brings the greatest happiness (‘to the greatest number’, although there is some conflict over this requirement).²⁷¹ As the good is judged by its consequences, utilitarianism can be a consequentialist philosophy.

Utilitarianism is also very malleable. Mill’s version of utilitarianism advocated that each person should be guaranteed a maximum of personal liberty in order to be able to maximise his or her happiness. As a liberal theory, it focused on the individual as a means for achieving the ‘greatest happiness’. However, that good could be maximised by granting groups or communities liberty to make their decisions. Thus utilitarianism could support Marxism and has been used to underpin views as diverse

²⁶⁷ WA Adams, ‘Confronting the Patentability Line in Biotechnological Innovation’ (2004) 41 Canadian Business LJ 393.

²⁶⁸ Eg M Horwitz, *Transformation of American Law, 1780-1860* (HUP, Cambridge 1976).

²⁶⁹ TC Grey, ‘The Disintegration of Property’ in RA Epstein (ed), *Liberty, Property and the Law* (Routledge, NY 2000).

²⁷⁰ ER Gold, ‘The Reach of Patent Law and Institutional Competence’ (2004) 1 U Ottawa Tech LJ 263, 264.

²⁷¹ J Bentham and R Hildreth (tr), *Theory of Legislation* (Weeks, Jordan & Co, Boston 1840); JS Mill *Utilitarianism* (OUP, Oxford 2005).

as socialism and libertarianism.²⁷² Utilitarian theory as popularly understood is often underpinned by economic reasoning, but can embrace much broader methodologies and evidence than merely the performance of the inventor in the market.

Utilitarianism, however, cannot be prescriptive as many of its underlying propositions remain unanswered. ‘Happiness’, ‘the good’, the means to achieve ‘happiness’, and whether or not the means chosen have in fact attained that goal all remain undefined. While utilitarian theory cannot decide any of the contested facts in the patent system today, it is continuously invoked in the literature to justify a course of action in IP.²⁷³ This is a recognised problem of a utilitarian philosophy run amok, which could justify situations as diverse as Nazism and the Mafia.

Despite this, utilitarianism has powerful rhetorical force. When one promotes the greatest happiness for the greatest number one is acting as an ethically responsible person. Ultimately, however, utilitarianism must be judged by the strength of its consequences. The discussion that follows outlines how utilitarianism justifies choices about patent law and considers how that utilitarian calculus might be re-tooled better to reflect bringing the greatest happiness to the greatest number.

Utilitarianism holds that granting a patent right to an inventor improves economic efficiency by encouraging innovation and the disclosure of new inventions.²⁷⁴ Thus patents are said to ‘incentivise’ innovation and information

²⁷² Eg L von Mises, *Human Action* (New Haven: Yale University, 1949); MT Polanyi and RT Allen (eds), *Society, Economics, and Philosophy: Selected Papers* (Piscataway NJ, Transaction Publishers 1997) 98.

²⁷³ RA Posner *Economic Analysis of Law* (4th edn Little Brown and Co 1992) 38-42; Harris (n 247) 296; Hettinger (n 262).

²⁷⁴ Gold (n 242) 300.

dissemination. This formulation appears in UK law, policy and legislation, from the UK Intellectual Property Office²⁷⁵ to pronouncements by judges,²⁷⁶ organizations and commentators.²⁷⁷ In addition to the UK, the economic efficiency reward incentive has been formalised in common law across the Commonwealth. For example, the Supreme Court of Canada has supported the notion of the patent bargain where the state grants a monopoly in exchange for disclosure of the invention to ‘hasten the availability of useful knowledge in the public sphere in the public interest.’²⁷⁸ The US Supreme Court has also held that the philosophy behind Jefferson’s protection of patents was based on the idea of economic incentives: ‘[t]he patent monopoly was not designed to secure to the inventor his natural right in his discoveries. Rather, it was a reward, an inducement, to bring forth new knowledge’.²⁷⁹

In theory, granting value to IPRs allows that value to end up in the hands of the user who most effectively exploits the IP. This solves the market failure of non-exclusivity (many people can use IP at the same time) and public-good nature of IP by providing incentives for its production, disclosure and exploitation. While some versions of utilitarianism are based on granting value to inventions already made, others promote granting patent rights based on first occupancy²⁸⁰ or natural rights,²⁸¹ melding utilitarianism with entitlements grounded in other claims (as will be

²⁷⁵ UK PO ‘What is intellectual property?’ <<http://www.ipo.gov.uk/whatis.htm>> accessed 5 July 2007.

²⁷⁶ Eg *CFPH LLC's Application* [2005] EWHC 1589 (Patents Ct Ch D) [10].

²⁷⁷ European Commission, *Report on the Development and Implications of Patent Law in the Field of Biotechnology and Genetic Engineering* (COM(2002) 545, not published in the OJ) (Commission Report); D Lambert, *Lambert Review of Business-University Collaboration* (London HM Treasury 2003) at 4, [1.20], [4.20], 128 (Lambert Review); P Drahos, ‘Biotechnology Patents, Markets and Morality’ (1999) 21(9) EIPR 441, 443; C Terrell *The Law and Practice Relating to Letters Patent for Inventions* (2nd edn Sweet & Sons London 1889) 15 (documenting recitals required on patents).

²⁷⁸ *Cadbury Schweppes Inc v FBI Foods Ltd* [1999] 1 SCR 142 [46].

²⁷⁹ *Graham v John Deere Co* 383 US 1 (1966) 10.

²⁸⁰ E Kitch, ‘The Nature and Function of the Patent System’ (1977) 20(2) J L & Economics 265; Cornish (n 198) 14.

²⁸¹ FS Kieff, ‘The Case for Registering Patents and the Law and Economics of Present-Obtaining Rules’ (2003) 45 Boston College LR 55.

discussed further in the next section).

Patents may incentivise innovation but have social and economic costs. The utilitarian calculus concludes that the greatest happiness (or most efficient outcome) means the public suffers the monopoly costs of limiting public access to inventions for the benefits of the invention.²⁸² Recent research by economists and others, however, has shown that the greatest happiness for the greatest number predicted by the grant of exclusive rights may be more speculative than real.²⁸³ In other words, researchers have not been able to prove that patents incentivise innovation or increase disclosure. In fact patent protection may hinder innovation and over-reward innovators in several ways, casting doubt on the traditional utilitarian calculus.

First, patents may limit innovation through overly-broad so-called ‘blocking-patents’, particularly innovation that builds on patented innovation.²⁸⁴ This is problematic as most innovation derives from previous creations and access to basic knowledge about the field. Secondly, the one-size-fits-all model of patent protection is poorly tailored to diverse products and innovation cycles, eg, for software and genes.²⁸⁵ Further, patents will have varying effects on different patentees, including small firms using patents to start up and established firms re-stocking their product base. Patent protection may over-reward innovators by allowing higher prices than are required to incentivise innovation, a consideration that is again very particular to

²⁸² Fisher (n 243).

²⁸³ Gold (n 274) 299.

²⁸⁴ C Langinier and G Moschini, ‘The Economics of Patents: An Overview’ in S Newman and M Rothschild (eds) *Intellectual Property Rights and Patenting in Animal Breeding and Genetics* (CAB International, Franklin KY 2003).

²⁸⁵ D Vaver, ‘Invention in Patent Law : A Review and a Modest Proposal’ (2003) 11(3) *Intl J Journal L & Info Tech* 286; LM Cloutier and AL Saives, ‘Propriété intellectuelle et hétérogénéité des capacités d’innovation des firmes du système bioalimentaire qui exploitent la biotechnologie au Québec’ (2002) 28(1) *Revue gestion* 64.

the product created, the innovation community an inventor belongs to, and the market for a product eventually commercialised. While economic data from the 1960s attributed 15-25% of innovation to patent protection,²⁸⁶ recent studies using more sophisticated methodologies including comparisons between countries have doubted those conclusions, finding the link between patents and innovation to be less clear, even non-existent.²⁸⁷ Isolating the effect of patents on innovation is very difficult given the multiple IP management tools used by corporations and the fact that many other factors (such as access to capital, first mover advantage, and geography) may contribute to innovation.²⁸⁸ Thus, even if patents do increase innovation, this outcome is very difficult to measure. Studies that have attempted to control for the effect of patents have shown in some cases that patents had either no effect or decreased innovation.²⁸⁹

Finally, the role of patents in disseminating information is once again highly contextual and driven by the situation in a given industry.²⁹⁰ Patent specifications are notoriously obscure and, some say, crafted to hinder information-sharing.²⁹¹ In some industries, patent disclosure is unnecessary because the core innovation in a product may be obvious by looking at it. A product whose innovation is less obvious may be disaggregated into component patents and the innovative core may actually be protected by trade secrets.²⁹²

²⁸⁶ Gold (n 274).

²⁸⁷ A Jaffe and J Lerner *Innovation and its Discontents: How Our Broken Patent System is Endangering Innovation and Progress, and What to Do About It* (Princeton U Press, Princeton 2004); Gold (n 274) 302.

²⁸⁸ Gold (n 274) 304.

²⁸⁹ M Sakakibara and L Branstetter, 'Do Stronger Patents Induce More Innovation? Evidence from the 1988 Japanese Patent Law Reforms' (2001) 32 RAND J Economics 77.

²⁹⁰ Gold (n 274) 302.

²⁹¹ D Vaver, *Intellectual Property Law: Copyright, Patents, Trade-Marks* (Irwin, Toronto 1997) 139.

Thus even if patents are granted to maximise innovation, there is limited evidence that they do in fact incentivise and reward innovation, providing the greatest happiness for the greatest number. While the utilitarian good of economically efficient innovation and disclosure is achieved through a patent's economic monopoly, its failure to achieve its goals requires a reconceptualization of the dominant utilitarian balance. The liberal vision of the individual bargaining with the state over economic rewards for innovative activity is neither necessary nor even helpful in all cases.²⁹³

In this thesis I advocate a much broader utilitarian calculus. Patents should increase the good, but what that good is (patents? non-proprietary means?) and how happiness is measured (economic efficiency?) is not prescribed. Central to this effort is a coherent understanding of patents and innovation as a complex, dialectical, communicative process involving not just individuals but groups and communities. Obtaining a patent is only the first step towards defining one's rights to an invention. A patent itself says very little about the kind of rights granted, particularly in the US which has many weak patents of dubious validity on the books.²⁹⁴ A patent that is likely to be found invalid if the holder claims infringement is a weak bargaining tool. Deciding to defend a patent against infringement is a business decision that must account for the cost, duration and likelihood of success of litigation relative to the damage caused by the infringement. Patent infringement does not immediately lead to patent enforcement and decisions to enforce patents often depend on the size of the

²⁹² Gold (n 274) 303.

²⁹³ S Ghosh, 'Patents and the Regulatory State: Rethinking the Patent Bargain Metaphor after Eldred' (2004) <<http://ssrn.com/abstract=574141>> accessed 15 December 2007.

²⁹⁴ Jaffe & Lerner (n 287) 12.

competitor and the perceived strength of the patent.²⁹⁵ This reality stands in opposition to a more idealistic vision that every patent is the demarcation of a right over a clearly defined invention in a business environment where competitors only sue when their patent is illegitimately infringed. While patents are often enforced defensively to protect a firm's innovation from imitation, they have been integrated into business strategy offensively to threaten and disrupt the operations of business competitors.²⁹⁶ Corporations frequently decide not to assert their patent rights, while some strategically decide to do so at certain times.²⁹⁷ These patent litigation characteristics vary from industry to industry.²⁹⁸

In addition to tolerated patent infringement between patent-holding business competitors, businesses also often ignore patent infringement by researchers using patented innovations in their research. As will be discussed in more detail in the final chapter, the empirical data suggest that patents rarely block innovation in research communities.²⁹⁹ In fact, patent holders tolerate a high degree of low level infringement as an informal research exception³⁰⁰ in many countries³⁰¹ including the UK, which (as discussed in Chapter 1) has a formal research exception. This is so even in the US, which has no formal research exemption and an unclear, informal and very narrow common law research exemption.³⁰² Further, high profile instances where litigious patent holders have been derided as blocking research and

²⁹⁵ J Lerner, 'Patenting in the Shadow of Competitors' (1995) 38 J L & Economics 563.

²⁹⁶ Jaffe & Lerner (n 287) 56.

²⁹⁷ Jaffe & Lerner (n 287) 58.

²⁹⁸ Jaffe & Lerner (n 287) 58.

²⁹⁹ JP Walsh and others, 'View from the Bench: Patents and Material Transfers' (2005) 309 Science 2002.

³⁰⁰ Walsh (n 299); C Weschler, 'The Informal Experimental Use Exception: University Research after *Madey v Duke University*' (2004) NYU LR 1536.

³⁰¹ OECD, *Genetic Inventions, Intellectual Property Rights and Licensing Practices* (OECD, Geneva 2002) 81.

³⁰² *Madey v Duke* 307 F3d 1351 (Fed Cir 2002), cert denied, 123 S Ct 2639 (2003).

development of valuable goods, have, upon closer examination, had less to do with patent rights and more to do with complex political and economic factors.³⁰³

Thus studying patents should adopt an industry-specific and local approach in order to understand their effect. Comparing patenting behaviour in, eg, the semiconductor and the food manufacturing sectors is of limited usefulness given the different business structure, customs and innovation practices of each. Further, the story of patent grant and litigation may only reveal part of the norms and practices that constitute the ‘patent system’. Facts about how the patent system operates must complement patent theorizing if one is fully to understand how patents function within a rich set of norms, complementary laws, regulations and practices.

In addition to deepening our understanding of patents in relation to one another, it will also be important to understand why individuals innovate. Individuals can be encouraged to labour, and the acquisition of property rights may be one incentive to do so. But theorists subsequent to Bentham, Locke and others³⁰⁴ (including Marx) have argued that property rights and economic reward are only one kind of incentive that encourages people both to innovate and also to disclose their innovation.³⁰⁵ Non-monetary motivations include altruism, the propagation of political, ethical or religious ideas, as well as the desire for recognition, promotion and security.³⁰⁶ In fact, in some cases, creativity may not even need to be tangibly rewarded. Individuals may create solely for personal satisfaction, the joy of problem-

³⁰³ R Gold and J Carbone, ‘Myriad Genetics: In the Eye of the Policy Storm’ (2007) (on file with author).

³⁰⁴ J Bentham and R Hildreth (tr), *Theory of Legislation* (Weeks, Jordan & Co, Boston 1840) 55.

³⁰⁵ Y Benkler *The Wealth of Networks: How Social Production Transforms Markets and Freedoms* (Yale U Press, New Haven CT 2006); Trosow (n 257).

³⁰⁶ Trosow (n 257) 239; Benkler (n 305).

solving and may just be inherently productive.³⁰⁷ The individualistic liberal subject seeking economic reward does not exhaustively or even adequately reflect the reality of creativity.

These observations have been borne out by recent initiatives that have intentionally experimented with either modifying or allowing creators to waive enforcement of IPRs to allow sharing of creative works. In the process, these initiatives have helped determine what IP protections may incentivise creativity. Two groups in particular, Creative Commons (CC) and the Free/Libre Open Source Software (FLOSS) movement, use standard licences that allow creators to choose which aspects of copyright protection such as use, reproduction, modification or distribution of the product they wish to allow third parties to exploit and in what circumstances. Creative Commons, for example, has found that most creators are willing to share their works freely with third parties provided they are acknowledged and, in many cases, provided the work is used non-commercially.

In the case of FLOSS and software, the norms of the software developing community and its commercialization practices fit poorly with traditional IP protection. Even though software is patentable in the UK³⁰⁸ and in the US,³⁰⁹ software has a short lifespan compared to the duration of a patent. Its cheap development costs and easy distribution channels also mean that the incentive and commercialization rationales of the patent grant are less relevant.³¹⁰ Furthermore, the ‘ideas’ proprietised by software patents more closely resemble unpatentable basic

³⁰⁷ Rai (n 230).

³⁰⁸ Despite the ‘as such’ exceptions in the UKPA s 1 and EPC 2000 s 52(2)(c).

³⁰⁹ Now comprising up to 15% of all patents granted: J Bessen and RM Hunt, ‘An Empirical Look at Software Patents’ (2007) 16(1) J Economics & Management Strategy 157.

mathematical algorithms than inventions.³¹¹ Software developers themselves often identify themselves as communities of collaborators who freely share innovations, attribute one another and learn from one other, guided by informal norms that contrast with formal legal protection and large-scale commercial practises.³¹² Once open source licences were introduced, they helped negotiate a complex social system of adding, editing, patching and modifying the software, which was hugely successful in producing a high quality product.³¹³ Furthermore, it became clear that software developers as a community were often driven by goals of altruism, eg, by creating a low cost, high quality operating system, and reputational rewards through being credited in software development and becoming known within the project community.³¹⁴

Open source and free software have been so successful that traditionally secretive and proprietary software companies like IBM and Microsoft now embrace open source methods in software development³¹⁵ and initiatives have developed to manage the proliferation of types of open source and free software licences available.³¹⁶ As these licences increasingly become standardised and are understood and accepted by the general public, they create new norms. As they become sufficiently widespread, they may form a standard or even, eventually, a 'law'.

³¹⁰ P Heckel, 'Debunking the Software Patent Myths' (1992) 35(6) Communications of the ACM 121.

³¹¹ D Freedman, 'Software and Computer-Related Business-Method Inventions: Must Europe Adopt American Patent Culture?' (2000) 8(3) Intl JL & Information Technology 285.

³¹² E Raymond, *The Cathedral and the Bazaar* (O'Reilly Media, Sebastopol CA 2001).

³¹³ Raymond (n 312).

³¹⁴ Raymond (n 312); N Economides and E Katsamakos, 'Linux vs. Windows: A Comparison of Application and Platform Innovation Incentives for Open Source and Proprietary Software Platforms' (2005) NYU Law and Economics Research Paper No. 05-21 <<http://ssrn.com/abstract=822894>> accessed 15 December 2007.

³¹⁵ IBM 'Open Source Tutorials and Projects' <<http://www.ibm.com/developerworks/opensource>> accessed 15 December 2007; Microsoft 'Open Source' <<http://www.microsoft.com/opensource/default.aspx>> accessed 15 December 2007.

The community of biotechnology researchers has drawn on the insights gleaned from open licensing to change its own practices. Driven by a sense that informal norms of the scientific community that traditionally encourage open collaboration and sharing of knowledge were being undermined by norms of secrecy encouraging proprietary protection,³¹⁷ the biotechnology community founded initiatives like PIPRA (the Public Intellectual Property Resource for Agriculture),³¹⁸ Cambia/BiOS,³¹⁹ Science Commons³²⁰ and the Tropical Disease Initiative³²¹ to reframe incentives to create and seek IP in biotechnology. Some of these initiatives, in addition to creating open source licences, have attempted to map the complex ecology of a technology through establishing patent clearinghouses and databases of licensing information from public and private institutions. These collections provide invaluable information about the breadth and strength of existing patents, terms of control and by whom, and suggest zones of ‘freedom to operate’.³²² These projects effectively undermine the unrealistic proposition that a patent disclosure provides sufficient information to spur further innovation.

³¹⁶ The Open Source Initiative (homepage) <<http://www.opensource.org/>> accessed 15 December 2007; Free Software Foundation ‘FSF Free Software Licensing and Compliance Lab’ <<http://www.fsf.org/licensing>> accessed 15 December 2007.

³¹⁷ Rai (n 230); Heller & Eisenberg (n 261).

³¹⁸ PIPRA (homepage) <<http://www.pipra.org>> accessed 15 December 2007.

³¹⁹ CAMBIA (homepage) <<http://www.cambia.org>> accessed 15 December 2007.

³²⁰ Science Commons (homepage) <<http://www.sciencecommons.org>> accessed 15 December 2007.

³²¹ Tropical Disease Initiative (homepage) <<http://www.tropicaldisease.org/>> accessed 15 December 2007.

³²² Eg PIPRA (n 318).

An outstanding question remains of how to measure ‘social benefit’. Patent policy should measure social benefit with measures much more sophisticated than those predicated by economic markers. Much as the Gross Domestic Product which measures standard of living, paradoxically increases from events like natural disasters that decrease the standard of living, and ignores externalities like environmental damage, the welfare generated through innovation should be measured by much more sensitive markers. These could include, for example, the social cohesion or division generated by new technologies (eg stem cells or gene patents) and the communicative and civic enhancement or detriment allowed by others (eg communication technologies). Initiatives that have proposed granting high profile prizes to successful medical researchers and a financial reward proportional to the measured contribution to social benefit are researching this question of adequately representing social benefit.³²³ This latter fine-tuning of measurement will be left to economists, political theorists and other scholars. However, this section argues that utilitarian theory can and should embrace a broader justification for patent rights.

(c) From Utilitarianism to Labour Theory

Utilitarianism alone provides an insufficient justification for the grant of patents. It is used in tandem with other political theories, such as labour³²⁴ and social contract theory,³²⁵ to ground entitlements. Utilitarianism sets up a framework where other theories do the work of justifying individual entitlements. Labour theory, for

³²³ J Love, ‘Would Cash Prizes Promote Cheap Drugs’ (12 November 2007) 2629 New Scientist 24.

³²⁴ CJ Craig, ‘Locke, Labor and Limiting the Author's Right: A Warning Against a Lockean Approach to Copyright Law’ (2002) 28 Queen’s LJ 1.

³²⁵ Ghosh (n 293).

example, provides the link between an individual's labour and her entitlement to a reward. The labour justification has not traditionally justified patent rights. An increasing tendency, however, to speak of IP broadly and to argue the importance of Locke in justifying IP entitlements has had the perverse effect of encompassing patents within a theory that historically and practically has little relevance to patents (while preoccupying copyright scholarship).³²⁶ It has led a small number of theorists to attempt explicitly to justify the patent grant on the basis of natural rights.³²⁷ A natural right to a patent could be taken to argue that inventors have an inherent right to economic exclusivity.³²⁸ Natural rights entrench an economic-based, individualistic, strong property as opposed to a statutory privilege perspective, that I argue bears little resemblance to how patent law functions in practice, thus creating justificatory incongruities.

Locke argued that every man has a property in his own person and also has property in the labour of his body and the work of his hands.³²⁹ Locke then said: 'whatsoever he removes out of the state of nature he hath mixed his labour with and joined to it something that is his own and thereby makes it his property'. This is subject to the proviso that the person has a right to what he has joined his labour to so long as there is enough and as good left in common. In addition Locke also enjoined waste, writing that '[a]s much as any one can make use of to any advantage of life before it spoils; so much he may by his labour fix a Property in'.³³⁰ Locke's labour theory applied to IPRs (analogously as to tangible property rights) creates strong

³²⁶ L Zemer, 'The Making of a New Copyright Lockean' (2006) 29(3) *Harvard JL & Public Policy* 891, 897.

³²⁷ A Mossoff, 'Rethinking the Development of Patents: An Intellectual History, 1550-1800' (2001) 52 *Hastings LJ* 1255; Ghosh (n 293).

³²⁸ Drahos (n 244) 201.

rights based on a natural entitlement, regulated by the ‘enough and as good’ and the ‘waste’ limitations. In the two versions of Locke’s theory applied to IP law, the first argues that we must reward labour with property, since without reward there would be no valuable labour.³³¹ The second argues that we should merely reward labour with property.

While the breadth and merit of Locke’s statements are the subject of controversy (eg whether it even applies to any kind of property or is just a theory of government),³³² his labour theory underpins IPR entitlements and is ubiquitous in IP scholarship as a justification. As Gordon has remarked: ‘Locke's labor theory of property and allied approaches have been used so frequently as a justification for creators' ownership rights that Locke's Two Treatises have been erroneously credited with having developed an explicit defense of intellectual property’.³³³ Locke has been interpreted as providing an individualistic, exclusive and strong property right supporting the continuing grant of ever stronger IPRs (particularly copyrights) to creators, at the expense of the public, culture and free and open use of copyrighted works.³³⁴

³²⁹ J Locke and P Laslett (ed) Chapter V, Book II of the *Two Treatises of Government* (CUP, Cambridge 1988).

³³⁰ Locke (n 329) s 31.

³³¹ W Gordon, ‘A Property Right in Self-Expression: Equality and Individualism in the Natural Law of Intellectual Property’ (1993) 102 Yale LJ 1533,1544 citing LC Becker, *Property Rights: Philosophic Foundations* (Routledge, NY 1977) 32-48.

³³² Zemer (n 326); Drahos (n 244) 42; Craig (n 324).

³³³ Gordon 1993 (n 331) 1540. For expression of similar statements in the copyright context see: Craig (n 324) 21; RA Epstein, ‘Liberty Versus Property? Cracks in the Foundations of Copyright Law’ (2005) 42 San Diego LR 1, 21.

³³⁴ Eg Craig (n 324). Less popularly, others have argued that Locke may accommodate more collectivist, less proprietary views that leave abundant room for a give-and-take between author’s and creator’s rights: Zemer (n 326); Gordon 1993 (n 331); J Tully, *A Discourse on Property: John Locke and his Adversaries* (CUP, Cambridge 2006).

While the justifications for copyright and patents³³⁵ are similar, they are also distinct. They are similar, as discussed earlier, because of the nature of IP: both patents and copyright are non-excludable public goods that can be infinitely reproduced without depriving the original owner of the good. Subsequent creations build on earlier ones. Once a story or an invention becomes available to the public, it can be reprinted, reproduced or recreated without depriving the original owner of the ability to use that story or invention. However, that unauthorised reproduction does deny the creator or the owner the ability to control and profit from the reproduction of that story or invention. Hence, IP addresses the harm of unauthorised reproduction by giving creators control of the products of their intellect. However, the similarity ends there. Patents and copyright have different histories, inherent characteristics (term, conditions for grant, etc), and target different forms of intellectual goods (innovations, creative works, business goodwill). IP theory and patent justifications in particular must consider each distinct system, embedded in its political, social, and economic context.

Locke's labour theory has been used, however, not only to justify copyright but also IP and patent law in a form of 'copyright creep'. The Lockean natural rights entitlement, as contrasted to a utilitarian statutory grant, presupposes a strong right, even a property right. This type of strong right was neither the intent of patent law nor the ideal tool to achieve its purported goals. The confusion arises from the practice of collapsing the two branches of copyright and patent into a single justification for intellectual property. This practice is ubiquitous amongst a diverse group of

³³⁵ Trade-marks will be left to the side for now.

influential commentators, text-book writers and philosophers.³³⁶ The tendency to collapse patent and copyright justifications has even been noted by the US Supreme Court.³³⁷

Considered historically, using Locke to justify patents is incorrect. While Locke's theory of labour has played a pivotal role in the history of copyright law it has not in patent law. In the 18th century judges grappled with the difference between the labour of the mind involved in creative works (copyright) and inventions (patent). The law had to justify why one form of intellectual labour grounded a property right and the other merely a statutory privilege.³³⁸ Some even argued that while copyright law had its roots in natural law, it was primarily justified economically and limited by the term of grant (much like a patent).³³⁹ Ultimately the English law concluded that 'authors create something while inventors merely uncover what is already there', justifying a strong reward for labour in copyright but not patent.³⁴⁰ The contrast between patent and copyright is highlighted by the fact that patent law has never even had to address questions like moral rights or perpetual rights³⁴¹ in the same way that copyright has had to.³⁴² The growing civic recognition over the 19th and 20th centuries that free expression was a right rather than a privilege further supported

³³⁶ Fisher (n 243); WJ Gordon, 'On Owning Information: Intellectual Property and the Restitutionary Impulse' (1992) 78 Virginia LR 149; Hettinger (n 262); L Becker, 'Deserving To Own Intellectual Property' (1993) 68 Chicago-Kent LR 609; AD Moore, 'A Lockean Theory of Intellectual Property' (2004) 21 Hamline LR 65; B Damstedt, 'Limiting Locke: A Natural Law Justification for the Fair Use Doctrine' (2003) 112 Yale LJ 1179; K Aoki, '(Intellectual) Property and Sovereignty: Notes Toward a Cultural Geography of Authorship' (1996) 48 Stanford LR 1293; J Hughes, 'The Philosophy of Intellectual Property' (1988) 77 Geo LJ 287.

³³⁷ *Eldred v Ashcroft* 537 US 186 (2003) 216; Ghosh (n 293).

³³⁸ *Millar v Taylor* (1769) 4 Burr 2303 (KB) 2349.

³³⁹ EC Walterscheid, 'The Early Evolution of the United States Patent Law: Antecedents (Part 4)' (1996) 78 J Patent & Trademark Office Society 77, 99.

³⁴⁰ Drahos (n 244) 29 citing Halsbury, *The Laws of England* (London, 1912) v 22, p 127, [267].

³⁴¹ *Millar* (n 338).

³⁴² DL Zimmerman, 'Information as Speech, Information as Goods: Some Thoughts on Marketplaces and the Bill of Rights' (1992) 33 Wm & Mary LR 665 for common-law copyright and Locke's labour justification.

copyright's formulation as a natural right.³⁴³ Locke was expansively applied without consideration of the 'enough and as good' and 'no waste' provisos. The continuing present debate is evident in conflicts over the originality required for copyright protection and whether the sweat of the brow suffices for copyright.³⁴⁴

The history of the application of Locke to patent law in the UK³⁴⁵ is not long. Patent law historians have provided careful support for the proposition that, while inventors may have claimed a natural right to invention, patent rights were consistently granted on instrumentalist grounds,³⁴⁶ '[e]ven in the heyday of natural rights [in] the late 18th century'.³⁴⁷ The development of patent law relied on the concept of privilege, rather than right, to support its doctrinal growth as a means of regulating trades and 'growing human capital'.³⁴⁸ The SOM (1623) justified granting patent monopolies, although clearly contrary to 'auncient and fundamental lawes', if they enhanced the public good, hardly strong support for a natural right.³⁴⁹ In 1769, Justice Yates opined in his dissent in the influential case of *Millar v. Taylor* 'that the mere labour and study of the inventor, how intense and ingenious soever it may be, will establish no property in the invention, will establish no right to exclude others

³⁴³ Zimmerman (n 342).

³⁴⁴ *Eg Feist Publications Inc v Rural Telephone Service Company Inc* 499 US 340 (SC) for a contemporary discussion of 'sweat of the brow'.

³⁴⁵ The history of US and Commonwealth patent law will not be addressed.

³⁴⁶ EC Walterscheid, 'The Early Evolution of the United States Patent Law: Antecedents (Part 1)' (1994) 76 J Patent & Trademark Office Society 697, 699. As Dutton remarks, 'no worthwhile commentator took [the natural law rights theory] seriously': HI Dutton *The Patent System and Inventive Activity During the Industrial Revolution 1750-1852* (Manchester U Press Manchester 1984) 18. Further, a well-known 19th century patent lawyer noted that '[t]hose who believe the inventor to have a natural right ... must have an entire misconception as what it is the inventor really achieves': Dutton, p 18 citing T Webster, *Law and Practice of Letters Patent for Invention* (1841). Only Mossoff (n 327) argues otherwise and even he asserts in a conclusory way that 'the evidence for the positivist position that natural rights philosophy did not contribute to the growth or development of patents as a legal doctrine is strong and I do not wish to indicate otherwise': 1315.

³⁴⁷ C MacLeod, *Inventing the Industrial Revolution: the English Patent System, 1660-1800* (CUP, Cambridge 1988) 197.

³⁴⁸ Drahos (n 244) 29, 31; eg *Darcy v Allein* (1602) Noy 173, 74 ER 1131.

³⁴⁹ Drahos (n 244) 32.

from making the same instrument, when once the inventor shall have published it', further undermining Lockean natural rights claims to a patent.³⁵⁰ Even when abolishing patents was debated in mid-19th century England,³⁵¹ arguments supporting the patent system rarely relied on a natural right to a patent over an invention.³⁵² The strongest arguments against patent abolition have traditionally relied on much more practical concerns about the strength of a patent holder's vested regulatory entitlements (and the nuisance of divesting these) and the difficulty of dismantling and designing a better patent system.³⁵³

While historically natural rights had limited purchase on patent theory, Locke's labour theory continues to enjoy more conceptual coherence with present-day copyright than it does with patent law. The requirement of 'novelty' for a patent ensures that the public is not prohibited from doing something they could do before, rather than granting a patent as a reward for a particularly bright idea.³⁵⁴ The patent application process does not consider the labour involved in a creation and does not even require a working prototype that could demonstrate some labour. A patent can be obtained for merely a bright applied idea. Although an inventor may remain attached to her work and see it as a part of her identity that view is not affirmed by Anglo-American patent law apart from requiring the inventor to be named in the

³⁵⁰ Millar (n 338) 2387.

³⁵¹ F Machlup and ET Penrose, 'The Patent Controversy of the 19th Century' (1950) 10(1) J Economic History 1; M Coulter, *Property in Ideas: The Patent Question in Mid-Victorian Britain* (Thomas Jefferson U Press, Kirksville 1991); MD Janis, 'Patent Abolitionism' (2002) 17 Berkeley Technology LJ 899.

³⁵² Janis (n 351) 931, 932 but see ET Penrose, *The Economics of the International Patent System* (Johns Hopkins University, Baltimore 1951).

³⁵³ F Machlup, *An Economic Review of the Patent System* (US Government Patent Office, Washington 1958).

³⁵⁴ Mossoff (n 327) 1289.

patent.³⁵⁵ Provisions allowing a patent to be revoked,³⁵⁶ compulsory licensing³⁵⁷ and expropriation³⁵⁸ of patents all suggest that an individual's claim to a patent must be balanced with the patent's contribution to society and welfare. As many patents are held by corporations or developed by teams the future likelihood of strong natural rights claims to patents is limited.³⁵⁹

This discussion yields two results. First, the fact that the individualistic proprietary Lockean justification has had a limited historical and present role in justifying patent law supports the introductory proposition that collective, contextual and non-economic justifications play a role in patent law. Secondly, patent law justification is best served by a nuanced analysis alive to context and historical contingency.

(d) From Labour to Social Contract Theory

As discussed thus far, utilitarian theory provides an ethical framework that has traditionally been informed by liberal economic values. Utilitarianism often fails to reflect the true nature and context of innovation. Labour theory, rooted in conceptions of natural rights to creative works, has historically justified copyright but not patent law. It similarly provides a limited justification or recognition of modern patent law. Social contract theory is a further justification often used to explain patent law. Social contract theory embodies the idea of a 'quid pro quo', or bargain between the inventor

³⁵⁵ But see more Hegelian notions of attachments by the inventor to the invention evident in continental patent law through the 'spirit of the invention' test.

³⁵⁶ s 72 UKPA.

³⁵⁷ s 48 UKPA.

³⁵⁸ Eg ss 49, 55 UKPA.

³⁵⁹ This problem also arises in modern copyright law.

and the state. Society grants an inventor an otherwise undesirable monopoly in return for the inventor's disclosure (and other possible benefits, including an increased incentive for the inventor to innovate). The concept of the patent bargain has gained prominence in recent years, particularly from the pronouncement of courts³⁶⁰ in the UK³⁶¹ and internationally³⁶² and the views of commentators and patent-holders.³⁶³

Social contract theory applied to the quid pro quo or patent bargain strengthens an inventor's claim to a patent, much in the same manner as labour theory or a claim from natural rights. It suggests that the inventor and the state stand as contracting agents and through their agreement or 'bargain' generate a moral claim to the enforcement of a patent.³⁶⁴ The quid pro quo raises the patent from a regulatory grant of privilege with a correlative duty, to a more open-ended right, thus emphasizing the importance of the individual in an agreement with the state.

This view, however, is not responsive to the history and practice of patent law in much the same way as the other theories outlined above have failed to reflect reality. First, historically, patents have been considered as a prerogative based privilege granted by the state, rather than as a quid pro quo.³⁶⁵ As a liberty-limiting

³⁶⁰ Although much of this caselaw is somewhat ambivalent as to the precise nature of this quid pro quo.

³⁶¹ *Beecham Group Ltd v Bristol Laboratories International SA* [1978] RPC 521, 579. This proposition was cited in *EI du Pont de Nemours & Co (Witsiepe's) Application* [1982] FSR 303 (HL); *Ranbaxy UK Limited, Arrow Generics Limited v Warner-Lambert Company* 2005 WL 2662679 [2005] EWHC 2142 (Ch D Patents Ct) [63]. See also *Biogen Inc v Medeva plc* [1997] RPC 1 (HL) 53-54; *Visx Inc v Nidek Co Ltd* [1999] FSR 405 (Ch D Patents Ct); *Split Roller Bearing Company Ltd's Licence of Right (Copyright) Application* [1996] RPC 225 (PO) 231; *Biogen Inc v Medeva Plc* [1995] FSR 4 (CA) 43; *American Cyanamid Co's (Fenbufen) Patent* [1991] RPC 409 (CA) 411; *Industrie Diensten Groep BV v JA Beele Handelmaatschappij BV* [1982] 3 CMLR 102 (ECJ) 115; *Pope Appliance Corporation v Spanish River Pulp and Paper Mills Ltd* [1929] AC 269 (PC) 279.

³⁶² Cadbury Schweppes (n 278).

³⁶³ See Ghosh (n 293) for a more detailed discussion. Others, including Ghosh and Vaver, have countered this view, eg D Vaver, *Intellectual Property Law: Copyright, Patents, Trade-Marks* (Irwin, Toronto 1997).

³⁶⁴ See for eg Lord Loughborough in *Arkwright v Nightingale* (1785) 1 Carp PC 38, 49-50.

³⁶⁵ Drahos (n 244) 29.

privilege a patent grant entails some form of consideration³⁶⁶ or correlative duty³⁶⁷ from the inventor but not on the basis of a social contract. Second, social contract theory overstates the relationship between the privilege granted by a patent and the obligations of the innovator, evoking a pre-modern notion of government inconsistent with the modern regulatory state.³⁶⁸ Arguing that the grant of a patent is analogous to a social contract is similar to claiming that a utilities service agreement between a citizen and a public utility forms a social contract. Third, one would have to conclude that bargain was weak if not broken given the notoriously poor disclosure of patent specifications noted repeatedly by courts and others. The government's right to manage patents through compulsory licensing, Crown use and other mechanisms suggest less of a right than a privilege. Finally, the individualistic premise of social contract theory, positing a two-party relationship between the innovator and the state, ignores the more complicated relationships of reciprocity and trust with multiple parties in the innovation process, including government and licensees.³⁶⁹

These complex relationships involved in a technology's development are mediated by legal agreements like licences. Rather than a social contract between the individual and the state, a patent allows further contractual agreements between parties. Thus the 'web of patents'³⁷⁰ usually refers not to the actual patents but to the web of practice and licensing where patent holders grant temporary rights to make, sell or reproduce patented innovations through licences. Licences have been

³⁶⁶ See, for eg, 'where any man by his own charge and industry ... doth bring any new trade into the realm ... the King may grant to him a monopoly patent for some reasonable time, until the subjects may learn the same, in consideration of the good that he doth bring by his invention to the commonwealth': *Darcy v Allein* (n 348) 1139.

³⁶⁷ Drahos (n 244).

³⁶⁸ Ghosh (n 293).

³⁶⁹ Ghosh (n 293).

³⁷⁰ OECD, 'Guidelines for the Licensing of Genetic Inventions' (2006) <<http://www.oecd.org/dataoecd/39/38/36198812.pdf>> accessed 11 July 2007, 7.

increasingly recognised as important, and have instead of patents been the focus of several patent reform initiatives.³⁷¹ Licences waive or modify a patent holder's right to exclude others from the use of a patented invention, typically for a royalty or other consideration. They are tailored to the business relationship of the parties and often remain confidential. However, recent licensing initiatives have altered these features of the licensing relationship and have, in the process, transformed our understanding of the nature of innovation, the role of patents, and the role of IPRs more generally.

Licences have also facilitated collective efforts at patent management through patent pools. Patent pools have historically been either required by government or designed by the participants in situations when cumulative patents cover most basic or improvement technologies in an area. These potentially or actually block further research or commercialization of a product. In other instances, patent pools have been established where a patent set an industry standard which necessitates licences available to all takers ('open-pooling'). Patent holders agree to license patents to one other or to a third party upon payment of a royalty. Historically patent pools were used in airline manufacture, electronics, telecommunications, sewing machines, radio and other industries.³⁷² Patent pools are currently being established to manage the development of a SARS vaccine³⁷³ and the manufacture and distribution of essential medicines for the treatment of Aids.³⁷⁴ Patent pools have even been considered for

³⁷¹ National Institutes of Health, 'Best Practices for the Licensing of Genomic Inventions' (2005) <<http://ott.od.nih.gov/pdfs/70FR18413.pdf>> accessed 11 July 2007; OECD Guidelines (n 370).

³⁷² ER Gold, T Piper, JF Morin, LK Durell, J Carbone and E Henry, 'Preliminary Legal Review of Proposed Medicines Patent Pool' submitted to UNITAID (WHO) 14 July 2007 (on file with author) 8.

³⁷³ J Simon 'Alternative Solutions to Intellectual Property Management: SARS vaccine' presented to the Workshop on Intellectual Property, Biotechnology Capacity and Development, Buenos Aires, Argentina 25-27 September 2006.

³⁷⁴ Preliminary Review (n 372).

use in the development of genetic diagnostic tests.³⁷⁵ Patent pools (and related activities like cross-licensing)³⁷⁶ increase collaboration between IP holders by developing industry standards or allowing cooperation to ensure the manufacture and distribution of important products.³⁷⁷

(e) Conclusions

What ultimately links unhelpful existing patent justifications is a focus on the individual inventor, in some cases with a rights-based claim to a discrete innovation embodied in a patent and incorrect assumptions about the role patents can play in encouraging disclosure and promoting innovation in all sectors. Property analogies are often inaccurate and over-emphasise the proprietization of the relationships and technologies in question. Utilitarianism, while creating a useful ethical framework for patent law, is limited in its current liberal economic formulation, failing to describe accurately and predict the actual behaviour of the patent system. Labour theory provides a strong justification for a natural right to IP more generally but has historically (and currently) played little role in justifying the patent grant. Social contract theory overstates the nature of the exchange between the State and the inventor, attempting to place the inventor in the moral position of a contractor with the state rather than the recipient of a statutory privilege. This view overstates the significance of the patent grant. Personhood theory provides some useful insights into why people may hold property entitlements.

³⁷⁵ B Verbeure, E van Zimmeren, G Matthijs and G Van Overwalle, 'Patent Pools and Diagnostic Testing' (March 2006) 24(3) Trends in Biotechnology 115.

³⁷⁶ Jaffe & Lerner (n 287) 59.

The increasing bureaucratization and reification of the patent system has over-emphasised its role as a technique that must be mastered, thus isolating it from a more purposive, polycentric and democratic position in social discourse. That discourse could discover what is already emerging from open licensing initiatives and the discussion above, namely that: IPRs do not necessarily best incentivise and disseminate innovation; innovation processes vary from community to community and depend on relationships; individuals create for a range of reasons including altruism, reputational reward and the pursuit of knowledge for knowledge's sake, in addition to economic reward; and groups that create develop informal rules or norms that govern their creativity, including decisions to tolerate patent infringement for research purposes. While the dominant discourse of formal international law is one of harmonization for the purposes of trade, the practical reality is one of highly varied local landscapes that depend on the nature of the technology. Further investigation of these informal networks, the norms they generate, the accountability and representativeness of these norms and how they become formal law require a theoretical framework of legal pluralism that will be discussed below. The next section will consider how the justifications for patent law could be re-formulated to account for a more contextual, relational vision of the operation of the patent system.

5 A New Theory

Rather than leave the discussion hanging with a critique, I would propose a justification which regards patents as instruments to achieve a particular outcome (ie a

³⁷⁷ G Graff and D Zilberman, 'An Intellectual Property Clearinghouse for Agricultural Biotechnology' (2001) 19 *Nature Biotechnology* 1179.

public purpose) as most appropriate. Such a theory would empirically determine how a patent works as almost a behavioural science;³⁷⁸ a patent would be justified if the goals sought are being achieved by the means used, as a brand of the broader moral theory of utilitarianism.³⁷⁹ The public purpose or goal sought could be defined, similarly to Fisher's formulation in copyright, as the desire to create a 'just and attractive culture'.³⁸⁰ Fisher's version of a just and attractive culture features a cornucopia of information and ideas, a rich artistic tradition, distributive justice, semiotic democracy, sociability and respect.³⁸¹ A similar theory for patent law would have some similar and some different features. A cornucopia of ideas and information would emphasise the importance to innovators of open access to knowledge, previous innovation, and ideas that would inspire the further innovation that serves broader social goals than those measured by standard economic markers. Patent law would pay attention to distributive justice concerns, particularly those of access to potentially life-saving technological products by citizens and developing countries.³⁸² A 'rich innovative tradition' considers the social processes and communities that innovate. The concept of 'semiotic democracy',³⁸³ inspires 'semiotic technologies', adverting to the interstitial and socially-embedded complexity of technology. Sociability would focus on the ability of people to create rewarding lives by access to a variety of communities of creation and rejects a technocratic focus on the patent document and technological artifact in isolation. Respect would value implementing a range of policies that recognise the diversity of

³⁷⁸ Drahos (n 244) 214.

³⁷⁹ While retaining Drahos' thesis that instrumentalism is not committed to any particular moral theory: Drahos (n 244) 216.

³⁸⁰ Fisher (n 243). As he outlines, elements of this theory have a rich provenance in legal realism, Marx and Jefferson among others.

³⁸¹ Fisher (n 243).

³⁸² Eg Commission for IPR (n 236).

³⁸³ Recognizes meaning recoded and reinterpreted by listeners differently from the artist's intent: J Fiske *Television Culture* (Routledge, NY 1987) 236, 239 in Fisher (n 243).

behaviours, goals and individual preferences that drive innovative behaviour.

As Drahos argues:

...when it comes to justifying intellectual property, the crucial choices are not between first order ethical theories (natural law versus utilitarianism) but rather the concept of community and the metaphysical scheme upon which that concept of community is dependent. As it happens, the modern emphasis on the question of justification is at the level of first order ethical theory. This does not mean that concepts of community are irrelevant to the question of justification. Rather it suggests that they are the silent drivers of the debate.³⁸⁴

Thus this metaphysical scheme would draw from relational³⁸⁵ and communitarian³⁸⁶ theories, and challenge the traditional liberal subject who structures her relationships and obligations through private property and contract. It would recognise that inventors are embedded in networks of collaboration and innovation. It would require a methodology different from the standard strict reliance on legislation, court cases, or even the content of publicly available contracts and licences.³⁸⁷

Considering patent law as diffuse networks of collaboration governed by rules that may not be evident in formal public sources poses a methodological problem of how to study these types of relations. A methodology for studying patent law through this lens must be contextual, attending to the complex economic, social, historical, cultural and political contexts and conditions in which individuals interact, as well as to personal relationships. It should also be empirical. The next section outlines various studies that have attempted this type of study of IP norms in particular

³⁸⁴ Drahos (n 244) 33.

³⁸⁵ M Minow and ML Shanley, 'Relational Rights and Responsibilities: Revisioning the Family in Liberal Political Theory and Law' (Winter 1996) 11(1) *Hypatia* 4.

³⁸⁶ M Walzer, 'The Communitarian Critique of Liberalism' (1990) 18(1) *Political Theory* 6.

communities of innovation.

6 Pluralist Studies of Intellectual Property Norms

Scholars have conducted in-depth research into the role of norms in communities that innovate, to elucidate rules that replicate or substitute for formal IP law within those groups. These studies have embraced a range of empirical methodologies, principally historical, questionnaire-based surveys, and interviews. These case studies have provided valuable insight into the operation of IP norms within specific communities, although it is difficult to generalise across the studies as the temporal, geographic and occupational characteristics of the groups are so different. Three of the most useful for this thesis will be discussed: research performed by Rai and others on university research norms,³⁸⁸ Fauchart and von Hippel on French chefs,³⁸⁹ and Nuvolari on the Cornish mining industry.³⁹⁰ Other studies³⁹¹ have considered IP normative practices in the 18th century iron industry,³⁹² current end-users of sports-equipment,³⁹³ 19th century steel production and 20th century developers of open source software.³⁹⁴

³⁸⁷ The normative content of collaborative relationships is often not evident at the beginning of the relationship when, for example, the licence is drafted.

³⁸⁸ Rai (n 230).

³⁸⁹ E Fauchart and E von Hippel, 'Norms-Based Intellectual Property Systems: The Case of French Chefs' (2006) MIT Sloan Research Paper No 4576-06 <<http://ssrn.com/abstract=881781>> accessed 15 December 2007.

³⁹⁰ A Nuvolari, 'Collective Invention during the British Industrial Revolution: The Case of the Cornish Pumping Engine' (2004) 28(3) Cambridge J Economics 347.

³⁹¹ Studies not explicitly adopting a legal pluralist perspective but still considering the development of IP law from a non formal legal perspective include: BZ Khan, 'Technological Innovations and Endogenous Changes in US Legal Institutions, 1790-1920' (2004) National Bureau of Economic Research Working Paper 10346; MacLeod (n 347); G Dutfield, 'The International Biotech, Conservation and Intellectual Property Rights' (DPhil thesis University of Oxford 2003).

³⁹² RC Allen 'Collective Invention' (1983) 4 J of Economic Behavior and Organization 1.

³⁹³ N Franke and S Shah, 'How communities support innovative activities: an exploration of assistance and sharing among end-users' (2003) 32(1) Research Policy 157.

³⁹⁴ PB Meyer 'Episodes of Collective Invention' (2003) US Dept of Labour, Office of Productivity and Technology Working Paper 368. See also: J Loshin, 'Secrets Revealed: How Magicians Protect

Rai's study examines the interdependence of the norms of research communities and the formal law.³⁹⁵ Academic scientific research has long been regarded as a community driven by highly defined norms of behaviour, classically formulated by Merton as universalism, communitarianism, disinterestedness, and organised scepticism.³⁹⁶ While researchers can be venal, biased and secretive,³⁹⁷ Merton's basic insights hold true as aspirational values that are then embodied in norms of scientific communities. Communitarianism expresses the insight that scientific knowledge is a shared resource and that discoveries depend on the insights of predecessors. Thus an individual proprietary interest in scientific discoveries is immoral. Secrecy runs counter to the communitarian ethic and the need for disclosure in order to promote the collective endeavour. Organised scepticism ensures that scientists freely critique the work of their peers and subject all findings to rigorous validation and testing.³⁹⁸ The creation, verification and dissemination of knowledge is achieved institutionally through learned societies, conferences, lectures, and journals that peer-review and then publish significant scientific advances. Rewards are provided by peer-judged competitions for funding, prizes, and public acknowledgement. Norms govern attribution of scientific authorship,³⁹⁹ sharing of basic data and materials,⁴⁰⁰ and acceptable uses of methods or research results. The

Intellectual Property without Law' (July 25, 2007) <<http://ssrn.com/abstract=1005564>> accessed 15 December 2007.

³⁹⁵ Rai (n 230).

³⁹⁶ R Merton, *The Sociology of Science: Theoretical and Empirical Investigations* (University of Chicago Press, Chicago 1973).

³⁹⁷ S Sismondo, *An Introduction to Science and Technology Studies* (Wiley-Blackwell, Toronto 2003); J Walsh and W Hong, 'For Money or Glory?: Secrecy, Competition and Commercialization in Science' presented at the Annual Meeting of the American Sociological Association, San Francisco, 14 August 2004 <http://www.allacademic.com/meta/p109531_index.html> accessed 15 December 2007.

³⁹⁸ Walsh & Hong (n 397) 3.

³⁹⁹ M Biagioli (ed), *Scientific Authorship: Credit and Intellectual Property in Science* (Routledge, NY 2003).

⁴⁰⁰ D Moerman, 'Is Public Domain Community Research Effective?: The Nematode *Caenorhabditis elegans* as a Positive Case Study' presentation to the GE3LS Project, Genomics and Intellectual Property: Considering Alternatives to Traditional Patenting, 9 March 2007

touchstone of professional success is the originality of the research: the more original the contribution is to scientific knowledge, the greater the rewards the community bestows on the researcher.⁴⁰¹ Originality is sufficiently important that it may justify some secrecy.⁴⁰²

Rai's research suggested that prior to 1980 and the passage of the US *Bayh-Dole Act*,⁴⁰³ research communities in molecular biology relied on 'communitarian' norms that rejected formal proprietary rights over scientific discoveries and innovations.⁴⁰⁴ However, after the passage of *Bayh-Dole* (legislation in the US designed to encourage universities to seek IP rights on inventions created by their research scientists) and caselaw in the same vein, Rai documents that IP-related norms held by university researchers changed as well. As she argues, consistently with law and norms theory, once a certain level of norm violation was reached, rapid norm breakdown ensued in the academic research community.⁴⁰⁵ Scientists proceeded to reject communalism and actively sought patents over scientific innovations.⁴⁰⁶ Norms surrounding secrecy began to break down as information needed to be concealed in advance of patent applications, and scientists became more reluctant to share research materials.⁴⁰⁷ While many support Rai's conclusion that proprietary norms are increasing,⁴⁰⁸ others have argued that her portrayal of the biomedical industry pre-

<<http://gels.ethics.ubc.ca:8213/ge3ls-arch/intellectual-property/genomics-and-intellectual-property-considering-alternatives-to-traditional-patenting>> accessed 15 December 2007.

⁴⁰¹ Rai (n 230) 21.

⁴⁰² Rai (n 230) 21.

⁴⁰³ Rai (n 230).

⁴⁰⁴ Note that a level of proprietarianism is clearly contemplated within norms governing attribution in the academic research community as researchers will claim discoveries as 'their own'. However, this is qualitatively different in terms of enforceability and legitimacy from the formal state grant of a property right, such as a patent.

⁴⁰⁵ Rai (n 230) 109.

⁴⁰⁶ Rai (n 230) 55.

⁴⁰⁷ Rai (n 230) 53.

⁴⁰⁸ PA David, 'The Economic Logic of "Open Science" and the Balance between Private Property Rights and the Public Domain in Scientific Data and Information: A Primer'

1980 is idealistic and that a normative shift was happening long before *Bayh-Dole*.⁴⁰⁹

Fauchart and von Hippel conducted an interview and questionnaire study of French chefs. They concluded that a norms-based IP system existed amongst haute cuisine chefs. Chefs' expertise is not easily protected by existing IPRs, even though the chefs themselves considered the recipes they developed to be a very important and economically valuable form of IP. Maintaining complete secrecy was an option, but was not viable when chefs were involved in educating trainees, sharing secrets, improving their recipes, and commercializing their creations through cookbooks, television cook shows and other means. Fauchart and von Hippel identified three norms that governed the community. First, one chef must not copy another chef's recipe innovation exactly.⁴¹⁰ Secondly, if a chef discloses secret recipe information to another chef, that chef must not pass the information on without permission.⁴¹¹ Thirdly, chefs must credit the developers of significant recipes as the authors of those recipes.⁴¹² The study also identified procedures for claiming IPRs in recipes and community-based sanctions for violators of those norms, including gossip, reduced reputation in the community, a refusal to share recipes and an unwillingness to believe or support the claims of a violator.⁴¹³ Interestingly, the study was also able to show that chefs increase their economic returns by relying on these norms.

Finally, Nuvolari provides a useful glimpse into the IP norms of a group of

<<http://www.siepr.stanford.edu/papers/pdf/02-30.pdf>> 15 April 2006; A Rai and R Eisenberg, 'Bayh-Dole Reform and the Progress of Biomedicine' (2003) 66 Law & Contemporary Problems 289.

⁴⁰⁹ FS Kieff 'Facilitating Scientific Research: Intellectual Property Rights and the Norms of Science - A Response to Rai and Eisenberg' (2000) 95 Northwestern U LR <<http://ssrn.com/abstract=240955>> accessed 15 December 2007.

⁴¹⁰ Fauchart (n 389) 4.

⁴¹¹ Fauchart (n 389) 4.

⁴¹² Fauchart (n 389) 4.

⁴¹³ Fauchart (n 389) 18.

Cornish mining engineers. The study considers the steam engine patented by James Watt, which was widely used in the Cornish coalmines in the 18th and early 19th centuries. Watt and his partner Boulton alienated local mine owners by charging oppressive royalties for the use of their licences and refusing to license their broad patent to allow the development of improvement inventions. This resulted in legal challenges by inventors who wished to patent improvements or who had installed steam engine technologies that directly challenged the blocking patent.⁴¹⁴ The legal system vindicated Watts' patent rights but also alienated the entire Cornish coal industry, which stopped ordering steam engines from Watt.⁴¹⁵ Instead, the Cornish coal industries developed what historians have labelled a 'collective invention setting',⁴¹⁶ where a group of competing firms share information on new technologies, improvements and operating procedures.

Nuvolari has identified three factors of the Cornish mining industry that made it a collective invention setting.⁴¹⁷ First, mining practice overtook scientific knowledge available at that time. Thus, the industries had to pool existing knowledge and expertise in order to advance the technology. Secondly, the Cornish mines' accounting system meant that mine managers were more interested in the aggregate, rather than the individual, success of mines. Thirdly, industry journals developed to publish technological developments. Publication would improve the reputations and career prospects of individual engineers in the tightly-knit Cornish mining

⁴¹⁴ *Hornblower and Maberly v Boulton and Watt* (1799) 8 TR 95, 101 ER 1285, best-known for its definition of 'manufacture': H Fox *Monopolies and Patents: A Study of the History and Future of the Patent Monopoly* (University of Toronto Press, Toronto 1947) 221-22.

⁴¹⁵ A Nuvolari, 'Collective Invention during the British Industrial Revolution: The Case of the Cornish Pumping Engine' (2004) 28(3) *Cambridge J Economics* 347, 350.

⁴¹⁶ RC Allen 'Collective Invention' (1983) 4 *J of Economic Behavior and Organization* 1. This has been determined as one of four main sources of invention in capitalist economies.

⁴¹⁷ Nuvolari (n 415) 9.

community.⁴¹⁸ These three factors led to a professional ethos of information-sharing and incentives to disclose and disseminate new technologies, that replicated prevailing patent norms. As Nuvolari demonstrates, the Cornish mining industry exited the 19th century patent system.⁴¹⁹

While it is difficult to generalise across three studies with such different subject-matters, it is possible to extract some common themes. First, certain cohesive social groups develop strong normative orders that govern group conduct, sometimes more effectively than formal norms. These norms may develop because formal norms do not exist or apply (as with chefs) or because those formal norms fit poorly with collective goals (as in the steam engine case-study). Secondly, these norms can protect IP in a manner that resembles, differs, or adds complexity to the dominant IP order. Thirdly, normative orders may be interdependent with formal norms, changing or self-destructing (as in Rai's example) or strengthening in response to events and developments in the formal law (as in Nuvolari's study). The informal normative order may even be independent of the formal law if it is so effective or fair that groups exit from regulation by the formal law (as in Nuvolari's example). Finally, these studies all express a more complicated collectivist, contextual and communitarian picture of innovation that is missing from the individualistic account of creativity in the formal law. These insights will inform the historical analysis that follows in the next three chapters.

⁴¹⁸ C MacLeod, *Inventing the Industrial Revolution: the English Patent System, 1660-1800* (CUP, Cambridge 1988) 104-105 observed the same thing with civil engineers.

⁴¹⁹ See also: C MacLeod 'Would There Have Been no Industrial Revolution Without Patents?', paper presented at the ESRC Research Seminar Series, Patent in Europe and North America: Past and Present Monday 26 April 2004 (on file with author).

7 Conclusion

The dominant economic model of the patent incentivizing an inventor to create and disclose critical innovation is a simple model of a much more complex ecology of innovative activity that includes formal patent law as one potential normative commitment of the parties involved. A broader model of patent law is better served by a reformulated justification that develops, among other things, a scheme of community and richer vision of the ‘greater good’. This broader justification can be given substance by empirical, contextual analyses that examine rule-creating and following behaviour in innovative SASFs. Thus this thesis adopts a legal pluralist analysis to consider the formal and informal norms that governed the UK medical profession in order to understand the development of the modern MME.

Chapters 3-5 of this thesis are not currently available online.

6. A CASE-STUDY AND CONCLUSIONS

This thesis has adopted a contextual analysis of the development of patent law to examine the history of medical diagnostic exceptions from patentability. This concluding chapter will draw together the various analytical strands and show, through the application of the insights of this piece to a current situation, the significance of the conclusions.

This thesis considers how the patent law deals with the patentability of medical technologies. The patentability of medical innovations is a prime focus of policy-makers as the progress of medicine affects the health and well-being of all people and is an area of massive scientific, public and industrial investment. Patent law and patents granted figure prominently for those who seek more equitable pricing and distribution of medical products in society. However, modern patent law generally does not single out medical technologies for special treatment. In the UK, pharmaceutical products are patentable (subject to safety regulatory regimes) and there is no practical public interest bar on the patentability of medical technologies provided the particular technology meets the other requirements of patentable subject-matter, novelty and inventive step. Compulsory licensing and Crown use remain available. The MME remains the only provision in the patent law that explicitly addresses the patentability of medical technologies and it does this weakly. The MME provides little substantive protection of technologies that promise great advances in treatment (and thus ought to remain accessible according to some), the protection it does provide is difficult to justify and long-standing questions remain about the exception's legitimacy.

I have shown that in response to the patent medicines crisis, the nascent UK medical profession developed a strong norm enjoining its members from patenting based on ethical concerns about conflicts of interest, preventing false advertising, enhancing public safety and improving the reputation of the medical profession. The norm was formally expressed by the common law in *Re C&W* in the early 1900s. The medical profession was largely successful in its professionalizing goals in the late 1800s and early 1900s. As the medical community's membership became more diverse and the conditions of medical innovation changed during the inter-war period, however, the ethical norm became increasingly incoherent to its members. Patent medicines and poor quality medical products posed less of a concern, due to regulation and consumer education. WWI had demonstrated the importance of science and the medical profession to national interests. The valuable medical technologies being developed, vaccines, vitamins and others, were increasingly found in industrial laboratories outside the medical profession's immediate control. The medical profession grew concerned about access to these valuable medical products and, spurred on by stories from the US and Canada, it lobbied industrial partners and then government for amendments to the patent law. At the same time, the medical profession found it increasingly difficult to justify its internal ethical norm to a heterogeneous profession and the norm shifted from being concerned with regulation and quality to access.

These efforts, particularly attempts to negotiate an informal compromise with industry, enjoyed some initial successes in the early post-WWI period. Ultimately, however, the medical profession (through the BMA and MRC) failed to convince

government that a formal medical exception was necessary. It did not succeed largely because the profession's claims that patenting was unethical were not consistently supported by the successes achieved through patents nor could the medical profession marshal a strong argument that patents inhibited access or damaged public interests. The medical profession gradually lost interest in the issue as no significant crises emerged and as some of its concerns were assuaged through the creation of the NRDC and NHS. Its earlier advocacy, and caselaw framing a medical exclusion from patentability meant the medical exception enjoyed a life as legal precedent throughout the 20th century. However, by the 1960s and 1970s the MME had been largely eroded in the caselaw and had limited judicial support. Extrinsic forces of international comity and an international law-making process, rather than a domestically negotiated consensus, resulted in a formal MME legislated into UK patent law in the 1970s.

Some overarching conclusions from this study follow. First, this analysis shows that on a theoretical and methodological level, a justificatory framework for patent law that accounts for the complexity of technologies, of communities that innovate and the diverse goals of innovation better justifies and explains the form of patent law than one based on a liberal, primarily economic theory of patents or one tied closely to formal legal sources. The rule-following behaviour of the medical profession not patenting medical technologies cannot be comprehended from considering only the formal law, either case law or legislation. A much richer picture of the origins of the exception becomes clear when the motivations of the interested groups are accounted for. Those motivations are much more complex than merely economic, provided the building blocks for articulating a broader 'greatest good'. The law that the various parties followed and understood derived from a wide range

of formal and informal processes that shaped their understanding of ‘legal’ behaviour.

Secondly, excluding technologies from the patent law is a solution that crops up repeatedly in the history of the regulation of medical products. This is so, even though unpatentability remains a blunt tool forcing innovators to resort to trade secrecy and leaving valuable technologies unpatented (and unprotected) and open to foreigners and competitors to patent. Remedies used in the past include defensive patenting and vesting those patents in a public trustee to manage them, a solution that even the abolitionist medical profession agreed to after carefully considering the issue. Advocating the exclusion of technologies from patentability may also over-estimate the power of the patent law to change or even affect the practice of research and innovation. Granting no patent rights of exploitation to a patented technology does not necessarily preserve it for the public good: it may in fact leave small improvements on it available to patenting by competitors and discourage manufacturers from investing in its manufacture and distribution. The problem, rather, is one of governance and who manages the patents obtained over important medical innovations.

Thirdly, the economic, political and social implications of medical treatment and the initial regulation of these through the patent law mean that the patentability of medical products attracts strong opinions from all interest groups involved particularly at moments of rapid or revolutionary technological advance. New technologies destabilise existing entitlements and may lead to a normative vacuum in groups as priorities change. In this situation parties will do a number of things. They will insist that existing norms apply to new situations, tweaking the rule if necessary.

Parties will also appeal to the formal law's authority to maintain existing entitlements leading to the observation that at times of change stakeholders give normative priority to legal rights over informal processes and practices. This reflects, I argue, a mistaken understanding of the true drivers of patent reform which can be characterised as often unwritten, political and negotiated.

Fourthly, historically UK common law and legislation have taken a light approach to the economic regulation of medical technologies in the patent law. The UK has, by and large, rejected heavy-handed compulsory approaches like abolition or patents dedication schemes. This has been so for a variety of reasons including a lack of data to suggest other approaches, a prevailing legislative parsimony, the slow speed of legislative deliberation and committee work, and the unwillingness of governments to interfere or over-regulate particularly at times of transition or in economic matters. This behaviour, while seemingly slow and unresponsive, may in fact be appropriate to avoid reactive laws in situations of rapid change when the implications of that change are unforeseeable. The study demonstrates that the common law is similarly slow-moving and may preserve norms through the power of precedent, although its reasoning prunes these at appropriate moments.

Fifthly, the formal law takes a light approach largely, I argue, because the norms governing behaviour are being imposed and negotiated elsewhere and formal law is not required to mediate disputes and allocate entitlements. It is particularly interesting that when the medical profession sought a solution post-WWI it turned to the normativity of the formal law, even though the medical profession had informally been using its own authority for many years to regulate the patentability of medical

products. This suggests that the stronger the norm, the less it needs to be formally legislated. The medical profession did not advocate a legislative exclusion from patentability until well into the inter-war period when its internal norm and authority on that question was weakening. The evidence about the medical profession's norm suggests that practice and norms may govern conduct more authoritatively than the common law. Legislation and the common law may have a relatively minor effect. Further, the history of the MME also suggests that formal and informal norms may interdepend, although the process by which this happens is unclear. The justification for the MME in formal law changed over the course of the 20th century from one focused on the non-vendible product to one concerned with access. This mirrors the evolution of the medical profession's informal norm.

Sixthly, groups may seek patent law reform or exit the patent law for reasons of group control and authority, particularly professionalization. Groups may also create informal patent-like regimes outside the formal patent law that are as strong as or more authoritative than the formal law in order to promote professionalization. This suggests at a deep level that certain principles of patent law, such as disclosure, incentive, reward, may be inherent or universal norms of creative activity. More broadly, this suggests that innovation cannot be separated from sociological processes of group authority, solidarity, reputation and professional closure that need to be investigated more fully.

Seventhly, UK patent law now enforces a medical exception that has survived long after its original purpose has disappeared. It is a vestigial organ of a prior economic and social space. Lacking a principled soil of justification, the exception

has grown in an unruly and irregular manner, to the point where few technologies are encompassed within its scope and the distinction between the technologies it excludes and includes is difficult to justify. It has a purpose re-shaped in an ad hoc manner as a public health objective. Its terms, however, do not provide the tools for it to fulfil this purpose. There is little elaboration of the scope, purpose or application of the exception, or even its utility. Many judges thus find it hard to craft and apply appropriately, consistently and in a manner that effects the provision's purpose. This law on the books is at its best a mild irritant; at its worst, it undermines the credibility of the formal law and reaffirms the irrelevance of formal law to innovation, providing grist for the mill of anti-patent sentiment.

Further conclusions also obtain. The use of the Steenbock and Dick patent examples in negotiations demonstrates that timely 'stories' at moments of rapid social, political or industrial change may be used to underpin demands for policy reform. The legislative process is sufficiently slow and consultative that by the time it responds, the policy storm has generally passed and the stories of policy failure have been resolved informally. Thus stories may lead to irrelevant law but the slowness of legislative reform may limit their effect in practice. In addition, formal legislation and caselaw may have no connection to the informal norms and practices of its stakeholders. They may instead represent a technocratic process of respecting precedent or harmonizing pre-existing statutory provisions based on earlier practices. This process may lead to vestigial formal legal provisions like the present-day MME. Practically, new technologies lead to changes in power between established players, and patent law bears witness to much of this through its requirements of novelty and obviousness. A major new field of scientific inquiry will be novel at its inception but

will rapidly be less new. The power of precedent and past practice may lead parties to strictly demand perceived entitlements, leading to concern from other interested stakeholders.

The case-study that follows applies conclusions from the thesis to a current example, Myriad Genetics, arguing that only by conducting a contextual, embedded study of innovation in medical communities can rational legal reform be undertaken. It considers a moment of rapid technological transition when attention turned once again to the patent law to resolve issues of access, pricing, safety and morality. It shows how certain parties will see the formal law as authoritative and appeal to it to take action. In the case of Myriad Genetics this means that the company relied on the formal law to cement its role in providing genetic diagnostic tests. Its opponents sought legislative solutions, including exceptions from patentability, to regulate Myriad's conduct. In fact, however, norms of conduct and solutions to the problem were being negotiated elsewhere and the formal law had little role to play. Myriad failed to understand the practical context of innovation in its field. Its opponents over-estimated the limited effect of legislative intervention. The policy storm arising from pre-existing fears that private interests would enclose genetic knowledge passed with almost no change to the formal law. The case study also elaborates the practical point that while the initial techniques for sequencing DNA were revolutionary at the time of invention, they have over time become a routine and mechanical part of standard laboratory procedure.¹⁰⁷² Moreover, the application of knowledge about genes and disease to diagnosis seems obvious, creating difficulties for the patent

¹⁰⁷² Nuffield Council on Bioethics, 'The Ethics of Patenting DNA' <<http://www.nuffieldbioethics.org/patentingdna/index.asp>> accessed 2 July 2003, 12 (Nuffield Report) 29; W Cornish and D Llewellyn *Intellectual Property: Patents, Copyright, Trade Marks & Allied Rights* (5 ed, Sweet & Maxwell, Andover 2003) 838.

regime similar to those encountered in the past.

1 A Modern Moment for Medical Exceptions: The Myriad Case-Study

The case-study will examine a recent debate over patents obtained by Myriad Genetics over genetic diagnostic tests for breast cancer that it then enforced against several domestic test providers. Myriad's actions in enforcing its patents, after the race to sequence the breast cancer genes and maintain them in the public domain, led to media reports, national patent law reform commissions, numerous reports and suggestions for proposed legal reform. Ultimately, however, legislative reform was not implemented in most jurisdictions and the dispute faded. A full discussion of this case-study is beyond the scope of this thesis,¹⁰⁷³ however I will highlight the key features that contribute to the preceding discussion.

(a) The Moment of Scientific Innovation

The evolution of medical treatment since the mid-20th century has been rapid, framed primarily by the 'genetics revolution' in biochemistry. Since the discovery of the structure of DNA in 1953, scientists have been identifying genetic information that encodes for certain proteins as well as those proteins' cell functions. There are an estimated 25 000 and 35 000 genes in the human body, many of which play a key role in disease and disorder. In particular, gene mutations may change or impede protein

¹⁰⁷³ See R Gold and J Carbone, 'Myriad Genetics: In the Eye of the Policy Storm' (2007) (on file with author) (RJ Myriad).

production, which may lead to disease.¹⁰⁷⁴ Thus genetics promises exciting therapeutics and discoveries to treat disease and improve quality of life.

The case-study considers the use of genetics to test for disease. The patentability of genetic diagnostic tests has been a lightning rod for concerns about the proper role of the patent system. Genetics can be used for a range of purposes particularly in healthcare and medical research, agriculture, food production and the pharmaceutical industry.¹⁰⁷⁵ Diagnostic testing is one of the four major medical uses to which DNA sequences can be put, including as research tools, in developing proteins for therapeutic uses and in gene therapy.¹⁰⁷⁶ Genetic diagnostic testing has long been used to detect disease, confirm diagnosis or detect the presence of a genetic mutation which predicts an increased likelihood of developing a disease.¹⁰⁷⁷ Recently, however, the nature, scope and prevalence of these tests have changed. Testing now includes people at present asymptomatic who *may* develop a disease or who currently have a disease but exhibit no symptoms ('predictive genetic testing')¹⁰⁷⁸ in order to suggest prophylactic treatments. Genetic testing is increasingly used to diagnose common, complex gene disorders affecting large proportions of the population¹⁰⁷⁹ increasing the number of people who could use genetic testing and the tests' impact on healthcare.

¹⁰⁷⁴ See generally CF Walter, 'Beyond the Harvard Mouse: Current Patent Practice and the Necessity of Clear Guidelines in Biotechnology Patent Law' (1998) 73 Indiana LJ 1025; Nuffield Report (n 1072); B William-Jones, 'History of a Gene Patent: Tracing the Development and Application of Commercial BRCA Testing' (2002) 10 Health LJ 123, 124, 127.

¹⁰⁷⁵ Walter (n 1074).

¹⁰⁷⁶ Nuffield Report (n 1072) xi.

¹⁰⁷⁷ Ontario Ministry of Health, 'Genetics, Testing & Gene Patenting: Charting New Territory in Healthcare (2002)' Ontario Ministry of Health
<http://www.health.gov.on.ca/english/public/pub/ministry_reports/geneticsrep02/genetics.html>
accessed 25 March 2004 89 (Ontario MOH Report) 6; F Miller and others, *Predictive Genetic Tests and Health Care Costs: A Policy Framework and Illustrative Estimates* (Hamilton McMaster Centre for Health Economics and Policy Analysis 2002) 1 (CHEPA Report).

¹⁰⁷⁸ CHEPA Report (n 1077) 1.

Predictive genetic diagnostic testing already exists on a large-scale in the UK and abroad with over 1000 tests internationally to test adults, children and fetuses for genetic disorders.¹⁰⁸⁰ This number is only expected to grow¹⁰⁸¹ given that up to 60% of British people may suffer from some form of genetic disease.¹⁰⁸² Predictive genetic tests are currently being used to diagnose a wide range of diseases (including breast and ovarian cancer)¹⁰⁸³ and their use may expand to include home-testing outside the clinical setting. The uptake of genetic tests, once made generally available, can be very dramatic.¹⁰⁸⁴ For example, in the UK uptake of the BRCA1 and BRCA2 tests increased by 240% in the first four years that they became generally available.¹⁰⁸⁵ Uptake of genetic testing creates demands on public healthcare and public regulation (for example, for testing criteria, counseling and ensuring equitable access to testing).¹⁰⁸⁶

Patents are central to commercialization strategies adopted by test developers and may encourage investment in developing these tests. On the other hand are those concerned that patents will increase the cost, and influence marketing and safe

¹⁰⁷⁹ FS Collins and VA McKusick, 'Implications of the Human Genome Project for Medical Science' (2001) 285(5) JAMA 540.

¹⁰⁸⁰ Human Genome Project, 'Information – Gene Testing' <http://www.ornl.gov/sci/techresources/Human_Genome/medicine/genetest.shtml> accessed 4 April 2004. For complete information an excellent resource is GeneTests, a US publicly funded medical genetics testing site <<http://www.genetests.org/>> accessed 6 April 2004.

¹⁰⁸¹ S Bunk, 'Researchers Feel Threatened by Disease Gene Patents' (11 October 1999) 13(20) The Scientist 7.

¹⁰⁸² Several studies have considered the broader regulatory and cost issues that are implicated in a regime providing predictive genetic testing, for eg CHEPA Report (n 1077).

¹⁰⁸³ Ontario MOH Report (n 1077) 6.

¹⁰⁸⁴ Ontario MOH Report (n 1077) 6.

¹⁰⁸⁵ Ontario MOH Report (n 1077) 6.

¹⁰⁸⁶ Ontario MOH Report (n 1077) iv.

distribution of tests¹⁰⁸⁷ leading to blockages in supply and research that will adversely affect the public, researchers and industry partners.¹⁰⁸⁸ The patentability of these tests is debated in the context of a long-standing discussion of the ethics of patenting genes between bioethicists, lawyers, activists, scientists and others¹⁰⁸⁹ as well as concerns about ‘genohype’ (groundlessly promoting the benefits of genetic research) in the media.¹⁰⁹⁰

While it is difficult to isolate research into predictive tests specifically to give a sense of its socio-political features, there are a broad range of stakeholders implicated by genetic research, in addition to the possible test takers and providers just discussed. Research in genetics is conducted by university labs, university-industry affiliated research centres, specialist institutes and laboratories and fully private facilities. Numerous funding organizations, charities, industry, research councils and the DH fund research within those units. In particular, the MRC continues to support medical research in the UK through its institutes, university researchers, and university researcher collaborations. It spent 38% of its £500 million funding on molecular and cellular research, of which genetic medicine is a large component.¹⁰⁹¹ Charities also play a significant funding role.¹⁰⁹² The NHS now has 18 specialist genetics centres and in 2006 completed a 3-year £50 million expansion

¹⁰⁸⁷ This case study will not consider predictive genetic testing of other diseases outlined above and more generally genetic testing to guide reproductive decision-making and genetic testing for the purposes of drug selection and delivery.

¹⁰⁸⁸ CHEPA Report (n 1077) 42.

¹⁰⁸⁹ Eg, D Beylerveld and R Brownsword, ‘Human Dignity, Human Rights, and Human Genetics’ (1998) 61(5) MLR 661; R Cole-Turner, ‘Religion and Gene Patenting’ (Oct 1995) 270(5233) Science 52.

¹⁰⁹⁰ TM Bubela and TA Caulfield, ‘Do the Print Media “Hype” Genetic Research? A Comparison of Newspaper Stories and Peer-Reviewed Research Papers’ (2004) 170(9) CMAJ 1399.

¹⁰⁹¹ MRC, ‘Facts & Figures’ <<http://www.mrc.ac.uk/AboutUs/FactsFigures/index.htm>> accessed 15 December 2007.

¹⁰⁹² The Association of Medical Research Charities, homepage <<http://www.amrc.org.uk/>> accessed 15 December 2007.

of its genetic medicine capabilities.¹⁰⁹³ Patents are one means through which researchers transfer knowledge and are generally used to commercialise products although offensive patent litigation by researchers is rare and even more infrequently reaches a court.¹⁰⁹⁴

(b) The Breast Cancer Gene Race

Predictive genetic tests have great promise for the effective diagnosis and treatment of breast cancer. Breast cancer is a significant disease in the UK: in 2000, approximately 30% of all cancer developed by women in the UK was breast cancer, and 5% was ovarian cancer.¹⁰⁹⁵ Women have a lifetime risk of 1 in 9 of developing breast cancer (approximately 11%),¹⁰⁹⁶ and 5-10% of women who develop breast and ovarian cancer possess an inherited gene associated with a higher risk of developing these cancers.¹⁰⁹⁷ BRCA1 and BRCA2 are the genes most strongly associated with the development of inherited breast cancer in men and women.¹⁰⁹⁸ Not all inherited breast cancer, however, is due to BRCA1 and BRCA2. Depending on the nature of the mutation and the family history, individuals with mutations have a lifetime risk of 40-85% of developing the cancer.¹⁰⁹⁹ Other genes and social and environmental

¹⁰⁹³ DH, *Our Inheritance, Our Future: Realising the Potential of Genetics in the NHS* (HMSO, Cmnd 5791 2003).

¹⁰⁹⁴ M van Hoorebeek, 'Government Policy and University Technology Transfer Practices in the UK' (2005) *Int J Technology Transfer & Commercialisation* 4(4) 502, 510.

¹⁰⁹⁵ Cancer Research UK, 'Statistics' <<http://www.cancerresearchuk.org/aboutcancer/statistics/incidence>> accessed 4 April 2004.

¹⁰⁹⁶ Cancer Research UK, 'Breast Cancer FactSheet' <<http://www.cancerresearchuk.org/aboutcancer/statistics/factsheets/>> accessed 4 April 2004.

¹⁰⁹⁷ CI Szabo & MC King, 'Population Genetics of BRCA1 and BRCA2' (1997) 60(5) *American J Human Genetics* 1013.

¹⁰⁹⁸ A Liede and others, 'Cancer Risks for Male Carriers of Germline Mutations in BRCA1 or BRCA2: A Review of the Literature' (2004) 22(4) *J Clinical Oncology* 735.

¹⁰⁹⁹ N Petrucelli and others, 'BRCA1 and BRCA2 Hereditary Breast/Ovarian Cancer' *GeneReviews* <<http://www.genetests.org>> accessed 6 April 2004.

factors play an important role in the development of breast cancer.¹¹⁰⁰ Thus predictive genetic tests pose the potential for quick and early diagnosis of a disease that is a serious health concern.

The scientific link between genetic mutations and the development of breast cancer is much better understood today than it was at the time when the race to sequence BRCA1 and BRCA2 started in the late 80s. A UK research group was founded in 1988 called the International Breast Cancer Linkage Consortium to sequence the BRCA1 and BRCA2 genes, which were known to be associated with a susceptibility to breast cancer. The BRCA1 gene was sequenced in 1994 by a team of researchers from private corporations (Myriad, Eli-Lilly) and public universities (McGill) that was funded by government money (including from the US NIH). Myriad Genetics, the University of Utah Research Foundation and the US Secretary of Health subsequently applied for US ‘composition of matter’ and ‘method of use’ patents on the gene in 1995.¹¹⁰¹ Myriad also applied for in 1995, and was granted in 2001, a European patent over the diagnostic use of BRCA1, though not over the sequence itself.¹¹⁰² Myriad holds two further European patents over diagnostic uses of BRCA1 mutations.¹¹⁰³

Myriad’s patents over BRCA1 raised the frightening spectre to researchers that Myriad could control access and testing related to the gene.¹¹⁰⁴ A race began to sequence the BRCA2 gene between a Myriad-led consortium and a consortium

¹¹⁰⁰ William-Jones (n 1074) 128.

¹¹⁰¹ US patents 5747282 and 5710001.

¹¹⁰² EPOLine ‘EP0699754’

<<http://register.epoline.org/espacenet/regviewer?AP=EP19950305602&PN=&CY=ep&LG=en&DB=REG>> access 15 December 2007.

¹¹⁰³ EPO705903 (granted May 2001) and EPO705902 (granted November 2001).

headed by the Institute for Cancer Research and the Sanger Centre. On 22 December 1995 the UK consortium held a press conference to announce that they had sequenced BRCA2, the day before they published the sequence in *Nature*. They also announced that CRC Technology (the commercial arm of the charity Cancer Research Campaign) was applying for a UK patent.¹¹⁰⁵ While UK researchers opposed this patent it was thought to be necessary to prevent monopolization and blockages by Myriad. An exclusive worldwide licence to the patent for diagnostic services was granted by CRC to OncorMed which had to follow strict conditions. These included royalty-free use of the techniques by the NHS, broad sub-licensing of the tests, a ban on direct advertising of tests and a requirement to provide pre- and post-test counseling to women.¹¹⁰⁶ CRC was finally granted the European patent for BRCA2 on February 11, 2004.¹¹⁰⁷ Myriad was granted a European patent on diagnostic screening of BRCA2 mutations in January 2003 (as well as claims for uses in gene therapy and drug screening for cancer therapy).¹¹⁰⁸

US patents were critical to Myriad's global business strategy. In this same period, the NIH and OncorMed applied for US patents on a 'consensus sequence' of the BRCA1 gene.¹¹⁰⁹ OncorMed was awarded a patent that overlapped somewhat with Myriad's patent.¹¹¹⁰ Myriad claimed patent infringement, settled out of court for

¹¹⁰⁴ M Rimmer, 'Myriad Genetics: Patent Law and Genetic Testing' (2003) 25(1) EIPR 20, 22.

¹¹⁰⁵ Granted as EPO858467.

¹¹⁰⁶ "'Constraints Imposed in Breast Cancer Gene Patents' *Nature* 27 November 1997' ScienceWeek <<http://scienceweek.com/1998/sw981127.htm>> accessed 15 December 2007.

¹¹⁰⁷ 'Charities to Make Breast Cancer (BRCA2) Gene Freely Available Across Europe' Press Release (11 February 2004), Cancer Research UK <http://www.cancerresearchuk.org/news/pressreleases/breastcancergene_11feb04> accessed 30 March 2004).

¹¹⁰⁸ EPO785216.

¹¹⁰⁹ Nuffield Report (n 1072) 39.

¹¹¹⁰ US Patent 5654155.

an undisclosed amount and bought OncorMed's patents.¹¹¹¹ The US patents granted over BRCA1 and BRCA2 were very broad, covering a large number of mutations as well as the use of these genes to diagnose and predict ovarian and breast cancer, and included other therapeutic and cancer screening applications. Myriad demonstrated a willingness to challenge any potential infringers. Its business plan hinged on cultivating a network of health care providers who would use its genetic diagnostic tests. These providers would fund and then serve as a ready market for the much more lucrative business of therapeutics. Myriad sought to implement its US strategy internationally with some modifications by seeking a sole sub-licensee in each jurisdiction. It, critically, failed to account for local socio-political conditions, especially public healthcare regimes.¹¹¹²

From the public knowledge about BRCA1 and BRCA2, public laboratories in a range of countries (eg Canada, UK) began providing their own version of BRCA testing that did not rely on Myriad's full DNA sequencing, using techniques such as protein truncation testing (PTT).¹¹¹³ A physician and genetic counselor would consider the results of the PTT and family history to determine whether the patient should go for a full BRCA test. That test would be conducted at an independent laboratory. There is significant debate over what method or combination of tests and assessment represents the 'gold standard' for diagnostic testing that I will not deal with in any more detail in this discussion.¹¹¹⁴

¹¹¹¹ William-Jones (n 1074) 133.

¹¹¹² For more details see RJ Myriad (n 1073).

¹¹¹³ PTT assesses whether the proteins produced by the gene are complete; if not they indicate the presence of a mutation. If they are complete there may still be a mutation.

¹¹¹⁴ C Sevilla and others, 'Testing for BRCA1 mutations: a cost-effectiveness analysis' (2002) 10 EJ Human Genetics 599, 603.

(c) The Myriad Controversy

Myriad's behaviour in managing the commercialization of the BRCA genes catalyzed worries over gene patents. Policy-makers, health-care specialists, religious groups and others had for years expressed concerns that granting gene patents would limit access to valuable technologies developed from those genes, increase the costs of healthcare and commodify the human body. An influential study indicated that 75% of scientists based at government, academic and private research institutions and corporations were opposed to the commercialization of the results of the Human Genome Project, and 90% of respondents thought that excessive DNA patenting was a problem.¹¹¹⁵ Few concrete examples, however, had substantiated those concerns or led to concrete policy reform.¹¹¹⁶

In addition, the international legal and scientific policy communities had been galvanised by opinion pieces telling the story of the growth of an 'anticommons' of biomedical research where an over-allocation of proprietary rights might block research. In an influential 1998 *Science* paper, Heller and Eisenberg had posited that competing proprietary rights and claims threatened to overwhelm biomedical research. Royalty stacking, concurrent patents on upstream research and exclusive licensing threatened to create a situation where downstream researchers would be unable to research or develop any products. Thus patents would have the unintended effect of limiting rather than stimulating innovation, both impeding research and the

¹¹¹⁵ I Rabino, 'How Human Geneticists in US View Commercialization of the Human Genome Project' (Sept 2001) 29 *Nature Genetics* 15.

¹¹¹⁶ T Caulfield and others, 'Evidence and Anecdotes: An Analysis of Human Gene Patenting Controversies' (Sept 2006) 24(9) *Nature* 1091.

provision of clinical genetic diagnostic tests. Research and clinical tests were linked as many researchers relied on the results of genetic diagnostic tests to inform their research into disease. Concerns that research might needlessly be blocked by over-broad or invalid patents further complicated the issue, as one study demonstrated that 38% of patent claims filed with the USPTO in a one-year period for nine selected genetic diseases had problems that might lead to their invalidity.¹¹¹⁷

The Myriad controversy also occurred in an environment of increasing applications for biotechnology patents. Applications for biotechnology patents to the EPO grew by 5.1% a year between 1995 and 2003, although the numbers have started to decrease since 2000.¹¹¹⁸ Institutionally, universities increasingly hold a greater number of life science patents and derive substantial licensing revenue from licensing innovations and technology transfer.¹¹¹⁹ 89% of EPO biotechnology patents are held by private companies while general trends show an increasing level of international collaboration in patent applications at the EPO.¹¹²⁰ Biotechnology patents tend to cite non-patent literature at a greater frequency than other patents, suggesting they have a closer link to scientific R&D.¹¹²¹

In the US, over 13,000 biotechnology patents were granted in 2000 from 3,000 in 1985, a number that demonstrates the rapid growth of patents on research tools that

¹¹¹⁷ A Paradise and others, 'Patents on Human Genes: An Analysis of Scope and Claims' (March 2005) 307 Science 1566.

¹¹¹⁸ OECD, 'Compendium of Patent Statistics' (2006) <<http://www.oecd.org/dataoecd/5/19/37569377.pdf>> accessed 15 December 2007, 20 (OECD Patent Statistics).

¹¹¹⁹ JP Walsh and others, 'Effects of Research Tool Patents and Licensing on Biomedical Innovation' in WM Cohen and SA Merrill (eds), *Committee on Intellectual Property Rights in the Knowledge-Based Economy*, (National Research Council 2004) <<http://www.nap.edu/catalog/10770.html>> accessed 15 December 2007 (Walsh 2004).

¹¹²⁰ OECD Patent Statistics (n 1118) 7.

¹¹²¹ OECD Patent Statistics (n 1118).

surround drug development.¹¹²² 78% of US DNA patents as of 2004 were held by for-profit institutions, and 22% held by non-profits, a proportion lower but similar to that of the EU.¹¹²³ 20% of human genes are held under 4270 US patents, the majority of which are assigned or held by private firms.¹¹²⁴ Claims centre around certain gene hotspots, leaving whole expanses of the human genome uncharted.

It was in this quickly-changing environment that Myriad began to enforce aggressively its BRCA1 and BRCA2 patents over mutations and became a policy catalyst.¹¹²⁵ Myriad Genetics and BRCA are the two most cited controversies by a factor of ten in major IP policy documents after 2002.¹¹²⁶ While a precise causal connection is difficult to substantiate, a slew of policy documents and recommendations around the world followed Myriad's activities,¹¹²⁷ which rarely led to concrete policy reform. In one case, however, Belgium did legislate a research exemption in its patent law as a result of the Myriad controversy.¹¹²⁸ The European Parliament also passed a resolution opposing the patenting of BRCA1 in October

¹¹²² Walsh 2004 (n 1119).

¹¹²³ L Pressman and others, 'The Licensing of DNA Patents by US Academic Institutions: An Empirical Survey' (January 2006) 24(1) *Nature* 31.

¹¹²⁴ K Jensen and F Murray, 'Intellectual Property Landscape of the Human Genome' (October 2005) 310 *Science* 239.

¹¹²⁵ Caulfield and others (n 1116) fig 1.

¹¹²⁶ Caulfield and others (n 1116) fig 2.

¹¹²⁷ Eg Nuffield (n 1072); Organization for Economic Cooperation and Development, 'Guidelines for the Licensing of Genetic Inventions' (OECD homepage) <www.oecd.org/sti/biotechnology/licensing> accessed 15 December 2007 (OECD Licensing Guidelines); Canadian Biotechnology Advisory Committee *Patenting of Higher Life Forms and Related Issues: Report to the Government of Canada* (Biotechnology Ministerial Coordinating Committee (2002) (CBAC Report); Ontario MOH Report (n 1077); W Cornish, M Llewelyn and M Adcock, *Intellectual Property Rights (IPRs) and Genetics: A Study into the Impact and Management of Intellectual Property Rights within the Healthcare Sector* (Cambridge Public Health Genetics Unit 2003) 16 (PHGU Report); Royal Society *Keeping Science Open: The Effects of Intellectual Property Policy on the Conduct of Science* <<http://royalsociety.org/displaypagedoc.asp?id=11403>> accessed 15 December 2007; SA Merrill, RC Levin, and MB Myers (eds), *A Patent System for the 21st Century* (Washington DC, National Academies Press, 2004); ALRC 'Gene Patenting and Human Health' ALRC <<http://www.alrc.gov.au/inquiries/current/patenting/index.htm>> accessed 15 December 2007 (ALRC Report); Danish Council of Ethics, *Patenting Human Genes: A Report* (2004) <http://www.etiskraad.dk/graphics/03_udgivelser/engelske_publicationer/patenting_human_genes/patents04/index.htm> accessed 15 December 2007.

2001.¹¹²⁹ Legislation was tabled in the US but never progressed.¹¹³⁰

What had Myriad done? Outside of its activities in the US and in sequencing the BRCA genes already discussed, Myriad held broad BRCA patents in the US, Europe, Canada, Australia and New Zealand over some or all of the BRCA genes, mutations of those genes and diagnostic tests respectively. Myriad's business strategy was based on partnering with local laboratories: Myriad would provide full scale 'pro-band testing' and local laboratories would provide scaled-down testing at a tenth of the cost of the full-scale test.¹¹³¹ Myriad hypothesised that every woman who discovered a mutation would have ten relatives who would want the scaled-down test, bringing in income for both Myriad and its licensees.¹¹³² Myriad eventually wanted to become the leading company in linking gene discovery to therapeutics and intended to finance this through diagnostic testing (as testing did not require clinical trials and could go straight to market). Myriad aimed to become the foremost genetic diagnostic testing company to ensure a steady income as well as to control subsequent entrants into that market and tests developed for other genes.¹¹³³

To pursue this business model, Myriad had signed licensing agreements with local companies in the UK, Ireland, Germany, Switzerland, Austria, Canada and Japan to provide exclusive BRCA testing in those countries.¹¹³⁴ While its model worked relatively well in the US with its system of privatised healthcare, the business

¹¹²⁸ RJ Myriad (n 1073).

¹¹²⁹ Nuffield (n 1072) 40.

¹¹³⁰ US Democratic representative Lynn Rivers tabled unsuccessful legislation that would limit healthcare worker liability upon infringing a patent on a genetic diagnostic test entitled the 'Genomic Research and Diagnostic Accessibility Act of 2002'.

¹¹³¹ RJ Myriad (n 1073).

¹¹³² RJ Myriad (n 1073).

¹¹³³ RJ Myriad (n 1073).

¹¹³⁴ William-Jones (n 1074) 136.

plan failed spectacularly in the other jurisdictions whose markets it sought to enter. Its entry into the US market had not been completely smooth. In the US it had sent cease and desist letters to competitors threatening litigation, in particular the Genetics and IVF Institute (GIVF) and the University of Pennsylvania's Genetic Diagnostic Laboratory (GDL) in 1998 who had both agreed to cease infringing commercial testing. Myriad eventually became the sole test provider in the US and viewed its business model as a success. This was despite the negative publicity and media comments that had arisen from its negotiations with GDL.¹¹³⁵ Legislators had responded with the Genomic Research and Diagnostic Accessibility Bill 2002¹¹³⁶ which proposed exempting researchers from infringement liability for the use of any patented gene sequence information in research. Prominent national charities¹¹³⁷ and the American College of Medical Geneticists expressed opposition to Myriad's business tactics using gene patents.¹¹³⁸ In April 2005 the National Institutes of Health in the US issued 'Best Practices for the Licensing of Genomic Inventions', which specifically referred to diagnostics.¹¹³⁹

Myriad decided to expand its operations to other countries where it held relevant patents. This proved much less successful. In Canada, Myriad entered into a licensing agreement with MDS Laboratories, who then entered into negotiations with provincial governments about providing genetic diagnostic testing through MDS and Myriad. The Ontario provincial government did not respond for six months, a

¹¹³⁵ William-Jones (n 1074) 136; RJ Myriad (n 1073).

¹¹³⁶ The Bill was referred to the House Subcommittee on the Courts, the Internet, and Intellectual Property on 5 May 2002, but lapsed at the end of the 107th Congress.

¹¹³⁷ William-Jones (n 1074) 137.

¹¹³⁸ William-Jones (n 1074) 137.

¹¹³⁹ National Institutes of Health, 'Best Practices for the Licensing of Genomic Inventions' (2005) <<http://ott.od.nih.gov/pdfs/70FR18413.pdf>> accessed 11 July 2007.

significant time for Myriad but reasonable within government.¹¹⁴⁰ The Ontario government had to consider the implications of the increased cost of Myriad's tests on government services. Public laboratories continued to administer their own tests during that period. Myriad became frustrated with the lack of response and on the advice of MDS sent public laboratories cease and desist letters threatening litigation should they continue in-house testing for the BRCA1 and BRCA2 genes rather than sending samples (at three times the cost) to Myriad's laboratories or exclusive licensee for testing.¹¹⁴¹ Myriad's cease and desist letters stopped PTT testing at the BC Hereditary Cancer Program due to the budgetary constraint of sending samples out for testing but other programs continued their testing activities.¹¹⁴²

Myriad's behaviour raised a furor in Canada, particularly after Myriad sent a series of letters to the Ontario government from US representatives threatening trade sanctions and from US scientists criticizing Canadian testing methods.¹¹⁴³ These actions and others were heavily covered in the media,¹¹⁴⁴ leading to expressed opposition from provincial ministers, premiers and national breast cancer charities.¹¹⁴⁵ A series of high level conferences and negotiations continued between the provincial governments, the federal government and Myriad. The Canadian side was unable to define a consensus position between the various departments involved and eventually the dispute petered out in the face of the 2003 SARS crisis in Ontario.¹¹⁴⁶ The controversy over Myriad led to reports and changes to the Canadian Intellectual

¹¹⁴⁰ RJ Myriad (n 1073).

¹¹⁴¹ For a detailed account of the situation that arose in Canada see William-Jones (n 1074) 141ff.

¹¹⁴² William-Jones (n 1074); Nuffield Report (n 1072) 40.

¹¹⁴³ RJ Myriad (n 1073).

¹¹⁴⁴ RJ Myriad (n 1073).

¹¹⁴⁵ William-Jones (n 1074) 143, 122.

¹¹⁴⁶ RJ Myriad (n 1073).

Property Office's Manual of Patent Office Practice and Procedure.¹¹⁴⁷ Two influential Canadian reports, spurred on by the Myriad crisis, recommended expanding and clarifying the research use exemption.¹¹⁴⁸

In the UK, Myriad's licensee Rosgen went bankrupt. Myriad entered into negotiations with the NHS but these eventually proved fruitless; pre-existing hostilities between Myriad's team and prominent UK researchers and the CRC's existing patents limited Myriad's negotiating power.¹¹⁴⁹ Myriad's BRCA patent was the first case study presented in the Nuffield Council's influential July 2002 report on the ethics of patenting DNA.¹¹⁵⁰ It recommended strictly applying patenting criteria to patents which assert rights over DNA sequences for diagnosis, with the expectation that these patents would become the rare exception rather than the norm.¹¹⁵¹ In 2005, the UKPO also issued guidelines governing the patenting of biotechnological inventions.¹¹⁵² The PHGU Report has concluded that 'diagnostic testing should be distinguished from therapy and treated as discovery without industrial application.'¹¹⁵³

The Paris-based Institut Curie spearheaded opposition procedures against Myriad at the EPO involving high-profile French scientists who were publicly hostile to Myriad.¹¹⁵⁴ As in-house BRCA testing in France has been calculated to cost one-third of the cost Myriad demanded, politicians and scientists argued that Myriad could

¹¹⁴⁷ Ontario MOH (n 1077); CBAC Report (n 1127).

¹¹⁴⁸ Ontario MOH (n 1077) 88; CBAC Report (n 1127) 15.

¹¹⁴⁹ RJ Myriad (n 1073).

¹¹⁵⁰ Nuffield Report (n 1072) 39.

¹¹⁵¹ Nuffield Report (n 1072) [6.7].

¹¹⁵² UKPO, *Examination Guidelines for Patent Applications Relating to Biotechnological Inventions in the UK* (Patent Office, May 2005).

¹¹⁵³ PHGU Report (n 1127) Part 1.C.3.

¹¹⁵⁴ RJ Myriad (n 1073).

restrict access to needed medical services and act against the public interest.¹¹⁵⁵ The French government required that Myriad negotiate with each public health laboratory if it wanted to license them to provide BRCA genetic diagnostic tests, which Myriad was unable to do. The French also amended their laws to allow compulsory licensing of genetic diagnostic tests and to prohibit the export of blood samples, thus thwarting Myriad's plans.¹¹⁵⁶ European MEPs, protesting Myriad's behaviour, adopted a resolution in October 2001 opposing the patenting of BRCA1, and calling on the appropriate parties to ensure 'that the human genetic code is freely available for research throughout the world and that medical applications of certain human genes are not impeded by means of monopolies based on patents'.¹¹⁵⁷ These patents 'could seriously impede or even completely prevent the further use of existing cheaper and more effective tests for the breast cancer genes BRCA1 and BRCA2.'¹¹⁵⁸

Myriad's efforts to expand genetic diagnostic testing to Australia were a significant impetus for an Australian Law Reform Commission report.¹¹⁵⁹ Myriad exclusively licensed its tests there and its local licensee promised that the patents would not be enforced against public institutions and laboratories.¹¹⁶⁰ Internationally, the Myriad controversy contributed to reports and research commissions including the OECD's licensing guidelines.¹¹⁶¹ A private member's Bill was introduced into the South Australian Parliament to stop companies charging fees for genetic testing in

¹¹⁵⁵ William-Jones (n 1074) 139.

¹¹⁵⁶ RJ Myriad (n 1073).

¹¹⁵⁷ European Parliament 'European Parliament Resolution on the Patenting of BRCA1 and BRCA2 ("breast cancer") genes' Texts Adopted by Parliament, Provisional Edition: 04/10/2001, B5-0633, 0641, 0651 and 0663/2001.

¹¹⁵⁸ R Watson 'MEPs Add Their Voice to Protest at Patent for Breast Cancer Gene' (2001) 323(7318) BMJ 888.

¹¹⁵⁹ ALRC Report (n 1127).

¹¹⁶⁰ RJ Myriad (n 1073).

¹¹⁶¹ OECD Licensing Guidelines (n 1127).

hospitals but did not succeed.¹¹⁶² Thus the Myriad controversy led policy-makers, health-care providers and other to propose principally legal solutions to address the problem created by Myriad's apparent willingness to strictly assert its patent rights.

(d) Legal Actions

In response to Myriad's claims, the parties attempted or proposed a series of primarily legal solutions, principally to invalidate Myriad's patents and to reform patent law. The Institut Curie coordinated the filing of four opposition procedures to Myriad's patents, three opposing BRCA1 patents¹¹⁶³ and one opposing a BRCA2 patent.¹¹⁶⁴ All four of the original patents claim the use of either BRCA1 or BRCA2 in diagnosing breast and ovarian cancer. The grounds of opposition to each patent are unique to each notice of opposition and can be briefly summarised as lack of novelty (predisposition tests were available before the patents were filed and the relevant protein sequences were made available to the public in public genetic databases and

¹¹⁶² Gene Testing Services (Public Availability) Bill 2003 (SA).

¹¹⁶³ An opposition to patent EP0705902 by the IC and seven other co-opponents including Greenpeace and the government of the Netherlands, EPOLine '17q-Linked breast and ovarian cancer susceptibility gene [1996/15] (BRCA1)' <<http://register.epoline.org/espacenet/regviewer?AP=EP19950305601&PN=&CY=ep&LG=en&DB=REG>> accessed 2 April 2004; an opposition filed against EP0699754 by the IC and four co-opponents, EPOLine 'Method for diagnosing a predisposition for breast and ovarian cancer [1996/10] (BRCA 1)' <<http://register.epoline.org/espacenet/regviewer?AP=EP19950305602&PN=&CY=ep&LG=en&DB=REG>> accessed 2 April 2004; and an opposition filed against patent EP0705903 by the IC and 5 co-opponents, EPOLine 'Mutations in the 17q-linked breast and ovarian cancer susceptibility gene [2000/28] (BRCA1)' <<http://register.epoline.org/espacenet/regviewer?AP=EP19950305605&PN=&CY=ep&LG=en&DB=REG>> accessed 2 April 2004.

¹¹⁶⁴ An opposition filed against patent EP0785216 by the IC and the Belgian Society of Human Genetics, EPOLine 'Chromosome 13-linked breast cancer susceptibility gene BRCA2 [1997/30]' <<http://register.epoline.org/espacenet/regviewer?AP=EP19960309211&PN=&CY=ep&LG=en&DB=REG>> accessed 2 April 2004.

publications);¹¹⁶⁵ lack of inventive step (much of the work done by a public consortium);¹¹⁶⁶ objections based on *ordre public* and morality (a patent that interferes with public healthcare provision violates the *ordre public*);¹¹⁶⁷ insufficient specification;¹¹⁶⁸ unpatentable subject-matter (the claimed invention is a discovery and/or that it is a mere sequence without any indication as to function, enjoined by the Biotech Directive and/or it lies within the scope of the diagnostic methods exception);¹¹⁶⁹ and a range of other grounds including concerns about the patents blocking research.¹¹⁷⁰

Although they are currently under appeal, three of four oppositions were decided against Myriad either completely or in part. On 11 November 2004, the EPO's Opposition Division completely revoked Myriad's EPO699754 patent over methods of diagnosing a predisposition to breast or ovarian cancer using the un-mutated BRCA1 sequence, on grounds of obviousness and over-breadth among others.¹¹⁷¹ Then on 9 June 2005, the Opposition Division ruled to maintain Myriad's EPO705903 patent over BRCA1 in amended form to exclude claims for diagnostic methods.¹¹⁷² Similarly, on 19 September 2005, the opposition to the BRCA1 EPO705902 patent was successful and the scope of the patent was significantly

¹¹⁶⁵ EPC Arts 52(1) and 54; Rimmer (n 1104) 24. For specific arguments see: Notice of Opposition filed against EPO705903 25 February 2002, 9; Notice of Opposition filed against EPO705903 25 February 2002.

¹¹⁶⁶ EPC Arts 52(1) and 56; Institut Curie, 'Against Myriad Genetics's Monopoly on Tests for Predisposition to Breast and Ovarian Cancer, the Institut Curie is Initiating an Opposition Procedure with the European Patent Office' Press Release (12 September 2001) 6 (Press Release EPO699754); Notice of Opposition filed against EPO705902 28 August 2002; Notice of Opposition filed against EPO705903 25 February 2002.

¹¹⁶⁷ EPC Art 53(a); Notice of Opposition filed against EPO705903 25 February 2002, 7.

¹¹⁶⁸ EPC Art 83; Rimmer (n 1104) 24; Press Release (n 1166) 6.

¹¹⁶⁹ Especially Arts 52(2) and 52(4); Notice of Opposition filed against EPO705903 25 February 2002, 5, 6; Notice of Opposition filed against EPO705902 28 August 2002; Notice of Opposition filed against EPO699754 10 October 2001 5, 6.

¹¹⁷⁰ PHGU Report (n 1127) 30.

¹¹⁷¹ 'Grounds for the Decision of the Opposition Division' (n 1163).

¹¹⁷² 'Grounds for the Decision of the Opposition Division' (n 1163).

reduced.¹¹⁷³ On 12 September 2005 the Opposition Division ruled that Myriad's patent EPO785216 over the mutation prevalent in people of Ashkenazi descent was valid.¹¹⁷⁴ In these decisions, the Opposition Division focused on technical matters and grounds as opposed to policy arguments. It is unclear that the results of these legal proceedings have played any role in mediating the conflict between Myriad and its opponents.¹¹⁷⁵

(e) Proposed Legal Reforms

The public health agencies, institutes and researchers subject to Myriad's patents and business strategy framed the problem as one rooted in patent law and appealed to the formal law's authority to resolve the dispute, reflecting the conclusions of the historical study. The patent law appeared, to those opposed to Myriad's patents, to be enabling Myriad's commodification and domination. Genetic diagnostic tests are patentable (and patented) in the US, Canada, Australia, New Zealand and in Europe. In the US this derives from the general patentability of genes,¹¹⁷⁶ and in the UK and Europe derives from legislation and directives.¹¹⁷⁷ Further, predictive diagnostic tests do not fall foul of the MME. In the US, genetic tests are not excluded from

¹¹⁷³ 'Grounds for the Decision of the Opposition Division' (n 1163).

¹¹⁷⁴ 'Grounds for the Decision of the Opposition Division' (n 1163).

¹¹⁷⁵ RJ Myriad (n 1073).

¹¹⁷⁶ *Diamond v Chakrabarty* [1980] 447 US 303.

¹¹⁷⁷ Convention on the Grant of a European Patent (adopted 5 October 1973, entered into force 7 October 1977) 1065 UNTS 255 as revised by the Act revising the EPC (adopted 29 November 2000 entered into force 13 December 2007); Patents Act 1977 (UK) c 37; Directive (EC) 98/44 of 6 July 1998 on the legal protection of biotechnological inventions [1998] OJ 213, enacted into UK law by the Patents Regulations 2000 (SI 2000, No 2037) (Biotech Directive). The UKPO has also published *Examination Guidelines for Patent Applications Relating to Biotechnological Inventions in the UK Patent Office* <<http://www.patent.gov.uk/patent/reference/biotechguide/index.htm>> accessed 7 April 2004. Its provisions have been implemented by the EPO as an aid to supplementary interpretation of the EPC (Decision of the Administrative Council of 16 June 1999 to Amend the Implementing Rules of the European Patent Convention [1999] OJEP 437, [1999] OJEP 573).

patentability or covered by the Ganske-Frist amendment. In Europe and the UK, the medical diagnostics exception does not apply to genetic diagnostic tests as they do not act ‘on or in’ the human body and the results of the diagnostic test do not lead to a diagnosis, given the indeterminacy of the presence of a mutation. Methods of diagnosis are also *prima facie* patentable in Canada, Australia and New Zealand.

Those opposed to Myriad’s patents and advocating legislative change have argued that, strictly speaking, genetic diagnostic tests are poor candidates for patenting. Genes resemble discoveries as they naturally occur in nature and hence they are not novel.¹¹⁷⁸ Similarly, linking a gene to a disease for which a diagnostic test is then developed is not a discovery of that gene’s function, as that gene always existed.¹¹⁷⁹ It may also be an obvious step, particularly since the human genome has been sequenced.¹¹⁸⁰ Further, biotechnology patents may be over-broad especially those issued for genetic diagnostic tests, particularly in light of evidence that claims to future uses are not being actualised once the patent is granted.¹¹⁸¹ Further an over-broad patent could inhibit the development of tests entirely different from Myriad’s even if they are more effective.¹¹⁸² Patents over genes lack industrial applicability if researchers have not demonstrated what in fact those genes do.¹¹⁸³ These arguments about the unpatentability of genetic diagnostic tests are the same as those raised by the medical profession in the inter-war period when it was dealing with an influx of new medical technologies.

¹¹⁷⁸ Nuffield Report (n 1072) 29..

¹¹⁷⁹ Nuffield Report (n 1072) 50.

¹¹⁸⁰ Nuffield Report (n 1072) 49.

¹¹⁸¹ M Llewelyn, ‘Industrial Applicability/Utility and Genetic Engineering: Current Practices in Europe and the United States’ (1994) EIPR 473, 474. The Human Genome Project demonstrated that it was often quick to isolate a specific gene but slow to determine the specific use that could be made of that gene: 475.

¹¹⁸² Press Release EPO699754 (n 1166) 2.

¹¹⁸³ Bently & Sherman (n 18) 364.

Those proposing legislative reform have also turned to existing patent law exceptions with little hope of success. The *ordre public* and morality exception has been given a limited interpretation that would likely see the balancing of polycentric considerations of access, cost and incentive involved in genetic diagnostic testing patents as lying outside the role of the EPO and the patent law.¹¹⁸⁴ The Biotech Directive lists certain inventions, among others,¹¹⁸⁵ as excluded from patentability because they are immoral, none of which includes genetic diagnostic tests.¹¹⁸⁶ The UK research exemption¹¹⁸⁷ is unclear and complicated by the fact that in the research area of genetics, treatment and the continuing search for genetic knowledge are often complementary.¹¹⁸⁸

Similar to earlier disputes about the role of the patent law when confronted with new technologies, parties threatened by Myriad's activities proposed a series of structural solutions external to the patent law. Many resemble solutions from the earlier debates recorded in Chapters 3 to 5. For example, proposals that the Department of Health (DH) could monitor applications made to the EPO and UKPO and file any relevant information with the granting office resemble suggestions by the medical profession to monitor patents.¹¹⁸⁹ Parties have proposed that decisions to grant patents over new or controversial technologies could shift to external parties

¹¹⁸⁴ P Drahos, 'Biotechnology Patents, Markets and Morality' (1999) 21(9) EIPR 441, 444; Bently & Sherman (n 18) 409. The Enlarged Board of Appeal's decision (G2/06) on the morality of stem cell patents is pending.

¹¹⁸⁵ UKPO Guidelines (n 1058) [78].

¹¹⁸⁶ Art 6(2) Biotech Directive.

¹¹⁸⁷ MA Heller and RS Eisenberg, 'Can Patents Deter Innovation? The Anticommons in Biomedical Research' (1998) 280 Science 698; RS Eisenberg, 'Technology Transfer and the Genome Project: Problems with Patenting Research Tools' (1994) 5(2) Risk: Health, Safety and Environment 163; RS Crespi, 'Biotechnology, Broad Claims and the EPC' (1995) 6 EIPR 267.

¹¹⁸⁸ PHGU Report (n 1127).

¹¹⁸⁹ PHGU Report (n 1127) Part 2.B.4.

including the EGE, other health regulatory agencies¹¹⁹⁰ or even the WHO or WTO.¹¹⁹¹ Patents dedication¹¹⁹² and defensive patenting¹¹⁹³ remain popular recommendations, similar to earlier debates. A further option frequently raised is to either create exceptions to patentability or to expand the definition of patentability to exclude certain subject-matter. This could include expanding the medical exception to include genetic diagnostic tests¹¹⁹⁴ or removing the exception altogether and strengthening the criteria for granting patents.¹¹⁹⁵

Finally, once the patent has been granted, the parties involved in the Myriad dispute have argued that existing legal mechanisms could control any abuse of its monopoly. These mechanisms include compulsory licensing¹¹⁹⁶ which was enacted by France for genetic diagnostic tests as a result of the Myriad dispute, as well as Crown use.¹¹⁹⁷ Both also played a significant role in the Swan and Banks Committee deliberations. Competition law has also entered the modern arsenal as a threat to prevent the abuse of monopoly rights by patent holders by seeking more than a proportionate return for their invention that reaches the standard of abuse of

¹¹⁹⁰ For a more extensive discussion consult *Greenpeace v Plant Genetic Systems NV* [1995] OJEP 545 (Tech Bd App); ALRC (n 1127) Proposal 7.3.

¹¹⁹¹ Rimmer (n 1104) 33.

¹¹⁹² Llewelyn (n 1181).

¹¹⁹³ During the race to sequence the human genome, the US National Institutes of Health (NIH) applied for a series of protective gene patents in 1992 which had the effect of undermining international collaboration, though was felt to be necessary and even the MRC was considering it. The MRC abandoned seeking its own patents only because the NIH did not succeed: Llewelyn (n 1181).

¹¹⁹⁴ PHGU Report (n 1127) Part 1.C.3. The Nuffield Report, while not pronouncing specifically on medical exclusions from patentability, believes that diagnostic test patents should be granted since it 'could provide an effective means of rewarding the inventor while providing an incentive for others to develop alternative tests': Nuffield Report (n 1072) xi. This would include protecting medical practitioners and institutions from liability for providing publicly funded medical services in the field of genetics, in particular genetic diagnostic tests. See also the Rivers legislation proposed: HR 3967 107th Congress (2002).

¹¹⁹⁵ PHGU Report (n 1127) Part 2.C.3(c).

¹¹⁹⁶ Nuffield Report (n 1072) 56; PHGU Report (n 1127) Part 2.C.2(c); Ontario MOH (n 1077) 89; CBAC Report (n 1148); Australia ALRC (n 1127).

¹¹⁹⁷ This would allow the government or authorized third parties to carry out certain acts with respect to the patent without requiring a license or approval of the patentee, so long as adequate compensation is

dominance.¹¹⁹⁸

(f) Informal Norms

The legal story is interesting in itself and follows a predictable arc: underlying concerns about new technologies deriving from genetic research lead to a full-blown policy storm when a company attempts to assert a patent over a potentially valuable clinical tool relating to genetic information. The actors are cast into predictable roles: the avaricious biotechnology company seeking to privatise and enclose knowledge through enforcing its patent rights against a beleaguered public health system and researchers labouring in the public interest. The policy generation process leads to many proposals but limited concrete legislative amendment, leaving the problem unresolved while the parties continue to function in their various roles of innovating, commercializing and providing healthcare.

As this thesis surmises, while historically the medical profession, government and others have made strong arguments about the problems posed by patents, formal legislation is rarely implemented. The ‘legal’ problem, while serious, is actually embedded not just in rights but also in practices and institutions and a formal legislative remedy may either be unnecessary or disruptive of the existing means that parties have developed to resolve their disputes.¹¹⁹⁹ Legislative reform should be

paid to the patentee. Crown use is not discussed in the Nuffield Report or the UKPO Guidelines though the ALRC (n 1127) devotes considerable attention to competition law and gene patents: c 26.

¹¹⁹⁸ PHGU Report (n 1127) Part 2.C.2(f). Competition law is not discussed in the Nuffield Report or the UKPO Guidelines. The ALRC (n 1127) devotes considerable attention to competition law and gene patents: c 24.

¹¹⁹⁹ Caulfield (n 1116).

considered in the context of how it can complement practices and institutions, but on their own, formal legal rights provide limited guidance.¹²⁰⁰ As discussed earlier, parties are usually already regulating themselves according to standards of behaviour, informal agreements and practices in a manner that dulls the sharp edges of the policy story.¹²⁰¹ In reality, the policy story may not be as clear as those advocating a legislative solution portray it to be. These propositions will be considered briefly in the case of the Myriad example.

Claims about Myriad's intent to block and proprietise genetic diagnostic testing may have been overstated by policy opponents in the legislative process. Myriad's initial actions led researchers to worry that Myriad would rigidly enforce its patents and many discontinued contributing data to public databases as this could be used as evidence of patent infringement.¹²⁰² Myriad claims that it had no interest in blocking researchers' access to BRCA. There is evidence to substantiate its claims. Myriad never required licences for researchers to conduct research on the BRCA1 and BRCA2 genes and in fact encouraged research since it would only 'confirm and expand the clinical utility of testing'.¹²⁰³ Proof of this is the substantial number of scientific articles published on BRCA research by other scientists and the fact that Myriad did not bring or threaten any lawsuits against researchers.¹²⁰⁴ Different types of genetic diagnostic tests for breast cancer continue to be developed. Myriad regularly continues to contribute mutation information to the public Breast Cancer

¹²⁰⁰ R Gold, 'Myriad Genetics: In the Eye of a Policy Storm' U of Toronto Health Law & Policy Workshop, 6 December 2007.

¹²⁰¹ Note that most of this research is based on the US.

¹²⁰² Gold Presentation (n 1200).

¹²⁰³ RJ Myriad (n 1073) 15.

¹²⁰⁴ RJ Myriad (n 1073).

Information Core Database such that the majority of entries are Myriad's.¹²⁰⁵

Further, in the US for example, Myriad had entered into Memoranda of Understanding (MOUs) with the National Cancer Institute¹²⁰⁶ in order to preserve researcher access to breast cancer gene testing. This includes providing its tests at or below cost to the NCI researchers and those working on NCI funded research projects. Where Myriad is unable to provide the right kind of breast cancer test, particularly in cases of so-called large-scale rearrangements, it refers researchers to tests provided by other labs.¹²⁰⁷ Many of Myriad's extreme responses at the initial stage of the dispute about its breast cancer diagnostics are attributable to political naïveté of the context of public healthcare (as opposed to malice or bad will), its culture of corporate secrecy that failed to communicate Myriad's openness to research uses of the patents and its frustration with the very slow pace of political discussion with national authorities (particularly in France and Canada). In France, Myriad attempted to license and build relationships with public laboratories but was largely unsuccessful. Its main opponent there, the Institut Curie, was also using patents to develop its own treatments. In Australia, Myriad's licensee took the position that it would not enforce the patent against public health laboratories;¹²⁰⁸ it confirmed again in 2003 that it would allow public hospital cancer genetics laboratories in Australia and New Zealand to continue testing.¹²⁰⁹ In Canada the debate about genetic diagnostic testing arose at a time when the protection of public healthcare had resurfaced as a major political issue. Myriad did not attempt to sue anyone in Canada

¹²⁰⁵ RJ Myriad (n 1073) 17.

¹²⁰⁶ And had offered to do the same with the National Institutes of Health.

¹²⁰⁷ RJ Myriad (n 1073).

¹²⁰⁸ I Goold and others, 'Quality and Safety of Genetic Testing in Australia and New Zealand: A Review of the Current Regulatory Framework' (2006) 3 Australia & NZ Health Policy 13.

¹²⁰⁹ Goold (n 1208) 8.

for patent infringement although it sent cease and desist letters out of frustration, it claims, with the slow pace of decision-making by politicians.¹²¹⁰ Thus, Myriad's business plan and its model of conducting business was poorly conceived and delivered, but few concrete ill-effects are attributable to the patent grant itself except perhaps its ability to create a chilling effect on researchers and test providers.

Stepping back from the facts of the Myriad dispute, the data to support the proposition that gene patents impede research and ultimately test provision are mixed. While there are more gene patentholders and patents on research tools, there is little evidence that those patents have impeded basic research.¹²¹¹ A survey of 414 researchers in government, universities and private labs concluded that none had been blocked from conducting a research project because of patents, and modifications or delays to research projects caused by patents affected only 1% of the sample.¹²¹² Only 5% of scientists regularly check for patents on knowledge inputs related to their research and only 2% of those have begun checking for patents in the 2 years since the USSC decision in *Madey v. Duke* significantly limited the legal scope of the US research exemption.¹²¹³ This suggests that biomedical researchers are rarely worried about patents and the 'law' constraining their research, as norms and practices have evolved to allow them to conduct their research.

In fact, research shows that the mechanisms that do prevent researchers

¹²¹⁰ RJ Myriad (n 1073).

¹²¹¹ Walsh 2004 (n 1119) 331; JP Walsh and others, 'View from the Bench: Patents and Material Transfers' (2005) 309 Science 2002 (Walsh 2005).

¹²¹² Walsh 2005 (n 1211). These results reinforce Walsh 2004, an interview based study of 70 IP lawyers, commercial researchers, university researchers, business managers, and scientists, technology transfer officers, and government and trade association personnel, found that respondents could not identify a single situation where lack of access to IP rights led to the cessation of a project. Projects were generally dropped because of pessimism about the likelihood of eventual commercial success and the size of the proposed target market.

gaining information in biomedical research are not usually patent-related.¹²¹⁴ A patent may not exist to block the research: once a research project is narrowed down to a specific project the patents considered for licensing generally decrease to 6-12 and in many cases no relevant patent exists.¹²¹⁵ Secrecy, denying access to unpublished research results and blocking access to published information, data, programming or materials is much more common.¹²¹⁶ Walsh's research shows that the existence of a patent over material has no effect on whether the material is made available to other researchers.¹²¹⁷ Better predictors are whether labs are in scientific competition with one another and whether the requested material is itself a drug.¹²¹⁸ While patents on research tools may impede research on marginal projects, important projects proceed because the parties find an accommodation. Their 'working solutions' encompass a range of legal and non-legal strategies which include licensing agreements, developing public databases, low level infringing of patents, inventing around patents, and operating under an informal research exemption.¹²¹⁹ Informal research exemptions preserve valuable links and benefits of community membership such as goodwill and sharing between researchers from all sectors. These links and benefits might be jeopardised by IP enforcement.¹²²⁰

Genetic diagnostic tests are generally developed in laboratories affiliated with

¹²¹³ Walsh 2005 (n 1211).

¹²¹⁴ Walsh 2005 (n 1211).

¹²¹⁵ Walsh 2004 (n 1119) 294; Heller & Eisenberg (1998); J Warcoin, "Intellectual Property and Development of Products in Biotechnology", paper presented at OECD Workshop on Genetic Inventions, Intellectual Property Rights and Licensing Practices, 24 January 2002, Berlin; RK Seide and JM MacLeod, "Comment on Heller and Eisenberg" (1998) ScienceOnline <<http://www.sciencemag.org/feature/data/980465/seide.shl>> accessed 15 December 2007.

¹²¹⁶ Defined as second-year or higher doctoral students and post-doctoral fellows: Walsh 2005 (n 1211).

¹²¹⁷ Walsh 2005 (n 1211). For example, 44% of geneticists in a comprehensive study of geneticists at U.S. universities admitted to participating in one of 13 forms of data withholding in the past 3 years.

¹²¹⁸ D Blumenthal and others, 'Data Withholding in Genetics and the Other Life Sciences: Prevalences and Predictors' (February 2006) 81(2) Academic Medicine 137.

¹²¹⁹ Walsh 2005 (n 1211).

¹²²⁰ Walsh 2004 (n 1119) 332.

universities, hospitals and other non-profit research institutions. 25% of researchers had reported abandoning efforts to develop a genetic diagnostic test as a result of patents. Myriad Genetics' patents on the BRCA1 and BRCA2 genes are most commonly cited.¹²²¹ A further study documents that over 30% of labs reported abandoning or not commencing attempts to develop genetic diagnostic testing for the HFE gene (for haemochromatosis) after the patent was issued.¹²²² These studies may not be completely accurate as the reduced provision of tests may have been due to decreased demand not patents¹²²³ and self-reporting may be reinforcing a 'genohype' narrative.¹²²⁴ Ultimately more research needs to be done in this area.¹²²⁵ Myriad's threatened legal action stopped testing briefly in one Canadian province, but had no effect otherwise on the provision of genetic diagnostic tests in Canada, similar to what happened in France, Australia and New Zealand. Eventually the legal dispute faded with little reform of law.

2 Conclusions

The Myriad case-study has demonstrated, albeit briefly, some of the conclusions of the thesis that a contextual, embedded study of innovation in medical communities allows a full appreciation of the potential of legal reform. The case-study demonstrated that Myriad's actions catalyzed concerns about new genetic

¹²²¹ MK Cho and others, 'Effects of Patents and Licenses on the Provision of Clinical Genetic Testing Services' (2003) 5(1) *J Molecular Diagnostics* 3.

¹²²² J Merz and others, 'Diagnostic Testing Fails the Test' (2002) (Feb 2002) 415 *Nature* 577: Two thirds of those laboratories were affiliated with non-profits. 22 of the 36 labs reported that patents were the reason the tests had stopped, while another 10 said that patents were one of the reasons.

¹²²³ Merz (n 1222) 579.

¹²²⁴ T Caulfield, 'Underwhelmed: Hyperbole, Regulatory Policy and the Genetic Revolution' (2000) 45 *McGill LJ* 437.

¹²²⁵ Caulfield and others (n 1116).

technologies. The parties appealed to formal law mechanisms, seeking resolution and to secure their position in a new technological landscape, although the formal law barely responded. In fact, many of the problems predicted by Myriad's opponents were not realised. In particular, genetic diagnostic testing and research into breast cancer continued, perhaps chilled, although the extent of this is unclear. Practices, institutions and norms regulated the conflict and the formal law had little role to play. Many of the representations, claims and proposed solutions mirror those raised over the three-quarters of a century of debate that led to a formal MME. Ultimately patent law could be a better partner to the informal norms with which it is locked in a perpetual dance.

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