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Preserving the Patent Paradox – Post-grant Balance and the Link Between Access and Ethics in Biotechnology

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Summary

Responses to contradictory objections to biotechnology patents have in the main been applied through validity requirements and exclusions to patentability, largely with reference to morality provisions at the time of grant. This is not appropriate because the legitimacy of each issue depends upon its expression at different stages within an innovation time line. This thesis examines, with reference to three case studies, defects in the current approach of European Patent law, which arise in part due to confusion in (or fusion of) objections to inventions as opposed to exploitation. The conclusion suggests that it is not the grant of patents per se that causes difficulties but rather the way in which inventions are exploited and patent law should be focused accordingly.

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Contents

Acknowledgements

This thesis is dedicated to my wife my mother and my three daughters. I have no doubt that the world is a better place because of them.

A thesis emphasising the importance of the protection of our genetic inheritance should acknowledge what we are made of, how we come to be what we are and the contributors to that complex process. I therefore thank my ancestry and those people that I have met and who have influenced the way I am and for the qualities that have helped me stay the course.

This work would never have begun without opportunity and I am greatly indebted to Professor Graeme Laurie for giving that to me. From the outset I felt that I had a need to embark upon this task and it has been a privilege to be able to do so under his supervision and within Edinburgh University. Every long and detailed research project must build and rely upon the work of others and I am therefore thankful and beholden to the authors who have enriched legal literature over the years. In particular I gratefully acknowledge that my understanding of morality, patent law and regulation has been nurtured and enhanced through the work of; inter alia, Beyleveld D and Brownsword R, Laurie L, Warren-Jones A, Mills O, Cornish W, Straus, Sterckx S, Drahos, Grubb P, Dutfield G, Overwalle G.

Research of the kind undertaken herein involves a long and oftentimes solitary journey but this for me has been eased by my three daughters, Nina, Verity and Isla each of which have contributed beneficially to my overall morale through lifting my heart in the way that only daughters can do to their fathers.

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and single minded person I am ever likely to meet. Without his encouragement I would never have begun this journey nor come near to completing. Rather more abstractly gratitude must go to Ernest Michaux and Ernest Colnago.

John Young

Abstract

The role of morality within patent law requires re-evaluation. The ambit of the morality clause has swollen to the extent that it is creating tension between patent law and the regulation of science with the result that it is usurping the role of regulation and conflicting with its aims. This expansion of a priori exclusions is unwelcome because it has manifested without due consideration of the causes of moral concern and the effect of patent exclusions. This thesis examines the relationship between patent law and other regulations so as to establish boundaries for the exclusion of inventions from patentability.

Biotechnology raises numerous difficult ethical questions which are not answerable by one specific 'biotechnology law' but instead there is a myriad of disparate legislation of which patent law is increasingly becoming an important component. The extent to which patent law can usefully play a part in this regulation is not yet settled, so this work seeks to discover what is possible for patent law to achieve and what ought to be dealt with by other means.

This thesis is divided into six chapters, as follows:

- Chapter one - introduction
- Chapter two examines the stages of influence of patent law through a hypothetical innovation time line and how the aims and justifications of patent law are realised within that time line. Patent law is effective only in the event

of achieving a paradox of decreasing access in order to increase access, and the section finishes with an outline of the difficulties that arise when a paradox is not achieved.

- Chapter three looks at the changes to patent law brought about by the patenting of biotechnology-related inventions. Difficulties of access explored in section one are potentially exacerbated and moral concerns become important.
- Chapter four illustrates how exclusions to patent law for moral reasons have expanded, giving rise to the 'new' patent law from traditional patent law.
- Chapter five explores regulation theory and patent law from both traditional and new perspectives. The section aims at understanding how 'new' patent questions can be addressed at different stages of the innovation time line. By way of illustration three case studies are used; the exploitation of human embryonic stem cells, the requirement for consent for the removal and exploitation of human material, and specific examples of breakdown in the patent paradox. The case studies illustrate the limitations of the current approach and this section looks at some alternatives to address the concerns raised.
- Chapter six concludes that the temptation to object to innovation through patent law should be resisted. Instead emphasis should be placed upon the effect that the grant of a patent has and not what particular inventions do or how they are created. This may call into question the methodology or the effect of exploitation of patented inventions and suggests a continuous role for morality after the grant rather than an on/off switch at the time of grant.

(1) Chapter One - Introduction

The purpose of this thesis is to ask whether there is a legitimate role for the a priori exclusion of patents or restriction of patent monopoly for moral reasons within patent law. The study will, inter alia, untangle objections to patents for biotechnology-related inventions and suggest achievable solutions to those objections which are consequent upon the grant of patents and relevant to the aim of patent law. It will do so through separating objections to the grant of patents into different stages within an innovation time line. Those aims should not be thwarted by issues, however important, that lie outside the remit of patent law. The conclusion indicates that focus should move away from the current trend of reacting to expanding objections on the grounds of morality towards control of patents after they have been granted.

Patent law has been challenged by many new issues raised by the activities of the bioscience industry which has sought patents for inventions ranging from DNA sequences to stem cells. Relevant law has risen to the challenge by methods of imaginative interpretation that have been extremely accommodating. Other possible methods of protection, such as trade secrets[1] or copyright[2], could be used, but these may not be as attractive to the bioscience industry and/or policy makers as patents, and so have not been adopted. Therefore there have been increasing demands for patent

[1] '...but patent protection is not the only such tool: other mechanisms exist to ensure exclusivity in an effort to secure market share', A Warren-Jones, 'Patenting DNA: A lot of controversy over a little intangibility', (2004) 12 Medical Law Review 97, 98.

[2] See Laddie, Prescott and Vitoria, '*The Modern Law of Copyright and Designs*' (2nd edition Butterworths, London 2000) Volume 1, paragraph 21.9, 'Could copyright be a solution?'.

protection to be extended to biotech products and processes. Much of the tension within patent law has been caused by the previously rarely-used morality clause which has been interpreted to take account of pressures from 'alternative voices'[3]. The result of this has been not only to increase the size of the arena in which patent law operates, but to place it in a different arena altogether. Traditionally patent law relates to encouraging innovation but new pressures have enabled wider questions of science and ethics to enter into the patenting process.

Patent law regulations govern the grant of monopoly rights over inventions. It is not necessary when considering the patentability of an invention to assess what it physically is (as long as it is an 'invention'[4]) or how it was made or what has been done with it. A patent is clearly a separate entity from the invention it protects and can be sold, licensed and mortgaged without affecting the invention in any way. It is detached and independent from the invention that it protects and often it will be under different ownership: '...patents can be sold or licensed even before a product based on the invention has been developed'[5][6]. A patent over invention 'X' is a singular concept but at the same time 'X' is likely to be numerous and to be owned by separate entities. Grants of patents create intangible rights whereas inventions are tangible property.

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[3] G Dutfield, '*Intellectual Property Rights and the Life Science Industries: A Twentieth-Century History*' (Ashgate, Aldershot 2002) 210.

[4] There is no definition of what amounts to an 'invention' within UK patent rules. Instead the law describes what is patentable, i.e. that an invention must be novel, involve inventive step and be capable of industrial application.

[5] G Dutfield, 'DNA Patenting: Implications for public health research' (2006) 84(5) .Bulletin of the World Health Organization, page 388-392, at page 388.

[6] See also S 30 (1) United Kingdom Patents Act 1977, " Any patent or application for a patent is personal property (without being a thing in action), and any patent or any such application and rights in or under it may be transferred, created or granted in accordance with subsections (2) to (7) below." These include, according to S30 (2) assigned or mortgaged, S30 (3) vest as any other personal property and by an assent of personal representatives, S30 (3) licence or sub-licence.

This distinction between the abstract right and the physical invention is fundamental at all stages of patent law.

Although these clearly defined entities are governed distinctly, issues have arisen that are relevant to both inventions per se and patents, and, as we shall see, are appearing in the patent grant process within Europe. The similarity of issues may account for a failure to distinguish between problems and solutions that should be outside patent law and those that are quite correctly answered within it. Distinguishing between issues will form part of the untangling process noted above. The thesis will argue that increasingly patent law, mainly through use of the morality provisions[7] to remove otherwise qualifying inventions from patent protection[8], is deployed in attempts to regulate the science and not the monopoly.

The patent system is intended to balance public interests through publication and enforcement of patents whilst at the same time encouraging increased growth through providing incentives to private interests in the form of a monopoly. In some cases a balance is not achieved so the thesis examines ways to redress the balance through greater post-grant control of the methodology of exploitation.

This thesis supports the control of patent monopoly. It will examine the ethical and economic pressures exerted upon patent law by biotechnological patents and will use

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[7] See Chapter four below and Biotechnology Directive Article 6

[8] The requirements of novelty, inventive step and industrial application (see chapter two) as applied to biotechnology innovation (see chapter three) have helped to shape the way in which the biotech industry has developed and how the protects valuable innovation. The thesis is more concerned with those inventions which may qualify for patentability but are opposed because of objections to the specific inventions rather than their failure to qualify for patentability.

a regulation theory perspective to establish how those pressures can best be managed or regulated. Its conclusion favours post-grant regulation rather than continuation of expansion of the current grant-stage influences, being primarily the morality provisions introduced into a number of patent systems. It will be argued that attempts to adapt patent law in response to repercussions of granting patents over biotechnology inventions through a simple on/off switch at the time of patent grant are insufficient when confronted by the increasingly complex, important and contentious but sometimes extraneous issues that are raised by inventions derived from human biology. It will be argued that a post-grant mechanism of regulation will provide for a more flexible and effective legal tool in hard cases.

The focus will be upon biotechnology patenting and the ethical rules that govern biotechnology research. This focus is maintained because the particular characteristics of biotechnology, combined with critical pressures, have led, inter alia, to much debate over the legal and ethical rules governing biotechnology spilling into the patent arena. The result has been that patent decisions are increasingly being influenced by ethical and legal questions in science, causing real and potential unforeseen knock-on effects from patent decisions. This may be because patent law has an increasingly broad role to play, so the thesis will examine whether, and or when, this is desirable.

Patent law is distinct from the ethical and legal regulations that operate within the realm of scientific research. Although patent law and the rules that govern the conduct of research in science have some similar interests, the aims of both are at times also contradictory. One enduring feature of patent law is the continuing balance of interests

by patent offices, courts and the legislature[9]. Some of the objections to biotechnology patenting, often reflected in the balance of decisions, can be met at different stages in the patent process, with varied effectiveness. So it is necessary to examine pre- and post-grant options to objections to patenting to assess efficacy and to suggest that a reassessment of post-grant controls could help address the patent balance in difficult cases.

(1) (a) Methodology

Objections to the application of patent law to biotechnological invention can be classified into two types. The first relates to patents hindering research and decreasing **access** to health care and the second relates to **ethical** objections to biotechnology. There are clear distinguishing features between the two but they are connected by an ethical dilemma in the granting of patents: access must be restricted against some in favour of others. In some circumstances this can be unethical.

Two objectives must be satisfied before a conclusion can be reached upon the role for patent law in exclusion of particular inventions from patentability; first a full appreciation of objections against patents and/or inventions, and second an understanding of how patent law can address them. The thesis therefore begins with a study of patent theory followed by an examination of how patent law has adapted to biotechnology and the impact that biotechnology has had upon patent law. In

[9] This balance of interests will be discussed in greater detail in section one, covering the nature of patent law. Suffice for now to indicate that there is a vast array of different interests, from the inventor, investors and business to the public, competitors and consumers, which can be affected by the patent system and the variety of interests, are, as we shall see, increasing.

particular, the work will look at how objections to biotechnology concerning access and the patenting of biotech inventions have been addressed in patent law.

Chapter four examines the morality provisions within European patent law and the extended use to which they have been put. It is understandable that concerns regarding inventions are being addressed, but the way in which they are being addressed will be questioned. In particular, it is important to note and to understand that ethical objections to biotechnology occur at different stages within the innovation process, yet the only remedy that patent law can provide is to refuse to grant patents at one specific point in an innovation process. In many cases this fails to address the core ethical issues at hand.

Chapter five questions whether, or to what extent, the objections discussed in the previous two sections can be addressed within patent law. This involves a number of tasks:

(1) An examination of regulation theory and how patent law offers different forms of regulation at different times within the innovation process.

(2) Case studies (two concerning pre-grant consent/specific exclusions and a third concerning post-grant restriction on access) to illustrate the different times and different regulation.

(3) Using the results of (1) and (2) to understand what patent law can achieve.

The way objections have been dealt with to date suggests that patent law should take a broader roll in regulation. The conclusion argues that, if this is so, it cannot be

approached in the way that patent law is set up at present but that it would be possible with a different emphasis. Specifically, patent law could take account of objections before grant, at the time of grant and post-grant; thus distinguishing objections to science from objections to exploitation of the science and from objections as to how the results are exploited. Only in this way could full effect be given to the range of objections which have been raised against biotechnological inventions on the grounds of "immorality".

(1) (b) Limitations

In this thesis, I do not intend to review the arguments for and against biotechnology and the patenting of biotechnological inventions[10] nor to look in detail at the various alternatives. The aim is to understand how objections to biotechnology can be addressed by patent law. I will argue that biotechnology is beneficial, that it should be encouraged and that patenting is the best way to do this, but it does not follow that other methods[11] and their advantages should be ignored. I am aware that there are alternatives to the legal protection of genetic inventions such as 'utility patents'[12], copyrights or separate sui generis regimes that may have advantages over patent

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[10] For a discussion of the arguments for and against patenting, see, inter alia: George Monboit, '*The age of consent: A manifesto for a new world order* (Flamingo 2003). Monboit's argument is that developing countries should ignore patent rules in order to develop because this is what the developing countries did. See also 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 Press 2004). For a general discussion of the justifications of patenting see, inter alia, T Cook, '*A User's Guide to Patents*' (Butterworths, London 2002) part 1 chapter 1; Sven JR Bostyn, '*Enabling Biotechnological Inventions in Europe and the United States: A study of the patentability of proteins and DNA sequences with special emphasis on the disclosure requirement*' (European Patent Office 2001); Gowers Review of Intellectual Property (HMSO, London, December 2006). For specific arguments for and against the justification for patents and biotechnology see, inter alia, Nuffield Council on Bioethics, 'The ethics of patenting DNA. A discussion paper' (July 2002); Sven JR Bostyn, 'Patenting Human Genes and Stem Cells, A Report to the Danish Council of Ethics' (2004); Sven JR Bostyn, 'Patenting DNA Sequences (polynucleotides) and Scope of Protection in the European Union, an evaluation. Background Study for the European Commission within the Framework of the Expert Group on Biotechnological Inventions', European Commission, 2004, EUR 21122.

[11] One such alternative method of protection for DNA was through copyright. Indeed in some ways the nature of DNA is quite suitable for this with its strings of unique combinations of A, G, T and C. An interesting comparison was made by Sir John Sulston: 'The essence of a gene is the information – the sequence – and copying it into another format makes no difference. It is as though I took a hardback book that you had written, published it in paperback, and called it mine…' (J Sulston and G Ferry, '*The Common Thread: A Story of Science, Ethics and the Human Genome*' (Bantam Press, 2002) 268. The theory did obtain some judicial support; see Laddie, Prescott and Vitoria, '*The Modern Law of Copyright and Designs*', vol.1, ch. 21. Another alternative would be to provide a sui generis regime for human biotechnology in the way that separate rules were drafted in respect of plant life or indeed industrial designs, thus specific rules could cater for the new challenges that are presented. Another possible alternative is more government funding for research and development so as to avoid the need to raise money through venture capitalists or to provide for a series of prizes, as suggested by Professor Joseph Stiglitz of Columbia University 'A Better Way to Crack it' (New Scientist, 16 September 2006, page 20).

[12] The utility patent model involves a second layer of patent protection whereby a cheaper and shorter form of patent could be obtained in 'fast' industries; similar systems operate in Finland and Denmark.

protection. However founding new rights can create further difficulties such as generating complex interactions between these new rights and existing rights, thereby creating new layers of bureaucracy with litigation risks and increased expense and which are, in any event, unlikely to be adopted in the UK[13]. Such novel extensions of intellectual property law are not contemplated by this work.

I am also aware that strong arguments against any forms of legal protection have been raised. Arguments against biotechnological patents are often submitted with weight, not only by pressure groups[14], but also by governments[15] and motivated by biodiversity, ethical or religious interests. This is not surprising as '...new technologies such as....genetics require IP protection but do not fit easily into existing categories'[16]. This is in part due to narrowing of differences between invention and discovery[17].

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[13] Such novel extensions of intellectual property are not contemplated in this thesis but see Gowers Review, paragraphs 4.109–113, 'Clarify the UK position on New Rights'.

[14] Greenpeace and the Green Party, and some religious groups, such as the Church of Scotland, have strongly opposed what they claim to be patents over life. See also work by Human Genetics Alert (www.hgalert.org), and Genewatch UK (www.genewatch.org). Strong arguments against the patenting of biotechnological invention have been made by 'open science' groups: see The Royal Society, 'Keeping Science Open: The effects of intellectual property on the conduct of science' (London, April 2003) and Joly, Yann, 'Open Source Approaches in Biotechnology: Utopia Revisited'. Maine Law Review, Vol. 59, No. 2, p. 386, 2007 Available at SSRN: http://ssrn.com/abstract=943011. See also Sulston and Ferry, The *'Common Thread'*. In the public 'race' to sequence the human genome between Craig Venter and Sir John Sulston, the latter strongly supporting open source.

[15] Developing countries have criticised patents over pharmaceuticals and biotechnology, partly because of the expense of paying for patented drugs but also because of criticism of patenting something which may have originated within their boundaries but which has been isolated and copied outside at their expense and loss. A good summary of these arguments can be found in Médecins Sans Frontières, 'Drug patents under the spotlight: Sharing practical knowledge about pharmaceutical patents' (June 2004). See also Commission on Intellectual Property Rights, 'Integrating Intellectual Property Rights and Development Policy', Report (London September 2002) (CIPR Report 2002), and the UK government's response, available from www.dfid.gov.uk.

[16] Gowers Review, paragraph 2.16.

[17] The difference between biological material amounting to a discovery that is not patentable and inventions that may be patentable is that the latter must be '...isolated from its natural environment or produced by means of a technical process...' (Article 3 of Directive 98/44 of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions (hereafter, 'Biotechnology Directive'). This is an artificial distinction to some.

Nevertheless it does seem that patenting of biological inventions is here to stay, so the practical reality is reflected in this work.

Discussions concerning biotechnology patenting are multidisciplinary, involving science, ethics and social science as well as law. Each of these disciplines will have diverse attitudes and language for particular problems:

> ... [p]articipants in the debate simply speak different languages. The languages of science, of commerce, of ethics, of ecology, of law are foreign to each other; each can hardly understand what the other is saying, let alone why they should be saying it.[18]

These linguistic and disciplinary factions complicate this area of law. Scientists assess an early embryo as a mere ball of cells, religious scholars argue that there is more to our early origins than simple cell structures, social scientists query whether or not embryos should have rights, and lawyers seek to define, in the form of clear rules, what is permitted and how that should be carried out.

This is a thesis in Law that does not attempt to reconcile the different perspectives of these disciplines, but the area of genetics is fraught with complex problems which the law cannot ignore. This work attempts to reflect this reality and identifies with policy makers who have to account for disparate interpretations and prejudices

[18] J Black, 'Regulation as facilitation: Negotiating the genetic revolution' in R Brownsword, WR Cornish and M Llewelyn (eds), '*Law and Human Genetics: Regulating a Revolution*' (Hart 1998) 29-68 at page 68.

relating to complex and ethically difficult areas to reflect and weigh concerns and to enable progress. The overall challenge is whether diverse views can be realistically incorporated.

This thesis will proceed on the assumption that patent law and patents over biotechnology, and stem cells in particular, are desirable for the progress of science. This stance cannot be supported by empirical evidence and thus is made in the knowledge that full justification may not be possible. It should therefore be appreciated that in order to discuss the topic of the thesis, the effect of exclusion from patentability, certain assumptions must be accepted. If the proposition was that patent law has a negative effect on technology or that biotechnology should not be patented then the discussion would be very different. Recognising that opposing arguments exist,[19] does not detract from the conclusion that this is a reasonable view to adopt[20] and it is a view that receives support. According to Sven Bostyn: 'That the patent system has positive effects on innovation is not the subject of much debate'[21]. He comments further:

> There is no doubt that the patent system has proved its value for technological developments, and as a means to find the financial resources to make them.

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[19] There is no certain proof of the effectiveness of patenting. Whilst there is empirical evidence to support the importance of patents to industry, there are also empirical studies that have 'found little evidence to support the view that there would be more and better public health-orientated research without DNA patenting' (Dutfield, 'DNA Patenting: Implications for public health research', Bulletin of the World Health Organisation, May 2006 84 (5) p.389). More on this later, but what is good for industry may not necessarily have a correlative positive effect on public benefit – and after all that is the ultimate aim of the patent system. See also Monboit. The age of consent.

[20] See also chapter two below.

[21] SJR Bostyn, 'DNA Patents in Europe: Controversy Remains' in The Danish Council of Ethics, The Ethics of Patenting Human Genes and Stem Cells, Conference Report and Summaries (University of Copenhagen, 28 September 2004) 27. Available from <http://etisk.inforce.dk/sw475.asp>.

> The patent system has also had an enormously stimulating effect on the development of medicaments and more generally for cures for diseases. [22]

Furthermore reports into the patenting of biotechnological inventions almost invariably proceed on the basis that patents are necessary for innovation and, despite the particular characteristics of biotechnology patents, are necessary for the biotech industry. This can be seen in the OECD Report, 'Patent and Innovation' (2004)[23], Article 16 of the European Commission Reports of 2002[24] and 2005[25], and the Gowers Review of Intellectual Property (2006)[26]. The pertinent issue that arises from the reports is not whether biotechnological inventions should be patented but how should their complex and competing interests be balanced at each stage of the patent process. Andrew Gowers comments, in the foreword to his 2006 report: 'I do not think the system is in need of radical overhaul. However, taking a holistic view of the system, I believe there is scope for reform to serve better the interests of consumers and industry alike'[27]. He goes on to refer to the importance of balance and ends by stating: 'Getting the balance right is vital to driving innovation, securing investment

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[22] Bostyn, '*Patenting DNA Sequences (polynucleotides) and Scope of Protection in the European Union*', 126.

[23] 'Patents play an increasingly important role in innovation and economic performance...the patent system has been instrumental in the recent waves of innovation which have occurred in the fields of biotechnology and ICT' (OECD, 'Patents and Innovation: Trends and Policy Challenges' (2004) 5 and 8).

[24] Report from the Commission to the Council and the European Parliament, 'Development and implications of patent law in the field of biotechnology and genetic engineering' Brussels, 7 October 2002, COM (2002) 545 final.

[25] Report from the Commission to the Council and the European Parliament, 'Development and implications of patent law in the field of biotechnology and genetic engineering', Brussels 14 July 2005, COM (2005) 312 final.

[26] 'In the modern world, knowledge capital, more than physical capital, drives the UK economy. Against the backdrop of the increasing importance of ideas, IP rights, which protect their value, are more vital than ever.' Gowers Review, Foreword.

[27] Gowers Review, page 1.

and stimulating competition'[28]. Balance is also a recurring theme throughout Sven Bostyn's[29] report for the European Commission which ends with the recommendation: '...the practice of the EPO, and the current patent system, are capable of providing solutions for most of the problems that were discussed in this report'. Bostyn also mentions that '...there are a number of unclarities[30] which require further analysis or clarification, with a view to make the system even more balanced...'[31]. Weaknesses have also been highlighted in other reports. The OECD[32], for example, stated: 'This strengthening of the patent system in European Union, Japan and the United States has, however, raised new concerns and exacerbated old ones'.

Concerns mentioned include hampering the 'diffusion of knowledge', concern over '...access to basic technologies and research tools...' and Bostyn's European Commission report[33] mentions uncertainty with compulsory licensing, blocking effects of patents on further research and patent pools.

The practice of patenting biotechnological inventions has created an industry reliant upon patents to encourage the raising of finance and creation of income[34].

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[28] Ibid.

[29] Bostyn, '*Patenting DNA sequences (polynucleotides) and scope of protection in the European Union*', 137.

[30] These include research exemption, patent and royalty stacking, patent pools which are discussed in more detail later.

[31] Supra note 26 at page 137.

[32] OECD, 'Patents and Innovation: Trends and Policy Challenges'.

[33] Supra note 26 at page 137.

[34] Several studies into the importance of patents for different industries have taken place. See note 5 above, but in the case of the pharmaceutical industry the potential for patent grant is rated by the industry as very important and the biotechnology industry has evolved around a culture of patenting to the extent that it could almost be claimed to be industry dependent. Patents have had such an effect on

Biotechnology is a capital intensive research industry but its results are easily reproduced or copied. Legal protection therefore is essential and so the biotechnology industry is particularly suited to and has become reliant upon the use of patents. This underpinning of the modern patent system is not a subject for contention herein but leaves open the opportunity to discuss how the operation of the patent system can be improved.

It is logical, with these points in mind, to examine areas of the patent system that are placed under stress and thereby open to criticism. Potential for rational questioning arises in the absence of means to react when criticisms metamorphose into attacks on the patent system per se when the sources of the criticisms are the real problems. In other words, the argument is that, rather than submitting that X should not be patented, the fact is that X can be patented but with limitations or means to provide redress to correct any imbalance.

The award of a patent need not always be commensurate with the contribution, for this would be impossible to achieve. Further the '...size of the monopoly profits earned under patent protection is not at all correlated with the efforts, capital funds, or sacrifices invested in the inventive work'[35]. So to quote the Gowers Review of Intellectual Property, in relation to competition law: '...regulating IP markets should not extend to price regulation: patents are exclusive rights which enable owners to

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the biotechnology industry that they have changed the way in which early stage inventions are brought on and how the science has developed. More on this topic later.

[35] Bostyn, *Enabling Biotechnological Inventions in Europe and the United States*, 34.

charge monopoly prices'. Patents should encourage, promote, provide and correctly balance opportunities in ways that do not inhibit beneficial objectives.

This work centres upon objections to biotechnology patents because the particular characteristics thereof emphasise the tensions within patent law as noted by the Royal Society:

> The area in which debate about excluded subject matter has been the most vigorous is the biosciences. The patenting of life forms and human tissue not only raises practical and, at least in some people's eyes, moral questions but also has the potential to impact upon the conduct of basic science. Yet nowhere is the debate more critical.[36]

However the same dilemmas are relevant to any form of inventive activity promoted through the patent system, in particular within new industries such as biotechnology or nanotechnology, where there are moral concerns with reference to inventions and where embryonic industries produce early stage innovation with potentially broad reaching patents. So although the thesis is primarily concerned with biotechnology it is not suggested that similar issues will not arise or be relevant for other areas of technology, just that biotechnology has highlighted the relevant concerns.

This study is concerned with European Patent Law although many of the issues discussed are relevant to the provision of patent protection in general in other

[36] The Royal Society, 'Keeping Science open'.

countries. European Patent Law is unique because moral[37] exclusions of patentability are decided in the absence of an accepted European moral standard, and this centralised European interpretation is affecting areas of innovation policy[38] within Member States. Thus the study provides a window through which to observe the interaction between regulatory systems and also, from a point of European political policy, to illustrate tensions between the European Patent Office and the practices of National States.

[37] Many jurisdictions allow patents to be excluded for moral reasons, such as in Europe and Japan, whilst others, including the United States, have no specific provision. The United States did take moral concerns into account if an invention was "...frivolous or injurious to the well-being, good policy, or sound morals of a society" Lowell v Lewis, 15 (a. 1018 No. 8568) (C.D. mass.1817)

[38] This is examined in chapter four and five and reflects the tension between countries which adopt a facilitative regulatory regime towards controversial innovation but incentive to carry out such research is thwarted centrally. The case of human embryonic stem cells below is such an example.

(1) (c) Grounds of Objection

It is important to examine the criticisms against biotech patenting and to assess how patent law is facing up to them. Opposition to the patenting of biotechnology falls into several categories ranging from objections to the science of biotechnology per se[39] to objections over the commodification of natural elements. These have been aired with the European Patent Office[40] and in opposition to the Biotechnology Directive[41]. These sorts of objections, although aimed at the patent system, can be out of kilter in that they can be contradictory and are sometimes confused and/or are misdirected. They relate in the main to ethical concerns about inventions although allegations have also been made that patenting unnecessarily restricts access without commensurate return. Rebuttals to the various objections can be put within and out-with patent rules and there is a need to assess how objections can best be met.

This work will untangle objections that have been made against the patenting of biotechnology and interpret them through understanding what a patent is, what it does and whether the objections can be answered by adapting patent law. The diverse objections arise in two categories; there are those that object to biotechnology as such and see patent law as a method to promote biotechnology, and those that are concerned that the commodification of limited resources restricts scientific progress. These distil

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[39] There is a fine dividing line between objecting to the science of an invention and objecting to its promotion through the patent system, and this will be discussed in due course.

[40] See cases such as *HARVARD/ ONCO-mouse* [1991] EPOR 525, *HOWARD FLOREY/Relaxin* [1995] EPOR 541, *PLANT GENETIC SYSTEMS/Glutamine Synthetase Inhibitors* [1995] EPOR 4, *NOVARTIS/Transgenic Plant* [2000] EPOR 303. See also below at section three for a fuller discussion

[41] Case C-377/98, *Kingdom of the Netherlands v European Parliament and the Council of the European Union*, 2001 ECR I-7079, especially the opinion of Advocate-General Jacobs, 14 June 2001.

into two extremes; the first opposes patents on biotechnology because patents encourage bioscience research[42] and the second because patents are deemed to stifle research in the biotechnological industry.

These grounds of opposition are not entirely incompatible nor are they mutually exclusive. One is an ethical issue, that biotechnology per se or its techniques, for example the use of embryos, is wrong and should not be encouraged by the provision of patent incentives – the classic uncompromising dogmatic that sees no shades of grey, only black or white. The second is an access issue[43] that alleges that biotechnology patents restrict the dissemination of information thereby hampering innovation and that they do not fulfil the objectives of patent law; it being related to the rights that a patent provides and how those rights affect research. Both arguments have validity but they are relevant at different stages of the patent process; the first at the grant stage and the second at the enforcement or validity stage. These two categories of opposition should be distinguished, the first is a paradox and the second questions the role of patent law within public policy.

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[42] There are some interesting statistics that support these 'for and against' positions. There had been 10,547 applications for patents for genetic engineering subject matter to the European Patent Office by 2006 (DTI Report, below). A simple search for 'DNA' at esp@cenet <http://gb.espacenet.com/search97cgi/s97_cgi.exe?Action=FormGen&Template=gb/en/quick.hts> produced 76,047 results on 9 August 2006. On the other hand, in support of stronger patent rights: 'It is worth bearing in mind that to date no UK court has upheld a biotech related patent' (Intellectual Property Institute, 'Patents for Genetic Sequences: The Competitiveness of Current UK Law and Practice. A study by the Intellectual Property Institute (IPI) on behalf of the DTI' (May 2004) 78, available from <www.dti.gov.uk>).

[43] This could also be an ethical issue as the 'right' thing to do is to share. As will be shown later there is a crossover between access, ethics and economics.

(1) (d) The Patent Paradox

A patent provides the patentee with a monopoly, usually for 20 years[44], that restricts others from making, disposing of, offering to dispose of, using or importing patented inventions[45]. It seems paradoxical to enable patent holders to block competition and thereby to restrict public access through the patent system; the purpose of which is to increase access: 'We limit access to innovative products now, to enhance incentive to innovate and commercialise new products, in respect of which access will also be limited'[46].

A monopoly situation arises when '...a firm or individual produces and sells the entire output of some commodity'[47]. The obvious consequence is that the monopolist can control the supply of the commodity to the level that maximises his profit and he will rarely choose other options such as allowing an optimum level of distribution to benefit the public or anyone else. This conflicts with open competition where demand and supply determine efficient and economic levels of price and quantity. A

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[44] See s. 60 Patents Act 1977 (UK). Although patent law allows for protection of 20 years, many patents do not survive for their full term. This may be for many reasons; there may be no economic reason to continue to pay for the patent fees, for example where the invention is no longer in demand. This often occurs in 'fast' industries where the rate of progress is swift, such as in the computer industry. A report by Science and Technology Policy Research at the University of Sussex suggested that the main reasons for abandoning granted patents were; lack of business, cost cutting and the scope of the claims being insufficient. See also The PATGEN Project, 'The Patenting of Human DNA: Global Trends in Public and Private Sector Activity' (Final Project Report, November 2006), Priority: FP6-2003-Lifescihealth-II, 26. In particular circumstances, patents for pharmaceuticals and agrochemicals can be extended for five years through Supplementary Protection Certificates. This is justified on the basis that there are often delays, due to safety regulations, before such inventions reach the market place (COUNCIL REGULATION (EEC) NO. 1768/92

[45] Section 60 Patents Act 1977

[46] E Cameron, 'Patents and Public Health: Principle, Politics and Paradox', Inaugural British Academy Law Lecture, Edinburgh University, 19 October 2004.

[47] G Bannock, RE Baxter and Rees, '*The Penguin Dictionary of Economics*' (2nd edition, Penguin, London, 1978) 313.

monopolist can therefore reduce supply to maintain a higher price and profits, the term for any excess being the 'monopoly profit'. There are valid economic objections to monopoly situations, not the least of which is that supply becomes artificially restricted so that a monopoly '...reduces aggregate economic welfare...'[48]. There is a moral argument that it is unfair that the monopolist should profit excessively at the expense of the public but that does not sit well with economics, which is concerned more with market efficiency. This is reflected in many areas of law including Competition Law and Articles 81 and 82 European Union Treaty.

Monopolies can however benefit the economy, for instance when higher profits encourage others into the same market resulting in increased competition and more production which increases supply thereby causing prices to fall. If others are prevented from entering the market place then monopolists can continue to restrict supply and charge monopoly prices. Monopolies can be artificially maintained with barriers to the entry of potential competitors into the marketplace and sometimes they may be acceptable; for example market barriers, regulatory barriers, natural barriers, legal barriers, intellectual property in particular patents, and so on.

Market barriers can occur when the demand for a product is so small that it would not be financially attractive for others to enter the market. Regulatory barriers, such as those within the pharmaceutical industry arise when government regulation of a specific industry creates expense to the extent that competition is discouraged. A

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[48] GJ Stigler, *'The Concise Encyclopaedia of Economics'*, available from <www.econlib.org/library/Enc/Monopoly.html> last accessed 30th December 2007

monopoly may resist market forces because set up costs are too high, as with the utility sector, or where there is government protection, such as in the postal service. Patents are special cases because patent law intentionally permits and facilitates monopolies that are seen to be ultimately for the public good. This creates the 'the patent paradox'.

The patent paradox - using early restriction of access to increase late access - can be seen in some of the arguments[49] used to support patent law as it has developed until now:

1. Incentives encourage more inventions, many of which will eventually benefit an increasing number of people;
2. Inventions become available to the public which in the absence of patent law may not have been developed;
3. Publication of patents inspires others to create alternatives thus increasing competition;
4. The hope of joining the 'band-wagon' instigates others to invent around patents to enter same market which may have the effect of increasing quality, knowledge, competition, commerce etc.;
5. Patenting encourages others to develop improvements to patented inventions which may be separately patentable in their own right;

[49] These are some of the common arguments used to support the grant of patents and can be seen in more detail in intellectual property and patent text books. See for example Cornish W R & Llewelyn D, '*Intellectual Property: Patents, Copyrights, Trademarks and Allied Rights*' (6th edition, Sweet & Maxwell, 2007) Dutfield G, '*Intellectual Property Rights and the Life Science Industries*': A Twentieth- century History (Globalisation and the Law series, Ashgate, Aldershot Hants. 2003 Cook T, '*A User's Guide to Patent's* (Butterworths, London 2002). See also Nuffield Council on Bioethics, 'The ethics of Patenting DNA, a discussion paper' July 2002

6. Patent law enables generic production after the patent expires resulting in cheaper alternatives.

It will be seen that if a patentee acts in a manner that reduces access and prohibits or inhibits the fulfilment of the paradox (i.e. restriction of access without subsequent increase in access represented by points 1–6 above) the patent system fails.

(1) (e) Stimulate or stipulate?

There is some confusion or perhaps fusion between the objections to biotechnology as a form of science and to the patenting of the inventions stemming from it. This may, in part, be due to the tendency to see promotion of inventions through patenting as having a direct correlative effect on research. This is understandable given the logic of incentive briefly outlined above but the two are different. The question (1) 'Is it acceptable to patent an invention?' requires a different set of values than (2) 'Is this an appropriate line of research?'. Also distinct is the issue as to whether it is appropriate to use the power of monopoly over research. Arguing that patents should not be granted for reasons relating to the appropriateness of research ignores many features of the nature[50] of a patent. As the potential grant of a patent is a strong incentive factor and if research is perceived to be unethical then the temptation arises to try to use patent law as a method of control or influence: remove the potential of a patent and the incentive for research goes too[51]. These questions have arisen on

[50] Chapter two below discusses the nature of a patent in more detail.

[51] There are other incentives; the wish to progress science, notoriety for doing so, the possibility of profit for being first on the market.

several occasions in commentaries and reports with the emphasis on the importance of distinguishing objections to research and objections to providing patent incentives. What the following commentaries appear to be saying is that patent law should not ask question (2). The Intellectual Property Institute in its 2003 study on behalf of the UK Department of Trade and Industry[52] summarised the issue thus:

> It will be particularly important to disentangle objections to the pursuit of any experimentation involving embryonic stem cells, where arguably the public policy decision should be left to bodies such as the Human Fertilisation and Embryology Authority which are already charged with making decisions about the legal ethical status of living tissue etc, from objections to offering the stimulus to medical research which is the objective of the patent system.

The point has been raised elsewhere too:

> ...but it is not for patent law to address that concern if the objection is to the science rather than to the grant of a monopoly right. Not only is it a matter more appropriately tackled by regulatory authorities using their entire gamut of legal tools, but the deep irony is that patent law *cannot*[53] address such a concern.[54]

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[52] WR 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', Public Health Genetics Unit, Cambridge Genetics Knowledge Park, funded by the Department of Health (UK), July 2003.

[53] This is addressed in more detail below. The refusal of a patent for a specific invention may have an influence through removal of incentive but using patent law as a method of addressing concerns regarding a particular form of inventive activity throughout an industry is flawed.

[54] G Laurie, 'Patenting Stem Cells of Human Origin' [2004] EIPR 14, 59-66, at page 64

The European Group on Ethics in Science and New Technologies noted this in their report on stem cell research in 2002:[55]

> Patent law and biomedical research regulations largely legislate the same issues, but from a different angle. Biomedical research regulations try to outline the type of research which is considered legitimate...Patent law deals with the same subject matter, but mainly focuses on the research applications and the ethical implications the exploitation[56] might entail.

...and

> There is a disturbing trend to consider patents as invalid under Article 53 (a)[57] EPC, not for anything to do with the *use* of the invention but because of what the inventor did before filing the application.[58]

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[55] European Group on Ethics in Science and New Technologies, 'Study on the Patenting of inventions related to human stem cell research', Report to the European Commission: Office for Official Publications of the European Communities, 2002.

[56] Although this quotation illustrates different questions that arise from patenting it is not strictly correct that patent law focuses on ethical implications of exploitation. The moral focus of patent law is discussed below and the thesis later makes the case that perhaps the patent system should concentrate more upon ethical implications of exploitation rather than the ethical implications of science.

[57] Article 53 (a) is the EPC version of what has become know as the 'morality clause' and states: 'European Patents should not be granted in respect of (a) inventions the publication or exploitation of which would be contrary to ordre public or morality provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the contracting states'.

[58] P W Grubb, '*Patents for Chemicals, Pharmaceuticals and Biotechnology, Fundamentals of Global Law, Practice and Strateg'y* (4th Edition, OUP 2004) 286.

These distinctions, between objections to research science and/or exploitation illustrate the time differences in which the influence of patent law is felt. The patent system creates an incentive to innovate and that incentive exists before any single patent is granted. At the time of patent grant the inventive quality of the invention is investigated and after a patent is granted the pertinent issue is the method by which the invention is exploited. Although it is possible to separate areas in respect of their position in time, pre-grant, grant, post-grant, the rules within each group have a bearing upon how balanced a patent system is and it is this important element of balance that will now be examined.

(1) (f) 'A Good Armchair'[59]

The primary function of a patent system is to encourage innovation by providing an incentive in the form of a limited, temporary monopoly over the claimed aspects of an invention and the disclosure of information that would otherwise be kept secret.[60]

> The overall goals of the patent system are to stimulate innovation for the public good and to reward people for useful new inventions....whilst at the same time promoting competition and innovation by ensuring that such inventions are fully disclosed to the public. [61]

The cost to society of providing an inventor with a reward in the form of a limited monopoly is reflected in the restriction in the use of the patented invention. This restriction is justified because it is believed that in the long run more inventions will emerge which compensate for the temporary restriction:

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[59] 'What I dream of is an art of balance, of purity and serenity devoid of troubling or depressing subject matter...a soothing, calming influence on the mind, rather like a good armchair...' (Henri Matisse 1908, '*Oxford Dictionary of Quotations*' (OUP 1999) 501:13).

[60] 'The aim has been to stimulate innovation and further technology diffusion. Besides adding the "fuel of interest to the fire of genius" the disclosure of information is the classical core of patent law.' (Jens Schovsbo, 'The ethics of patenting human genes and stem cells' (The Danish Council of Ethics, 2005) 95-101, at 95. This is a simplified description and the following section deals with the justifications and aims of patent law in more detail. In 1988 the report of the Commission to the European Council stated: 'The primary purpose of the modern patent system is to promote technical innovation as the major factor of economic growth by encouraging inventive activity through rewarding inventors for their creative efforts....Simultaneously, the patent system encourages an early and beneficial dissemination of knowledge in the field of activity involved which, without such protection, might be kept secret.' (Com(88) 496 final SYN 159, 17 October 1988; [1989] OJ C10/3 para. 11 page 6). We shall see in the following chapter that there are several theories which attempt to justify the patent system, ranging from the protection of the personal rights of the 'inventor' to disclosure of information for the greater benefit of all to creating an incentive for other inventive people to seek a method of financing research. There are differing views as to the importance of each but stimulation of innovation and distribution of information remain at the core of the patent system.

[61] Nuffield Council on Bioethics: 'The ethics of patenting DNA. A discussion paper' (July 2002), page 12, paragraph 2.3.

> On the one hand IP rights provide economic incentives to innovate, but on the other hand, the exclusive rights they confer to achieve this allow monopoly prices and associated welfare losses. So there is a trade-off between incentives on the one side and costs to consumers and limited access for follow on innovators on the other.[62]

Admittedly this oversimplifies the role of patent law because within every patent decision there are complex balances of interests to be considered. This is well summarised in *Holyoak and Torremans*:

> Clearly no one interest group can shape the patent system. If there is a single justification or common purpose that underpins the system it must be the attainment of a balance between the different interests involved.[63]

These interests include the patent applicant seeking to protect his invention and the public[64] having to pay more for a patented invention because of the existence of a patent. The public can be said to be benefiting nevertheless because it achieves access to that invention, which might not have been created in the absence of potential to profit at the earlier marketing stages in order to recoup research costs.

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[62] Gowers Review, Foreword, paragraph 3.6

[63] P. Torremans (ed.), '*Holyoak & Torremans Intellectual Property Law*' (4th Edition, Butterworths, London 2005) 41.

[64] 'The system is intended to balance the interests of the public with those of the inventors', Nuffield Council on Bioethics, ' The ethics of patenting DNA', page 12, paragraph 2.3.

Balance is a vital quality at each stage of the patent process. 'Understanding and applying patent law presumes a continuous balancing of interests...'[65] and the patent system is equipped with a number of '...checks and balances...' with which to address or achieve harmony. The issue of patent equilibrium cannot be overstated and is a recurring theme within the 2006 Gowers Review which from the start emphasises that 'It must strike the right balance...', that it must concentrate on 'improving the balance...', and that 'Getting the balance right is vital to driving innovation securing investment and stimulating competition'[66]. The factors that are weighed in the balance change throughout the innovation time line and the argument will be made that correct considerations should be given at the appropriate stages not only at the time of grant.

Achieving a balanced patent system is made all the more difficult because the life of a patent is fluid and is influenced by diverse factors at different stages. The innovation process reveals four main phases within what could be called the patent time line; incentive stage, grant, exploitation and generic competition.

(1) Incentive Stage – The effect of a patent regime begins with knowledge of the potential or availability of patent rights. Inventors have different motivations to proceed down particular roads so the part the availability of patents will play will differ from one person to another and from industry to industry[67]. Thus the

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[65] Bostyn, '*Patenting DNA Sequences (polynucleotides) and Scope of Protection in the European Union*', 125.

[66] Gowers Review, Foreword, page 1.

[67] See Ernst & Young, 'Total Value of Information' (2004) available from www.ey.com/global/content.nsf/US/Health_sciences_-_Articles_-_WEF_2004_-_Innovation_Divide Ernst & Young and Yale Levin Survey 1987, Carnegie-Mellon University survey 2000. See also OECD, 'Patents and Innovation: Trends and Policy Challenges', which includes a suggestion that the differences in characteristics of inventions could require: '...a more differentiated approach to patent protection that depends on specific characteristics of the inventions, such as their life cycle or their value (as opposed to the current uniform system)'.

importance of the availability of patent protection varies but at the very least there will be awareness of the availability of patent protection and what is excluded from it that could be decisive in taking strategic decisions. To put it another way, if patents are seen to be difficult to obtain or are not granted over particular inventions this is likely to have a bearing on the direction of research taken. The effects of excluding patents over particular inventions will be discussed later but an important issue is whether the patent system can be or should be used to influence the direction of inventive activity. Individual patent decisions within the system can have far reaching consequences within science generally and it is highly debatable whether specific cases should address the broader picture.

(2) At the application/grant stage there is an assessment of how patent criteria are formulated to achieve a balance. Reports repeatedly[68] stress the importance of applying the criteria for patentability; novelty, inventive step and commercial application/utility strictly, so as to maintain quality and balance. Certain inventions may also be excluded from patentability for reasons of morality or if considered to be contrary to ordre public. The test for this is applied at grant stage but the specific objection may relate to an event in the past or may relate to a possible event that might be objectionable in the future. The patent system is not capable, in its present form[69], of effectively addressing different moral issues which arise at each stage within the innovation time line.

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[68] Including: Nuffield Council on Bioethics, *'The ethics of patenting DNA'*, *Bostyn, 'Patenting DNA Sequences (polynucleotides) and Scope of Protection in the European Union'*, and Gowers Review.

[69] The moral issues that arise at different stages and the problems that may arise for patent law as means of addressing those issues will be examined.

(3) The patent holder profits most assuming commercial circumstances are favourable during the exploitation stage, between patent grant and the end of its validity. It is at that stage that the tension between access and exploitation is most acute. That is when competitors are encouraged to produce alternatives to patented products and/or processes or to improve upon technology that becomes available, and patent law does not normally[70] stand in the way of such activities. The extent that this is enabled depends upon the breadth of the patent – too narrow then incentive too is weak – too broad could lead to market control which could in turn hinder further research or otherwise frustrate the aims of the patent system.

(4) At end of the patent term it is open to competitors to manufacture, sell and/or distribute versions of the previously protected invention. If demand exists then in all likelihood copies will soon appear on the market in direct competition resulting in falling prices and more consumer choice. This open season is a beneficial part of the initial patent bargain. Full disclosure of the invention means that on patent expiry[71] copies can be made but the inventor has already been rewarded through the monopoly that he has enjoyed for the designated period. The length of the period, up to 20 years[72], is intended to be an appropriate length for all types of inventions so as to balance the interest of the

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[70] Patent law usually contains provisions for compulsory licences, revocation and opposition proceedings. See the UK Patents Act 1977 SS 48 – 50 regarding compulsory licences and discussion below page 65, Patents Act s 72 regarding revocation and opposition proceedings. However providing a patent is not infringed the patent system will encourage alternatives and improvements to patented inventions by allowing separate patents for such activities.

[71] Clinical trials can begin before this.

[72] The term is potentially longer for pharmaceutical, agrochemicals and pharmaceutical patents and extended protection may be granted by way of Supplementary Protection Certificates ('SPC') to compensate patentee for time lost, for up to five years, due to regulatory delay - Supplementary Protection Certificate Regulations 1992 and 1996.

> inventor and public. Thus there is a short term restriction of supply compensated for by a long term benefit of availability. The term of a patent may be limited in time but the effects are much greater, reaching from initial concept to after patent expiry.

Bostyn also points out that there are some types of innovation that may not be suited to promotion through the patent system. Even supporters of strong patent rights have some doubts about some aspects of the patent system, as Bostyn continues: 'No one will doubt that for some types of innovations, the patent system is probably not the most suited system, but that does not take away the positive effects of the system in general'[73]. He also indicates that:

> One should not refrain from pointing to features of the patent system which might give rise to objections to the system. In view of the fact that a patent provides an exclusionary right, it could be used by patent holders in a way which is not necessarily beneficial to society, but is more concentrated on the financial interests of patent holders and/or investors.[74]

These two negative points, system/invention unsuitability and abuse by patent holder, may be exceptions but they are real possibilities nevertheless.

The factors to be weighed within this balance became more complex and more numerous with the development of biotechnology. Research costs in the biotechnology

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[73] Bostyn, '*Patenting DNA Sequences (polynucleotides) and Scope of Protection in the European Union*', 126.

[74] ibid at page 126

industry are enormous but are compatible when compared to the potential benefits in, for example, health care and the specific profit for those fortunate enough to be first on the market with the particular product. Thus the traditional patent balance between incentive/cost on the one hand and availability/access on the other is further highlighted.

(1) (f) (i) Moral Balance

This complexity is not merely expressed within the traditional patent equation; it extends to morality issues which are specifically considered in, inter alia, European patent law. No longer is patent morality confined to obvious immoral inventions, such as the letter bomb, but is being directed at new and complex questions affecting embryonic life[75], slavery[76] and harm to the environment[77].

No correct answer can be given to the issues posed within the 'new' moral equation so this 'new' situation has a number of consequences. First, patent law is straying into the territory of ethics (and vice versa) that govern science as distinct from invention. There are precedents in the history of patent law that tackle a range of issues not merely the granting of a privilege. In England, for example, the prime impetus for the origins of a strong patent system was to encourage the inwards migration of engineers from abroad[78]. Similarly the Venetian State in the fifteenth century[79] began granting patent privileges partly for disclosure of invention but these '...were often not a reward for

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[75] See discussion below in chapter four, and also see Edinburgh Patent (EP 0695351).

[76] *HOWARD FLOREY/Relaxin* [1995] EPOR 541.

[77] *PLANT GENETIC SYSTEMS/ Glutamine Synthetase Inhibitors* [1995] EPOR 4.

[78] Dutfield, *'Intellectual Property Rights and the Life Science Industrie's*, 3.

[79] The first recorded patent was issued in Venice in 1474 but there also seems to have been a patent issued in Florence in 1421 and before that in ancient Greece. See GA Stobbs, (2000); *'Software patents'* [1996] Aspen Law & Business, and Grubb, *'Patents For Chemicals, Pharmaceuticals and Biotechnology'*, 10.

invention but a reward for royal supporters, and patents were granted simply so as to reward loyalty with monopoly'.[80] Despite these previous examples of the use of patent reward to control behaviour through incentive, the success of this is limited by the extent that the incentive of a patent influences those who are involved in its invention. If patent protection is prohibited for a specific subject matter, that does not prevent further invention because inventors have other methods such as secrecy to deter rivals.

Second, this ethical balance has the potential to upset the traditional patent balance. If an invention is controversial the morality of providing a patent has to be balanced against the morality of not granting it. How far do these issues of weight/balance extend? If, for example, research is ethically controversial but the potential invention promises great benefit, is it the place of patent law to address this difficult balance?

It is reasonable to assume that if the system does not balance these sorts of interests appropriately it is not working effectively, and if that is the case what reforms to patent law are appropriate? If the grant of a patent carries with it the probability of unforeseen harm or undesirable consequences, is it the role of patent law to interfere in any way[81]? Does the role extend further to influence, for instance, invention that could be harmful to the environment? Indeed could the role reach back in time into elements of research or forward to take into account and impose conditions upon how an invention is manufactured or exploited?

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[80] '*Holyoak and Torremans Intellectual Property Law,*' 38. This can be differentiated from the patent incentive in modern patent law which rewards inventiveness rather than loyalty to the Crown. It serves to illustrate that there have been other reasons behind the grant of patents. The thesis examines 'other reasons' behind the refusal of patent grants.

[81] At the time of patent grant it is debatable whether such interference is warranted but once consequences are apparent could patent law have a role to play? The final chapter explores this possibility.

Whilst it is important to appreciate the influence of a patent grant this ought not to be overstated because there are other factors relevant to assessing the success of an invention. These include the ethical and economical rules that are outside patent law[82], the effect of not granting a patent, the applicants position in the marketplace and the tactics of the applicant, competitors and consumers. These factors affect the importance of a patent in a given situation yet are not known at the material time so are not capable of being assessed in the grant-time balancing act. On the other hand, moral questions are emerging more frequently in the patent grant process and some of these are, arguably, irrelevant to patent law.

In conclusion, there are four separate time sectors within which patent rules can be changed so as to achieve a balanced decision process. Each sector has different questions and different emphasis so as to maintain the overall aim of creating an innovative environment without at the same time restricting further development. Like Matisse's armchair if the balance is achieved it is devoid of 'trouble', but there is plenty of 'trouble' lurking for biotech patents.

[82] The existence of a patent does not provide permission to use the invention and this could be limited through separate regulation such as the Human Fertilisation and Embryology Act in the UK. Competition law may prevent a patentee from abusing a dominant position.

(1) (g) A Regulatory Chameleon

Table One - Innovation Time Line and Patent Effect

	Stage 1 innovation or incentive stage	Stage 2 grant stage	Stage 3 exploitation stage	Stage 4 generic stage
The patent effect	Incentive to commence research and development distinguish between incentive to research and incentive to commercialise the results of research	Assess inventive quality – novelty/inventive step and utility – morality priority date (application) publication within 18 months – nb s. 21 applications representations by third parties Maximum. time to grant 4.5 years	Monopoly publication – encourages (a) further research (b) inventing around patent (c) compulsory licenses (d) research exemption patent pools/stacks/abuse/restrictive effects?	Open competition
Morality	Is research moral? To what extent is research influenced by individual patent decisions. is research regulated and if so should patent law adopt a variant stance if research is controversial?	What is the moral objection – research – the actual provision of incentive or to keep invention in the public domain? Each of these examples is relevant to different stages of innovation. the effect of not granting a patent is to allow competition and potentially to reduce incentive generally in similar areas of science	Is commercial exploitation immoral? Can this be anticipated at the time of grant?	An important part of the patent bargain is disclosure so as to enable reproduction after patent expiry.

The four stages of innovation process are represented in the above table and I have touched upon the balancing act required during the patent decision making process. During these four stages of the innovation process the effects of changes to patent rules will be different and will involve various regulatory strategies. For example the result of the incentive created by the potential for a patent will be seen initially within stage

one. The incentive of a patent may be different for different people within a particular development. A hypothetical inventor embarking upon research may be influenced by his area of expertise, his peers, the wish to spread knowledge and suchlike, but a venture capitalist will more likely be on the look out for commercial gain that is capable of being ring fenced through the patent system.

Stage three on the other hand relates to exploitation of inventions under protection of a patent. Incentive no longer plays a part – at least on the part of the exploiter – because he is reaping his reward. A balance must be achieved at stage three regarding the exploitation of inventions as it does over stage two over the breadth of patent granted. These different questions require different regulatory approaches in order to achieve equilibrium.

It is important to appreciate where patent law sits in each of the stages within the regulatory system in each of the stages. In other words, we need to see how it functions so as to understand the effects that changes to patent law may have upon wider issues. Focusing concerns upon granting patents is no longer appropriate and so the intention is to understand how else patent law can address those concerns of ethics and access. How can the custodians of patent law, the patent examiners, the patent agents and lawyers, the judges and the arbitrators, perform; what methodology can they adopt to help achieve equilibrium?

It is difficult to pin down the position of patent law within the regulatory structure, in part because patent law illustrates a wide variety of regulatory characteristics and also

in part, and despite this, it is atypical of what is perceived to be regulation. As Ogus has said, 'It is not a term of art, and unfortunately it has acquired a bewildering variety of meanings'[83]. This perception may arise because it is difficult to define the concept of regulation, though some have tried with differing results: '...a sustained and focused control exercised by a public agency over activities that are valued by a community' [84], and 'a specific set of commands...deliberate state influence...all forms of social control or influence...'[85], are two such examples. There does, however, appear to be agreement on the complexity of regulation both in terms of concept and execution and this complexity usually has the result that in order to understand or explain what is meant by regulation, the term is split into several categories. The categories could be in the form of their social goals, such as free market regulation[86] or collectivist regulation,[87] or they could be classed according to their purpose, for example, economic regulation[88] or social regulation[89]. Alternatively classification could be addressed according to the methodology of execution[90] as with self regulation[91],

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[83] AI Ogus, Regulation. *'Legal Form and Economic Theory'* (Hart 2004) 1.

[84] Noll R G, *'Regulatory policy and the social sciences'*. Berkeley: University of California Press, 1985:9-64.

[85] R Baldwin and M Cave, *'Understanding Regulation: Theory, Strategy and Practice'* (OUP 1999) 2.

[86] Ogus, Regulation: *'Legal Form and Economic Theory'*. In brief, the free market regulation could be characterised as having the aim of preserving the freedom to act and choose at will and regulation is necessary only insofar as it promotes that purpose. Property rights, tort, monetary systems, are examples. Thus patent law as a method of protecting property could fall within this category.

[87] Collectivist regulation could be described as interventions in free market regulation so as to achieve a goal which would not occur without intervention. Instances of market failure for example may require interference, as with competition law. Social welfare law is a good example. Patent law is aimed at correcting market failure – see below – and so could also fall into this category. As we shall see, however, patent law is not easily categorised.

[88] For example, taxation, competition law.

[89] As with health and safety law or social welfare law, town planning.

[90] See discussion in Baldwin and Cave, *'Understanding Regulation: Theory Strategy and Practice'*, chapter 4, 'Regulatory Strategies'.

[91] This can be seen in some industries such as insurance, advertising or finance. Self-regulation will be discussed in due course as will the position of patent law and self regulation but is generally

command and control regulation[92], incentive based regulation, or categorised through manner of enforcement; is action taken by the state or by individual complainant? The manner in which regulation operates varies between each category. Patent law, as we shall see, is interesting as it shows characteristics of different forms of regulation and we shall examine these in the following chapters. It is useful now to remind ourselves of the distinction between an invention and the monopoly that a patent provides. Changes to patent rules may exercise control over the monopoly but will only be able to challenge wider issues relating to an invention indirectly and in order to do so will use a different form of regulatory strategy.

A traditional or narrow view of regulation would appear to exclude patent law from discussion under that topic: 'Regulation is often thought of as an activity that restricts behaviour and prevents the occurrence of certain undesirable activities (a red light concept)'[93]. This understandably contracted initial reaction to patent law is summarised concisely by Black, 'At first glance, including intellectual property rights in a discussion of the regulation of genetic technology seems misplaced'[94]. Patent law encourages an action, it does not restrict it, but at the same time it is complex and this complexity allows patent law to provide a platform to study the various forms of regulation. The aim of this study is to support the view that patent law is a form of regulation albeit sui generis, and that a post-grant control mechanism is beneficial.

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characterised by control exerted through the individual members of a particular group taking some form of control over their own members.

[92] In other words regulation that aims at forcing a certain type of behaviour. This may be characterised by being backed by sanctions of some sort, e.g. fines or criminal penalties.

[93] Baldwin and Cave, '*Understanding Regulation: Theory Strategy and Practice*', 2.

[94] Black, 'Regulation as Facilitation: Negotiating the genetic revolution', 52.

The regulatory impact of patent law changes during the phases of a patent. Starting from the point when a patent may be an incentive to begin research through to the period after a patent has expired, we can see that there are distinct stages which offer a number of different perspectives with which to study patents. Stage one is the incentive stage where the potential for a patent creates the stimulus for research – research that may lead to stage two, the application stage, which if successful leads to a patent grant and on to stage three, the exploitation stage. After the term of a patent of 20 years[95], stage four, competition, is open to all comers with the result that cheap generic copies may appear. Patent law plays a different 'role' or at least places a different influence on each stage and these will be examined in chapter five whilst looking at patent law from a regulatory perspective.

[95] Although a patent may be granted for 20 years the average life of a patent in the United Kingdom is 10 to 11 years. Further a patent application takes on average a little less than 4½ years before being granted. The term of a patent is calculated from the date of application and so the 'exploitable time' of a patent is not as long as may be expected. The exploitable period may be reduced further if lengthy testing is required by the government which I the case of drugs and biotechnology will inevitably be the case.

	stage 1 Innovation or incentive stage	stage 2 grant stage	stage 3 exploitation stage	stage 4 generic stage
The patent effect	incentive to commence research and development distinguish between incentive to research and incentive to commercialise the results of research	assess inventive quality – novelty/inventive step and utility – morality priority date (application) publication within 18 months – nb s. 21 applications representations by third parties max. time to grant 4.5 years	monopoly publication – encourages (a) further research (b) inventing around patent (c) compulsory licenses (d) research exemption patent pools/stacks/abuse/restrictive effects?	Open competition
Morality	Is research moral? To what extent is research influenced by individual patent decisions. Is research regulated and if so should patent law adopt a variant stance if research is controversial?	What is the moral objection – research – the actual provision of incentive or to keep invention in the public domain? Each of these examples is relevant to different stages of innovation. The effect of not granting a patent is to allow competition and potentially to reduce incentive generally in similar areas of science	Is commercial exploitation immoral? Can this be anticipated at the time of grant?	An important part of the patent bargain is disclosure so as to enable reproduction after patent expiry.
Regulation	Ethical and legal rules that govern the envelope of research e.g. HFEA. Any other legal requirements – e.g. Health and safety/environmental regulations etc – consent from participants. Human Tissue Act 2004		(a) Strength of market demand (b)licensing practices (c) Competition Law	Generics still under regulations – i.e. will still have to comply with any regulatory requirements re safety etc

Table Two – Regulation and Morality

Consider, for now, how research takes place in a different time to exploitation of an invention. There may be valid objections to particular research but these may differ from objections to exploitation and or use of any invention resulting from research. For instance, country A opposes stem cell research for ethical reasons but country B does not and so proceeds to produce stem cell lines leading to treatments for various ailments and diseases. Country A will have different ethical considerations if it were either to import the treatment or stem cells produced in country B. Similarly there will be different questions about whether that particular invention should be monopolised through the patent system.

(1) (h) Conclusion

An effective patent system must balance the negative effects of granting and maintaining a monopoly with the positive effects of providing an incentive. The patent process is lengthy, and the effects of the grant of a single patent are felt in an industry before an application is made and long after a patent expires. In order to keep the various interests in harmony patent law has a variety of legal methods upon which it can draw at different stages of the patent process.

Much of the emphasis on calming the negative effects of patent grant monopoly arises when a patent is granted, yet negative effects, if any, of patent grant are not felt until after this stage[96]. Despite this there are only a limited number of resources open to confront relevant negative effects of a patent monopoly post-grant. If a balancing process is to be effective it should be assessed after the grant of a patent, which is the appropriate time to consider the stability of a decision.

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[96] Effects of refusal of patent grant are felt in stage one of a new innovation time line in similar area of science

A patent system that provides a level of protection that blocks further research is unstable in favour of patentees but on the other hand any threat to the monopoly that is provided by the grant of a patent will have repercussions as to the effectiveness of the incentive. In other words an imbalance at incentive stage may result in unequal or unfair reduction in access during post-grant stage but if access is too flexible against the patentee during post-grant then that may reflect negatively upon other innovation. The thesis first looks at patent law in general so as to understand what it is about patent law, which should encourage and promote innovation, but which can in fact do the opposite. Secondly an understanding of patent law is necessary to appreciate what steps patent law can take to address an imbalance. The following chapter examines these issues and chapter three looks at them from the perspective of biotechnology. The work will commence with the premise that the pressure that is being exerted upon patent law is likely to create a fissure somewhere in the system and will argue that this is best tackled during the exploitation of patented inventions rather than through moral equations at the times of grants.

(2) Chapter Two – Patent Law

This chapter explores patent law with particular reference to the aims of the patent system[97] and how and when those aims are achieved. A central issue is the importance of balancing varieties of interests at different times during the innovation process so as to achieve those aims and therefore justify the award of a monopoly. The chapter is divided as follows:

- (1) Describes a hypothetical innovation time line illustrating different stages of an innovation process. The aim is to apprise the reader of the part that patent law can play at each individual stage.

- (2) Examines, in more detail, the factors that may be taken into account within patent decisions when trying to obtain a balance between encouraging both information disclosure and innovation whilst at the same time addressing wider issues. The aim is to illustrate: (a) a diverse range of issues, and (b) how different issues are relevant at each stage within the innovation time line discussed in sub-section one (c) how some issues should not and cannot be addressed at particular stages.

- (3) – Looks at the aims and justification of patent law and how they are addressed at each stage of the innovation process. It is of value to appreciate that patents exert dissimilar influences upon different objectives at each stage

[97] 97 Many books on intellectual property contain a section on the development of patent law. A good description is contained in Bostyn, *'Enabling Biotechnological Inventions in Europe and the United State's.* See also Cook, *'A User's Guide to Patents'*, chapter 1; *'Holyoak & Torremans Intellectual Property Law'*, chapter 2, and WR Cornish and D Llewelyn, *'Intellectual Property: Patents, Copyrights, Trademarks and Allied Rights'* (5th edition, Sweet & Maxwell 2003) Part II, chapter 3

of an innovation process[98] – incentive during early stages and a unique form of exploitation post grant[99]. Excluding patents for moral reasons will have diverse consequences at each stage and the effect will be different depending upon when objections arise. Understanding when and how the aims of patent law are achieved will help to understand the effects of exclusion of particular inventions may have.

- (4) – Examines a breakdown in the patent paradox, (A) when further innovation could be hindered, and (B) where reward far exceeds the contribution.

This chapter is about access; how the patent system is intended to increase information flow and innovation through the provision of monopoly incentive (which can decrease access) and it illustrates the circumstances that may give rise to a potential breakdown of the patent paradox. The issue can be particularly acute in biotechnological innovation, as will be discussed in the next chapter.

[98] See innovation time line table page 48

[99] Unique in that a patent provides the holder with a limited monopoly enforceable in the courts. See discussion below pp 76-86

(2) (a) The Patent or Innovation Time line

This sub-section describes a hypothetical innovation time-line which illustrates how and at what stage the aims and justifications of patent law are realised. The time line can be separated into different stages of innovation offering the opportunity to assess how the influence or promise of patents is felt at various times in the process of innovation.

The hypothetical innovation time line shows the following processes: conception of an idea, research and development, definition of inventive concept, draft of patent, grant of patent and journey to market. The distinct stages are; pre-grant, grant, post-grant and expiry. It will be used to illustrate the following throughout the thesis:

(1) The manner in which patent law interacts in the innovation process.

(2) Objections against (a) particular inventions and (b) particular patent/monopoly, and

(3) Means available to patent law at different stages of inventive process.

Table Three – Innovation Time Line – 2nd Stage

Pre-Grant – Innovation Stage	Grant Stage	Post-grant – Exploitation Stage	End of Term – Generic competition
Conception of invention-development and research encouraged by potential of patent protection. Patent encourages the commercialisation of invention	Patent application and assessment of inventive qualities Details of invention published. Exclusions considered	Exploitation of inventions with patent protection – compare with exploitation of invention without patent protection	Trade off for patent is knowledge of how invention functions so others can copy and exploit after expiry
Inventor subject to regulations relating to health and safety, limits of controversial research, licensing	Different regulations may be relevant from research to exploitation.	(a) Strength of market demand (b)licensing practices (c) Competition Law	Generics still under regulations – i.e. will still have to comply with any regulatory requirements re safety etc

(2) (A) (I) INNOVATION STAGE

The innovation stage begins with the research and development of an invention. At this stage, according to patent theory, knowledge and access (through new invention) will be increased through encouraging development of something new thus fulfilling part one of the patent paradox[100]. The effect of the patent system, at this time, is the incentive created by the possibility of a monopoly over the invention at some later date. Meanwhile the inventor has to comply with the regulations applicable to the relevant area of research and depending upon its nature that could be complex, costly and onerous. In the event that the prospect of a patent is removed then one would anticipate that there would be an adverse effect upon innovation. The effect that would have upon development depends upon each particular industry[101], what finance is

[100] That patent law increases access and knowledge over time through enabling patentees to decrease access through patent monopoly. The incentive of the ability to use the monopoly is the first step in the paradox.

101 See Ernst & Young 'Total Value of Information' (2004) available from <www.ey.com/global/content.nsf/US/Health_sciences_-_Articles_-_WEF_2004_Innovation_Divide>.

available, whether other methods of protection[102] are available etc. In an industry reliant upon patent protection there will doubtless be a subsequent negative effect in the same way as withdrawal of funding would have a reducing effect (but not preventative altogether) upon a particular area. The withdrawal of patent incentive could have an effect, albeit not a decisive one, upon the direction of research. To use the analogy of traffic lights[103], the withdrawal of patent incentive acts as an amber light, neither stopping (red light) nor encouraging (green light) innovation, although such withdrawal could encourage scientists to carry out research in more facilitative jurisdictions.

If patents were used for that purpose it would be inconsistent if regulation outside the patent system encouraged or facilitated the same area. Further such a stance would be an indecisive and inadequate method of attempting to direct the course of innovation and would create an atmosphere of uncertainty. Nevertheless questions arise as to whether patent law has a role to play at this stage in directing research. Such a role envisages a greater connection between patent law and other regulations and also therefore greater cohesion between rules that govern inventions and those that relate to patents.

102 Trade marks or trade secrets, for example.

103 R Brownsword, 'Red lights and rogues: regulating human genetics' in H Somsen (ed), *'The Regulatory Challenge of Biotechnology: Human Genetics, Food and Patents'* (Edward Elgar 2007) 39.

(2) (A) (II) GRANT STAGE

The inventive qualities of each invention are assessed between application for and grant of patent. These tests show whether an applicant can be a member of the patent club. They provide for patent protection only over those inventions which are new[104], involve an inventive step[105] and are capable of industrial application[106]. There are a number of exclusions from patentability, for example, in the UK, Section 1 (2) of the Patents Act 1977 lists entities which are 'not regarded as inventions'[107] for the purposes of patentability. These include discoveries, mathematical methods, literary works, schemes for performing mental acts and presentation of information. These non-inventions are a mix of creations or abstracts that may already be protected by other forms of intellectual property law[108] or else be unsuitable for any protection[109].

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[104] An invention is considered to be 'new' according to s. 2(1) Patents Act 1977 (UK) 'if it does not form part of the state of the art'. The 'state of the art' is defined expansively by section 2(2) 'to comprise all matter (whether a product a process, information about either, or anything else) which has at any time before the priority date of that invention been made available to the public whether in the UK or elsewhere) by written or oral description, by use or in any other way'.

[105] '...not obvious to a person skilled in the art, having regard to any matter which forms part of the state of the art by virtue only of section 2(2)'. Section 2(3) is excluded from the definition of the state of the art. Section 2(3) includes published patent applications if the priority date is earlier than the application in question. The result of this exclusion is that obviousness does not entail taking into account patent applications that are filed but not published.

[106] '...any kind of industry, including agriculture.' (s. 4(1) Patents Act). A further interesting question arises below in relation to industrial applications. Inventions are excluded from patentability on the grounds of morality if they are for '...uses of human embryos for industrial or commercial purposes.' As there is a requirement for industrial application and uses of embryos for industrial purposes is excluded, this would exclude embryo-related inventions. If an invention does not claim such a use but has required such a use in order to be created then will that invention be precluded from protection? More on this shortly, but at what point in the inventive process is it appropriate for patent law to question?

[107] In the UK the following are 'not regarded as inventions' by s. 1 (2) Patents Act 1977: (a) a discovery, scientific theory or mathematical method; (b) a literary, dramatic, musical or artistic work or any other aesthetic creation whatsoever; (c) a scheme, rule or method for performing a mental act, playing a game or doing business or a program for a computer; (d) the presentation of information.

[108] For example aesthetic creations; literary, dramatic, musical and artistic works could be protected through copyright or perhaps industrial design.

[109] As with discoveries, scientific theories and mathematical methods are excluded in so far as a '...patent or application for a patent relates to that thing as such.' (S1 (2) Patents Act 1977) There has been much debate about the distinction between invention and discovery, some of which is discussed

Some inventions which may appear to qualify for patent protection can be excluded, in European Patent Law, for moral reasons. There are slight variations in the wording of morality within European Patent Law. For example, Section 1 (3) of the Patents Act 1977 (UK)[110] states:

> A patent shall not be granted for an invention the commercial exploitation of which would be contrary to public policy or morality....For the purposes of subsection (3) above exploitation shall not be regarded as contrary to public policy or morality only because it is prohibited by any law in force in the United Kingdom or any part of it.

Article 53 (a) of the European Patent Convention stipulates:

> European Patents should not be granted in respect of:
>
> (a) inventions the publication or exploitation of which would be contrary to 'ordre public' [111]or morality, provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States.

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below, in relation to biotechnology. Essentially a discovery already exists in nature whereas invention applies such information to specific needs.

[110] As amended by Statutory Instrument 2000 No. 2037.

[111] 'Ordre public and morality have a long and distinguished history as criteria for the lawfulness of the grant or exercise of intellectual property rights.' (Opinion of Advocate General Jacobs, *Case C-377/98, Kingdom of Netherlands*, 14 June 2001, para. 95). The United Kingdom does not share the same historical connections and refers instead to public policy in s. 1 (3) Patents Act 1977.

This slight difference in wording should be of little consequence[112] but interpretation of what is moral or not differs in many instances between countries. There are of course some instances where there is a consensus as to what is immoral[113] whilst in others there may be disagreement[114].

The terms '*ordre public*' and 'public policy' are slightly different to the scholar but in practical terms it is suggested that they make no difference; there being no equivalent English phrase for *ordre public* which for some may 'have come in from the continent like the influenza'[115] however the closest referable equivalent is public policy. Some European countries exclude inventions where the 'application' runs counter to *ordre public* or morality and it '...is rather unclear to what extent this different redactions lead to a different scope in exclusion'[116]. Apart from the morality clause, issues relating to the acceptability of inventions per se or questions about whether an invention should have commercial protection are not relevant for the purposes of patent grant. Inevitably the morality clause has been used to object to particular inventions[117]. The European Patent Office has aired ethical arguments against

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[112] Lord Justice Jacob in the case of *Aerotel Ltd v Telco Holdings and Others* [2006] EWCA Civ 1371on the interpretation of Article 52 (2) and 53 (3) stated "The provision was implemented in the UK law by s.1 (2) of the Patents Act 1977. Although s1 (2) pointlessly uses somewhat different wording from that of the EPC no-one suggests that it has any different meaning.", at para. 6. The word "publication" in EPC Article 53 (a) has been removed by European Patent Convention 2000, which came into force on 13th December 2007, so as to bring the clause into line with Article 6 of the Biotechnology Directive.

[113] Instruments of torture, anti-personnel mines and letter bombs, for example.

[114] Research upon human embryos, for example.

[115] Joseph Conrad, '*The Secret Agent: A simple Tale*' (Twentieth Century Classics), 31st May 1990

[116] European Group on Ethics in Science and New Technologies, 'Study on the patenting of inventions related to human stem cell research', Report to the European Commission Office for Official Publications of the European Communities, 2002.

[117] See chapter four.

inventions[118] thereby raising interesting grant-stage questions about the relationship between the morality clause and ethical rules of science. This in turn has led to discussions as to what is the appropriate role for the morality clause. It is open to parties to object to a patent application at the time of grant but the effects of (a) patent grant and (b) refusal to grant are felt at different stages of innovation. Whether this is a problem or not will be discussed in due course.

(2) (A) (III) EXPLOITATION STAGE

One way of looking at the patent grant procedure is that the grant stage tests for membership of the patent club and the exploitation stage explains the membership rules. The period between the time of grant and the end of a patent term provides a patent holder with opportunity to exploit the benefit of the monopoly conferred by the patent. Exploitation is enabled or more precisely supported through the ability to deter infringers or obtain compensation in the event of infringement, which is defined in Section 60 United Kingdom Patents Act as when: 'a person ....without the consent of the proprietor of the patent.... (a) makes, disposes of, offers to dispose of, uses or imports the product or keeps it whether for disposal or otherwise...'[119].

But the existence of a patent does not itself determine commercial success or create a position whereby there is danger to public policy or welfare, therefore consideration

[118] Such as inventions that may cause harm to the environment *PLANT GENETIC SYSTEMS/Glutamine Synthesase Inhibitors* [1995] EPOR 4 or those that are used for euthanasia in animals *MICHIGAN STATE UNIVERSITY/Euthanasia Compositions* [2005] T 0866/01, see discussion in chapter four.

[119] Further provisions apply to patentable processes

has to be given to outside factors that must be present that may combine to create such a situation.

(2) (a) (iii) (a) 'Interplanetary Alignment'

This expression illustrates the commercial equivalent to the personal astrological bonus supposedly experienced when planets come into line. A patent is of little use by itself and will be worth very little in the absence of important additional factors. The existence of a patent does not give rise to a legal presumption that the holder has harnessed market power or dominant position[120], which is the 'ability to raise the price profitably above the competitive price'[121], a situation which is possible only if 'no substitute exists'[122]. The holder of a patent may be in a position to control pricing through restricting supply but other factors such as, for example high demand and few if any substitutes, need for the invention, must be present.

It is clear that market demand plays a vital role and the greater the demand the more opportunity there is for a patent holder to enjoy control over pricing or licensing. Demand is raised further when alternatives for the invention are unavailable. In markets for medicinal products or other essentials, for example, the demand is often inelastic; so high prices through patent protection do not deter demand. The longer a patent holder is the sole market provider, the greater the profit and, better still, if a patent is obtained over an early stage process or product and/or the protection provided is broad in scope. It is unusual for such a situation to arise of high demand coupled

[120] See F Leveque and Y Menière, *The Economics of Patents and Copyright* (2004), 83 and RTE Case, 1-00743.

[121] Ibid at 83.

[122] Ibid.

with no or few alternatives in favour of one party simultaneously but it is easy to see how aggressive business models coupled with preference could lead to abuse of the system and give rise to reservations about the justification for awarding patents in the first place.

(2) (a) (iii) (b) Restrictions on Patents

In certain restricted circumstances the monopoly power of a patent may be curtailed. These circumstances are described below and will only arise if specific factors are present and thus they are not designed to curb excesses that may arise through exploitation of a patented invention.

(2) (a) (iii) (b) (1) Compulsory Licences

A patent can be a powerful commercial tool and compulsory licences are intended '...to qualify this full potential in the name of some other policy objective.'[123] The grounds for compulsory licences are restrictive[124] and so they are not easily obtained nor are they granted frequently[125]. The Patents Act 1977 (UK) provides for compulsory licences three years after the grants of patents in the following circumstances:

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[123] Cornish and Llewelyn, *'Intellectual Property: Patents, Copyrights, Trademarks and Allied Rights'*, page 289.

[124] The TRIPS Agreement permitted compulsory licenses but only subject to stringent requirements due mainly to opposition to such licenses by the United States.

[125] This is probably due in the main to the restrictive hurdles that are required before a compulsory license may be applicable. The aim is mainly to ensure that patents are not used to prevent the commercialisation of inventions rather than opening up competition.

(1) Where the patented invention is capable of being commercially worked in the United Kingdom, that it is not being worked or not worked to the fullest extent practicable.

(2) Where the demand for a patented invention in the UK is not being met on reasonable terms or is being met to a substantial extent by importation.

(3) Where the invention is being hindered from being commercially worked in the UK because of importation.

(4) Unreasonable refusal of a licence on reasonable terms by the proprietor in three specific circumstances; market for export not being supplied, prevention of working of other patented invention or unfair prejudice to development of commercial or industrial activities in UK.

(5) Unfair prejudice to industrial or commercial activities in the UK.

(6) The patent must have been granted for three years

Added to these restrictions is the discretion of the Comptroller to refuse a licence, so it is not surprising that compulsory licences are rarities: '...a compulsory licence system which is directed at one or other form of insufficient exploitation, and which thus requires careful investigation of the circumstances before grant, is not likely to be much used'.[126]

[126] Cornish W R & Llewelyn D, '*Intellectual Property: Patents, Copyrights, Trademarks and Allied Right's* ibid note 123 at page 293

Despite this there have been, calls for the system to be used more widely[127] in respect of biotech inventions, but this could be seen to be a change in direction that conflicts with the objectives of the patent system and so may attract opposition from business and supporters of the purity of the present patent system. The debate continues because in some circumstances further innovation is hampered by a combination of broad patents and inflexible commercialisation.

(2) (a) (iii) (b) (2) Crown Rights

The government of the UK, in exceptional circumstances, can compel use of patented inventions without infringement of patent subject to the provisions for reasonable licence fees. The most obvious justification is national security, but crown licence for pharmaceuticals for the National Health Service[128] is an example that has been the subject of a House of Lords decision. This is a rarely used Crown power and other governments, particularly those within the EC, have reservations about it and are not equipped with legislation to dent the power of the patent monopoly.

(2) (a) (iii)(c)(3) Research Exemption

The research or experimental use exemption stipulates, according to section 60 (5) (b) of the UK Patents Act 1977, that an act which would otherwise constitute an infringement shall not do so if, 'it is done for experimental purposes relating to the subject matter of the invention'[129].

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[127] 'Broadening the application of the compulsory licensing scheme has also been suggested as a possible solution to tackle unwanted patents, such as e.g. the BRCA patents', Bostyn, 'DNA Patents in Europe: Controversy Remains', 27.

[128] This was the justification provided in 1965 when the House of Lords held that the Ministry of Health could import drugs not manufactured by the patentee (*Pfizer v Ministry of Health* [1965] AC 512).

[129] See also Article 27 (b) of the European Patent Convention.

The research exemption has been particularly controversial in relation to biotechnology patents[130]. It is difficult to define what differentiates experimental purposes from other purposes or activities. This is an obvious problem made all the more perplexing because the subject matter of inventions has to be taken into account and because there is no definition of 'experimental purposes': 'Confusion arises because there is no definition of what is in relation to, and what is different from the subject matter. Some technologies, such as genes, may fall into both categories'[131].

The issue arises with clinical trials because it may be unclear whether they fall into research or commercial activity. The interpretation of this varies across Europe[132] and as there are different stages during clinical trials some may fall into research and others into commercialisation. As it stands ambiguity causes inhibition of research for fear of litigation and/or because of expensive licence fees[133]. This situation frustrates the purposes of the patent system which exists to encourage research. So the '... research exemption remains an important, but difficult concept under patent law'[134]. Expansion of research exemptions and compulsory licences could ease some of the concerns raised against biotechnology patents but could have a negative effect upon incentives.

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[130] Cornish and Llewelyn, '*Intellectual Property: Patents, Copyrights, Trademarks and Allied Rights*'. 'This exception has proved increasingly controversial in connection with patents over pharmaceutical products' See Rebecca Eisenberg, Genes, Patents, and Product Development, 257 Science 903 Rebecca S. Eisenberg, Patents and the Progress of Science: Exclusive Rights and Experimental Use, 56 U. CHI. L. REV. 1017, 1076-77

[131] Gowers Review, paragraph 4.5

[132] The Netherlands sees clinical trials as part of the commercialisation process whilst Germany sees them as a way of continuing knowledge. See Danish Council of Ethics, The Ethics of Patenting Human Genes and Stem Cells, 38.

[133] See Gowers Review, paragraph 4.5; IPI, 'Patents for Genetic Sequences: The Competitiveness of Current UK Law and Practice', A study by the Intellectual Property Institute (IPI) on behalf of the DTI, May 2004, available from <www.dti.gov.uk>.

[134] Danish Council of Ethics, The Ethics of Patenting Human Genes and Stem Cells.

The core problem that may arise within exploitation stage is one of **access** or the extent that patent law frustrates its own purpose of increasing availability of new inventions for public benefit. Different issues arise within the innovation stage, mentioned above, which are relevant more to **ethical** questions that may arise from inventions under patent protection and the extent that patent law is complicit in those inventions or the research behind them. i.e. because patents create an incentive they may encourage immoral inventions. The incentive of patents occurs because patents enable patent holders to restrict others and this too is a moral issue and in certain circumstances, which will be discussed later, raises an immoral problem. Importantly patent law does not create the problem at the core of the ethical issues during the innovation stage because inventions arise independently of patent law, whereas patents can result in difficulties of access by virtue of their grant and use. There is an overlap between the two in the event that an invention, for example, a form of medical treatment, is exploited in such a way that the grant of a patent enables the patentee to unreasonably restrict not only those in need but also those who are seeking to establish further treatments, then that too is a moral concern.

(2) (A) (IV) GENERIC STAGE

The benefits of patents are expressed in different ways over different stages. They are a long-term policy instrument. Initially they are to the advantage of the patent holders and to those who can afford to benefit from new patented inventions. So the public benefits through later publication of information and the availability of the invention (albeit with high costs during the life span of the patent), transforming into lower costs

after expiry and incentive for other possible inventions to emerge. It is easy to criticise patents and in particular patents over biotechnology and pharmaceuticals for increasing the price of medical treatments. An increase in cost of treatments can be seen as an acceptable certainty: 'There is no denial here that biotechnological innovation in the sphere of medicine will mean that treatments become more expensive'[135].

It can be argued that whilst commercially successful patentees will likely profit to a greater extent, through the restriction of access, than would be the case in the absence of patents, it is the provisions for patents that drives innovation, much of which may not have occurred otherwise. In any event, the patent system restricts the term of the monopoly so the patentee's profit period is limited to the period of restriction and thereby curtailed. At the end of the patent term competitors can copy and reproduce inventions without fear of litigation thus generally reducing prices and increasing access.

There are therefore different stages within the timeline of innovation and at each stage patent law exerts a different influence whilst raising potentially diverse moral questions. The point for this work is to understand how moral issues which arise at each stage can be addressed so as to present a balanced system which, as the following section discusses is a vital component for patent law.

[135] Warren-Jones, 'Patenting DNA: A lot of controversy over a little intangibility', 124.

(2) (c) The Patent Balance

'If there is a single justification or common purpose that underpins the system it must be the attainment of a balance between the different interests involved'[136]. Ultimately the public interest[137] is intended to be served by the innovation encouraged through the patent system. Two separate 'equations' are balanced through the process of innovation and the patent system, the first an ethical equation and the second an access equation and both have played a greater part in the patent process as biotechnology issues have developed.

(2) (c) (i) Access Balance

It can be argued that the patent system creates broad rights for commercial interests at the short-term expense of the public, but the character of the patent system is that the encouragement of commerce prompts further invention thereby creating increased public benefit overall. The increase in access brought about by patent incentive occurs in different period of the time line and in different ways: for example increasing access through (a) incentive, (b) publication, and (c) encouraging generics after patent term has ended. There is a restriction in access associated with the grant of patents which occurs in the exploitation stage in varying degrees depending upon all the relevant circumstances. This may be through consumers who may not be able to afford the higher prices of patented inventions. The nature of a monopoly is that the monopolist

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[136] '*Holyoak and Torremans Intellectual Property Law*', 41.

[137] There can be arguments against this view, for example, 'The fact that it can actually promote activities which are contrary to the public interest is well documented and this leads to the conclusion that securing the public's interest is not the primary purpose: promoting innovation is', Warren-Jones 'Patenting DNA: A lot of controversy over a little intangibility', 103.

will produce enough to maximise profit rather than maximising distribution[138] and the steeper the demand curve the more the supply can be reduced so as to maximise the profit. We shall see that there can be restrictions upon further research in some situations caused because of the grant of a patent and these potential restrictions can be weighed against the increase in access provided, discussed above. It is helpful to relate this to the innovation time line:

	Pre-Grant – Innovation Stage	**Grant Stage**	**Post-grant – Exploitation Stage**	**End of Term – Generic competition**
	Conception of invention- development and research encouraged by potential of patent protection. Patent encourages the commercialisation of invention	Patent application and assessment of inventive qualities Details of Invention Published	Exploitation of inventions with patent protection – compare with exploitation of invention without patent protection	Trade off for patent is knowledge of how invention functions so others can copy and exploit after expiry
	Access through provision of incentive	Access through publication	Access through new invention but restriction if patentee produces quantities to maximise profit rather than public welfare. Possible restriction also if further research hampered	Access increased through generic copies

Table Four – Patent Access and Restrictions

The interests of patentees are set off against the interests of consumers and other inventors who will have to pay higher prices for patented inventions or obtain licences to use or sell. The different justifications for a patent system are reflected within this

[138] See discussion in the introduction 'The Patent Paradox'

balance: - inventors with claims to protection for risk investment and innovation and the public receiving opportunity to purchase something new and to obtain information about it.

Increasing incentive through offering patent rights may encourage innovation but if patent rights are too broad there is less scope for others to improve or invent around inventions which could decease innovation. Consumers do not benefit from new inventions unless they can afford to buy them. 'The interests of consumers as a class is of course served by the invention of new products and processes but not if their inventor is able to take advantage of his monopoly position by abuse of it'[139]. The OECD in its 2004 report, 'Patents and Innovation: Trends and Policy Challenges' summarised the basic patent balance as follows:

> The positive effect of patents on innovation as incentive mechanisms has been traditionally contrasted with their negative effects on competition and technology diffusion. Patents have long been considered to represent a trade-off between incentives to innovate on the one hand, and competition in the market and diffusion of technology on the other.[140]

But the report continues that this traditional view has become eroded by the proliferation of new technology and so the traditional view must be qualified by understanding that '...patents can hamper innovation under certain conditions...and that fine tuning of patent design is critical if they are to become an effective policy instrument'.

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[139] '*Holyoak and Torremans Intellectual Property Law*', 41.

[140] OECD, 'Patents and Innovation: Trends and Policy Challenges', 9.

Therefore if patent rights are excessively weighted in favour of patent holders consumers lose benefits, competitors are unfairly prejudiced and the purposes of patent law frustrated. This 'traditional' balance is one of access because variations in the balance either restrict access or expand access for the benefit of competitors and the public.

Situations of imbalance in favour of patent holders are bound to occur from time to time because they are in the driving seat, they are usually astute and can exploit their situation. There is evidence that potential exists for the patent system to act against the public interest. The current patent system developed in the absence of biotechnology[141] but it has adjusted in the face of the difficulties presented by new technologies. Biotechnology patents have faced persistent objections some of which have not yet been dealt with fully. The Biotechnology Directive has been added to patent law but its effects have more to do with facilitating biotechnology by attempting to standardise European patentability in face of definitional difficulties than with improving rights of access to genetic material. Thus although the Directive confirmed the patentability[142] of biotechnological inventions in European Union States and broadened the role of morality[143], which both are assessed at grant stage, it did little to address questions of access after the grant of patent. It is submitted, and will be discussed in greater detail in

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[141] '...techniques such as recombinant DNA technology have posed problems for a patent system which was not designed with the specific needs of the biotechnology sector in mind', Cook, *'A Users Guide to Patents'*, page 319.

[142] Discussed in more detail in the following section

[143] See chapter four

chapter five, that in some cases there should be scope to revisit the grant of a patent and that in the event that particular circumstances suggest that it is appropriate.

(2) (C) (II) ETHICAL BALANCE

The grant of patent rights, because of the access issues discussed above, inevitably invokes ethical issues because the 'right' thing to do is to share. Other moral questions associated with the grant of, in particular biotechnological patent rights, relate more to details of inventions than to the qualities of what a patent is and what it provides. Such ethical questions have become more pertinent in relation to biotechnology patents. European patent law has been armed with a morality clause for many years but it is now more readily invoked and its interpretation has become more complex as a result of the diverse issues that have arisen in the race to commercialise biotechnology and the manner in which the morality clause has been interpreted by the various European institutions.

Ethically sensitive issues that have been raised through the medium of European patent law include protection of the environment[144], prevention of cruelty to animals[145], slavery[146], right to life[147] and consent[148] over the use of bodily material, human dignity[149] and euthanasia[150]. These 'new' issues raise somewhat different

144 *PLANT GENETIC SYSTEMS/Glutamine Synthetase Inhibitors* [1995] EPOR 4.

145 *HARVARD/ ONCO-mouse* [1991] EPOR 525.

146 *HOWARD FLOREY/Relaxin* [1995] EPOR 541.

147 See below in relation to stem cell patents, chapter five.

148 See below at chapter five and Recital 26 of the Biotechnology Directive (1998).

149 *HOWARD FLOREY/Relaxin*

150 *MICHIGAN STATE UNIVERSITY/Euthanasia Compositions* [2005] T 0866/01

considerations compared to the traditional or access balance which measures what is awarded on the one hand with what is taken away on the other. The 'new' or ethical balance is about the benefit of inventions as against the harm or perceived harm arising as a consequence of inventions. An example is the potential of human embryonic stem cell research to provide treatment for debilitating diseases against the destruction of embryos. It will be seen that these 'new' ethical issues raise difficult questions for patent law when trying to find appropriate answers and also when attempting to discover how answers are obtained. Indeed it is open to question whether this attempt to strike a new balance is appropriate.

In order to understand these recent attempts to strike a new balance within patent law, and indeed to assess whether it is appropriate, we need to return to basics and consider the foundational aims and justifications of patent law.

(2) (d) Aims and Justifications of Patent Law

(2) (D) (I) FUNCTION OF A PATENT

Patent law has evolved from rewards by rulers dispensing patronage[151] into a complex international system supervised legally and politically which is aimed at encouraging inventors to create new and useful inventions and to inform the public properly at all material times. Patents are for the general good of the public and not specifically for advancing the prosperity of any individual manufacturer or inventor:

> The primary purpose of the modern patent system is to promote technical innovation as the major factor of economic growth by encouraging inventive activity through rewarding inventors for their creative efforts. The patent system thus secures costly investment in research and development and industrial exploitation of research results. Simultaneously, the patent system encourages an early and beneficial dissemination of knowledge in the field of activity involved which, without such protection, might be kept secret. [152]

Patents must be awarded and this occurs only on satisfying strict criteria applied through the patent application process. The patent process produces a simple equation; the exchange of a monopoly for invention and publication. Inventions may have potential and their patents may hold substantial value, but their journey begins with a

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[151] 'The patent system has come into being as a system to grant privileges to specific classes of people, especially the guilds…The privilege starts from the ruler granting a privilege to a subject, under which everything more or less to a matter of grace exercised by a ruler.' (Bostyn, '*Enabling Biotechnological Inventions in Europe and the United States*').

152 COM (88) 496 final SYN 159, 17 October 1988; [1989] OJ C10/3.

single step; in this case a carefully-worded patent application. The aims and justifications of patent law, '...concentrate upon their role [*i.e. patents*] as a 'public' instrument of economic policy. Patents are looked upon to provide two kinds of aid towards the technical efficiency, and hence the growing wealth, of the community as a whole'[153].

The patent system has an anomalous existence in that the provision of a monopoly to one person does not immediately lend itself to a shining example of a springboard for public benefit. It is a complex system which interacts with many parties, inventors, investors, competitors, researchers, consumers and the public. The complexity of patent law substantiates the many justifications for the monopoly right which have arisen and which have been given greater relative weight at different periods of the development of patent law[154]. It is suggested herein that part of the reason for the diversity of justifications for patent law is that the effects of patent grant are felt over a long period of time as illustrated by the innovation time line[155].

A patent has been described as a "social contract"[156] between the inventor/patentee and the public whereby the inventor is rewarded for ingenuity and disclosure in the

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[153] Cornish and Llewelyn, '*Intellectual Property: Patents, Copyrights, Trademarks and Allied Right*s', 6th Edition 2007, page 134.

[154] See "...it is probably the case that each has held sway at one time or another in the development of patent law policy." MacQueen H, Waelde C & Laurie G, '*Contemporary Intellectual Property*', Oxford University Press, 2007, at page 365 para 10.16 and Bostyn S J R, '*Enabling biotechnological inventions in Europe and the United States. A study of the patentability of Proteins and DNA sequences with special emphasis on the Disclosure Requirement*' (European Patent Office, Maastricht, December 2001), page 33, "The grounds upon which this justification was based varied considerably." See chapter two generally

[155] See above page 57

[156] See Bostyn J R, ibid note 155 at page 15

specification with a monopoly.[157] Inventions are expensive to make and exploit but once the technical knowledge of how to reproduce them is known they can be cheap to reproduce and without some form of protection through an exclusive right either inventors will keep the knowledge secret or will not take the risk of researching and innovating in the first place. For economists who may in general be reticent about arguments supporting the existence of monopolies in a market economy this solution to the "appropriability problem" is justification for the negative repercussion of restrictions within the market place. Overall the question arises whether the public benefits by the grant of monopoly to the inventor.[158]

The patent system is far from perfect and patents have attracted criticism but given the contradictions that are part of patent law this is not surprising.

> "Since it is rooted in contradiction, there can be no such thing as an ideally beneficial patent system, and it is bound to produce negative results in particular instances, impeding progress unnecessarily even if its general effect is favourable on balance"[159]

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[157] See *Boulton v Bull* 126 Eng.Rep., 656 – "...the specification is the price which the patentee is to pay for the monopoly". The requirement for a specification as part of patent reputedly first arose in the case of *Liardet v Johnson* (K.B. 1778), 1 WPC 53 in which Judge Mansfield instructed the jury the "The third point is whether the specification is such as instructs others to make it"

[158] "The main problem with the patent system is to try to reconcile stimulation of competition, which creates social welfare for all, and allowing the inventor to reap the fruits of his invention, which will create social welfare for the inventor. The question is then of course whether the social welfare provided to the inventor by granting him a patent can have a positive effect for society at large." Bostyn, ibid note 155, page 25

[159] Robinson J, *'The Accumulation of Capital'*, Homewood, Illinois, Irwin, 1956, 87

This quote hints at general or macro increase in benefit despite specific or micro decrease in benefit in relation to specific patents. It also suggests long term benefit of patents rather than short term[160]:

> It is meant to encourage over the long period the widest possible use of knowledge, but it starts out by conferring upon the inventor the power to restrict himself to the use of that knowledge.[161]

The picture painted above is one that could be criticised for hiding the arguments against patents as a short term and necessary evil towards the overall long term good. However it should be realised that many arguments are made against the patent system in its entirety and that the negative points outlined above are sufficient to remove any justification for the system at all. Other arguments may be in the form of an imbalance of bargaining positions in that only the wealthy have the ability to enforce their patents and defend their position. It may also be argued that the patent system is open to abuse because the nature of the language of patent specifications requires particular talents to draft and understand.[162] Patents can be criticised because the reward does not reflect the contribution and that they are increasingly slowing the availability of information and access to medicines.

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[160] See also Schumpeter JA, '*Capitalism, Socialism and Democracy*', London, George Allen & Unwin Ltd, 1976, 87-106, page 103 – 'The main value to a concern of a single seller position....is...in the protection it affords against temporary disorganization of the market and the space it secures for long-range planning."

[161] Bostyn ibid page 25

[162] See Drahos P and Mayne R, '*Global Intellectual Property Rights: Knowledge Access and Development*', Oxfam, 2002 in particular Macdonald S, 'Exploring the Hidden costs of patents', page 13

This work takes the view that there are pros and cons of patent grants, that these are reflected at different stages within innovation and that the nature of patents is that the system needs to be organised in such a way that any detriment is balanced against the benefits. It does not take issue with the argument that patents in general are beneficial although it recognises that alternatives[163] exist which could answer some of the objections raised against the system. Instead the work takes issue with the ability for patent law to control the particular form of exploitation in particular instances. It is not therefore intended to review the arguments against the patent system in detail but readers should be aware that strong arguments exist the proponents of which would see an end to the system altogether.

(2) (D) (II) SEPARATION OF PATENT AND INVENTION

Patent law is an economic instrument that uses rules to govern the exploitation and publication of inventions that a patent protects. An invention may for example be objectionable, hazardous or environmentally unfriendly but:

> Patent law traditionally has not been applied as a means to inhibit technological development that poses safety or other risks to society. And the only thing that has been excluded by legislation was patenting of nuclear weapons technology in 1954.[164]

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[163] Such as open source – see below

[164] R Dresser, 'Ethical and legal issues in patenting new animal life' [1998] Jurimetrics Journal, 399–435, regarding the position in the United States.

A patent is a form of property[165] right[166], separate from the invention it protects[167], and it can therefore be sold and licensed[168] independently, and is subject to separate laws and regulations. Indeed a legal prohibition on an invention need not affect the validity of the patent covering its exploitation[169]. There are qualifications on the extent that a patent can be seen as a full property right, in particular '...because it does not last as long as the good that it protects. Its validity is limited to 20 years whereas the information it protects will never disappear.'[170]

It is necessary to discuss the separation of rules that govern the use and grants of patents from those rules that relate to the use of the invention. The clear distinction between patents and inventions necessitates differences between their respective rules. These two different forms of rules can converge because of the incentives that are at the heart of the patent system. The question is whether the removal or weakening of the patent incentive is a justified and appropriate method of reacting to moral concern regarding particular inventions? If reasons exist to support such action then at what

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[165] 'Any patent or application for a patent is personal property (without being a thing in action), and any patent or any such application and rights in or under it may be transferred created or granted in accordance with subsection (2) to (7) below' (s. 30 (1) Patents Act 1977).

[166] Whether a patent is property is to a certain extent a moot point. Certainly there are limitations upon a valid patent that would not be pertinent to other forms of property, compulsory licences, crown rights, 20-year validity period for example. A patent can also be revoked or declared invalid. On the other hand a patent can be sold, licensed and have an independent value. Just like patents other forms of property have restrictions on their use. Thus it is reasonable to look on patent law as a form of property, but one that is subject to particular restrictions.

[167] 'A patent has little or nothing to do with the ownership of the physical material as such...' (Crespi, 'Patents on Genes: Can the Issues be Clarified?' (1999/2000) 5 (3) Bio-Science Law Review 199, at 199–200.

[168] 'Subject to section 36 (3) below, any patent or such application, or any right in it, may be assigned or mortgaged' (s. 30 (2) Patents Act 1977). Similar provisions also apply within the European Patent Convention.

[169] 'For the purposes of subsection 3 above exploitation shall not be regarded as contrary to public policy or morality only because it is prohibited by any law in force in the United Kingdom or any part of it' (s. 1(4) Patents Act 1977). This is discussed in detail below but similar provisions are contained also in Article 53 (a) European Patent Convention, Article 6 Biotechnology Directive and Article 27 (2) TRIPS.

[170] Leveque & Menière, *'The Economics of Patents and Copyright'*, 83.

stage in the innovation process is it appropriate to interfere and what mechanisms ought to be used?

With this in mind it will be beneficial to examine the rationale behind patent law and the influences upon it. Justifications for granting patent rights include the rights of inventors to protect their inventions and the encouragement of further developments through the provision of awards and publication. This results in individual and public justification[171] or natural rights and utilitarian justification[172].

(2) (D) (III) A PATENT AS A NATURAL RIGHT

Natural Law theory[173] justifies awards of patents on the basis that everyone has the natural right to ownership of their own products of labour. This theory, '...famously propounded by Locke, holds that there is a 'natural right' to that with which one has 'mixed one's Labour''[174]. Bostyn argues that the natural law theory '...plays no role anymore in any thinking about the patent system'[175]. This is true to the point that it is not used to justify the existence of the patent system which still reflects inventors' entitlements to protection on the basis of their inventive contributions. Furthermore seeing the grant of a '...patent as an instrument of justice to the inventor has proved attractive and the power of this sort of argument is by no means exhausted.'[176] 'Yet rewarding inventive activity may seem little more than an incidental consequence of

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[171] Cornish and Llewelyn, *'Intellectual Property: Patents, Copyrights, Trademarks and Allied Rights,'* 130.

[172] Nuffield Council on Bioethics, 'The Ethics of Patenting DNA' 12.

[173] Bostyn, *'Enabling Biotechnological Inventions in Europe and the United States'*, 33.

[174] Nuffield Council on Bioethics, ibid note 172, page 12.

[175] Bostyn, ibid note 173, page 33.

[176] Cornish and Llewelyn, ibid note 171, at page 130. The Patents Act 1977 also allows for employee/inventor compensation which reflects this natural law approach.

modern patent systems.'[177] In other words the inventor's monopoly is the basis for the workings of the patent system but is not justification for it:

> The goal of the patent system is to serve the public good, here by not only encouraging biomedical research but also providing access to the results of that research. Giving exclusive rights to inventors is simply the means through which the system reaches this goal but is not the goal itself.[178]

Awards of monopolies are vital to ensure realisation of the advantages that the modern patent system offers but awards should never be at the expense of public interest nor contrary to the utilitarian justification.

(2) (D) (IV) UTILITARIAN JUSTIFICATION

The modern patent system has a strong utilitarian perspective which justifies '...property rights as a system of public rules which provide security and incentives for investment by individual owners of property, but which can and should be adapted whenever the public interest is thereby served'[179]. Patent law, from this perspective, provides incentives, not because of inventor's rights, but to further the public interest through increased investment and proliferation of information. It is clear from this standpoint that public interest is, or should be, overriding, therefore if the patent system fails the interests of the public it will surrender advantage to the private sector at the expense of the public and dilute the raison d'être of the patent system.

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[177] Cornish and Llewelyn, ibid note 171, page 130.

[178] 'Gene Patents and the Public Good' (2003) 423 Nature, 207.

[179] Nuffield Council on Bioethics, ibid note 172, page 12

(2) (D) (V) INCENTIVE

A widely used justification[180] for the existence of patents is that inventors and entrepreneurs will not take the time nor risk the investment in the absence of opportunity to develop the invention and profit from it with greater prospects than under contemporaneous market conditions. Patent grants enable patent holders to recoup costs of development and to make allowances for future growth and associated profits. These opportunities are the mainstay of patent law, the reason being that the greater the incentives the better the prospects for beneficial development to improve the comfort, wellbeing and prosperity of society at large.

Patents, once granted, are great levellers in their early stages because they do not recognise the quantity of effort and the quality of ingenuity contributed to any inventive concept which made the invention patentable in the first place. Returns, if any, from patented inventions are determined by factors such as market size, market demand and how essential an invention is perceived to be to the market. Bostyn[181] refers to the 'reward by monopoly theory' which equates monopolies provided by grant of patents as commensurate with the contributions made by the inventions. Risk has always been a factor in that contribution and potential reward are not linked to potential risk so enormous effort could fail, and vice versa, thus any correlation between amount of effort, inventive activity, cost of creation of an invention and patent

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[180] Bostyn, *'Biotechnological Inventions in Europe and the United States'*, 2001; Nuffield Council on Bioethics, ibid note 172, July 2002, 12. 'The justification for the patent system is that it provides an incentive for investments in new ideas, without which technological development would be much slower and more difficult' (Grubb, Patents for Chemicals, Pharmaceuticals and Biotechnology, 14).

[181] Bostyn, ibid note 180

and the likely gains from exploitation will be hostages to fortune. Patent law is essentially seen as blind to the effects of its grants as it is to the circumstances giving rise to inventions. Mechanisms do not exist to rebalance the position where circumstances permit an award grossly in excess of the contribution and vice versa. These discrepancies may be accepted as part of commercial reality and because all the participants are aware of the risks. If situations arise which create instances where access is restricted so that further development is hampered or they are against the public interest then objections to patent law are more justifiable. It is argued that patent law should be in a position to interfere in the event that such situations arise and will discuss how that will occur and why in chapters five and six.

(2) (D) (VI) DISCLOSURE

Patent applicants are obliged to disclose their inventions as stated in Section 14 (3) of the United Kingdom Patents Act:

> For the specification of an application shall disclose the invention in a manner which is clear enough and complete enough for the invention to be performed by a person skilled in the art.[182]

Inventions must be properly described and be full enough to be performed by those skilled in the art in question. This allows others to recreate it or to improve upon the work. Therefore publication enables proof that the invention does what the inventor claims and allows for generic copying at the expiry of the patent term and for others to research the invention further with the aim of either 'inventing around' the patent or

[182] Section 14(3) Patents Act 1977.

improving upon it with the possibility of obtaining a separate patent for the improvements. Granting of patents helps to achieve the spread of inventive activity through dissemination of the workings of each invention.

By way of enablement, patent law in Europe permits for research on patented inventions without fear of actions from patent owners. Distinguishing between research and commercialisation is open to interpretation but the position should be clarified[183]. Disclosure therefore plays an important part in the ethos of patent law at all stages of innovation.

(2) (D) (VII) A SOURCE OF FUNDS

The Nuffield Council on Bioethics subscribes to the view of justifying the patent system through both utilitarian and natural law theories: '...combination of the two approaches [utilitarian and natural right] to the justification of intellectual property rights'[184]. This is a reasonable view which helps to illustrate the separate interests of inventors and the public and that the patent system should always be alert to achieving a balance of those interests.

Another way of looking upon the utilitarian aspect of the patent theory is to view the grant of a patent as a method of finance[185] or of democratic taxation. This suggestion is

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[183] See Gowers Review, 'Recommendation 1: Amend section 60 (5) of the Patents Act 1977 to clarify the research exemption to facilitate experimentation, innovation and education'. See also above page 66 experimental use exemption

[184] Nuffield Council on Bioethics, 'The Ethics of Patenting DNA', 12.

[185] See, for example, the Commission on Intellectual Property Report: 'Over time, the emphasis has shifted towards viewing the patent system as a means of generating the resources required to finance R&D and to protect investments', CIPR Report 2002.

based on the often-quoted justification for the granting of patent rights, that if a business has no hope of recovering the additional costs of researching and manufacturing an invention, which is made possible by a patent, then there would be much less innovation. Thus a patent provides the opportunity to raise finance for research, the recognition of investment being that those willing to pay higher prices during period of grant will finance their profit and so it is arguably a fair method of raising funds.

Put simply, patents' monetary values reflect patent owners' abilities to extract high profits arising out of the advantageous monopolies gained by virtue of having patents. Purchasers of patented products at high prices pay indirectly for the research and development of inventions and so subsidise later generic copies that evolve subsequent to the end of the period of exclusivity. So those who pay high prices for, say, a patented drug, help those who follow to enjoy the benefits of cheaper generic drugs. Indeed society benefits eventually from the higher prices paid for inventions created comparatively recently[186].

The justifications can be seen in different sectors of the innovation time line **Table Five – Patent Time Line – Patent Theory** overleaf:

[186] This comment is aimed at a social perspective rather than being literally true.

	Innovation or Incentive Stage	Grant Stage	Exploitation Stage	Generic Stage
Patent Theory	Utility Theory/incentive Fund raising	Disclosure	Reward or Natural Right theory – Democratic tax theory	Distribution to all funded by prior higher prices
The Patent Effect	The prospect of a patent provides an incentive to commence research and development. Patents may also encourage commercialisation so distinguish between incentive to research and incentive to commercialise the results of research	Assess inventive quality – novelty/inventive step and Utility – Morality Priority date (application) Publication within 18 months – nb section 21 applications representations by 3rd parties Max, time to grant 4.5 years NB – EPO 9 months for 3rd party to oppose patent grant	Monopoly Publication – encourages (a) further research (b) inventing around patent (c) compulsory licenses (d) research exemption	Open competition
Regulation	Ethical and legal rules that govern the envelope of research e.g. HFEA. Any other legal requirements – e.g. Health and safety/environmental regulations etc – consent from participants. Human Tissue Act 2004 **Regulation relating to research**	Different regulation may be relevant i.e. from that which governs particular research to that which is pertinent for resulting inventions. **Regulation relating to invention resulting from research**	(a) Strength of market demand (b)licensing practices (c) Competition Law **Regulation relating to method of exploitation**	Generics still under regulations – i.e. will still have to comply with any regulatory requirements re safety etc
Benefit to Public	Incentive created with long term aim of increasing public welfare	Information in public domain and invention becomes available	Invention available albeit at higher than normal market price Publication -	Generic competition means prices likely to reduce
Moral Concerns	Unnecessary blocking effect of patents already granted – a direct cause of patent grant Research – danger to environment/animal cruelty/unknown potentially hazardous outcomes – not caused by grant of patents	Encouraging or rewarding particular immoral innovation. Symbolism of acceptance in event of absence of regulation	Stacks/reach-through licences – potential blocking – research – restrictive licenses caused by patent grants	Other IP – Trade secrets/
Patent and Regulation Interaction	Incentive effect of patent in direction of research? Conflict between what is patentable and what is legally permissible?	Morality clause – invention/commercialisation – have consent procedures been followed? – Recital 26	Competition law – monopolies	

The justifications for patent law are expressed at different stages of the innovation time line and different ethical questions arise during each stage in relation to each justification. For example, inventions that have arisen out of unethical research may still benefit from the patent incentive, thereby rewarding unethical researchers. Rewarding an unethical researcher is a different question from enabling immoral exploitation of an invention. Both examples are important issues but the extent that patent law is a relevant or practical instrument with which to address them is a moot point. The first example could envisage patent law as part of wider regulatory mechanisms which could utilise the incentive (or rather the disincentive of not granting) as a method of reflecting society's moral stance and it is questionable whether this is an appropriate mechanism for this. The second example relates more to regulation of exploitation, for which, although aided through the grant of patents, has a separate body of law to regulate economic issues. So arguably neither is directly relevant for questions relating to the grant of patents. On the other hand there is a clear connection between them; the first connected through incentive and the second through patent law enabling monopolistic exploitation. A significant difference is that the grant of patents cannot create immoral inventions but the grant of patent rights can create immoral exploitation. Perhaps more importantly refusal of patent grants does not eliminate immoral inventions but exploitation can be changed through alteration of the conditions of patent monopoly. I suggest that these differences in effect should be an important basis for deciding what steps should be open to patent law to address some the criticisms levied upon grants of patents. The attainment and expression or realisation of the justifications for the grant of patent rights has a negative side. The

following chapter examines some of the difficulties that may occur through exploitation of patented inventions.

(2) (e) Negative Patent Effects

These last few points outline some of the negative effects of patents which may arise in certain circumstances. Patent law exerts influence at different stages of innovation. During each stage competing interests arise, each of which can be influenced or affected by patent grants or refusal to grant. Competing interests can be ethical or related to access, i.e. the extent of restrictions that may arise as a result of the grant of patents. The restrictions are justified by a number of patent theories and these also illustrate the patent effect over time. Although patent requirements remain the same regardless of the type of innovation, the characteristics of innovation processes within individual industries can differ.[187] Some of which can give rise to specific problems and which are, as we shall see, more prevalent, or are more likely to give rise to issues within biotechnology and so they will be revisited in the following chapter. The following sub-sections outline some negative consequences of patenting that can arise after a patent is granted.

(2) (E) (I) WASTAGE, CHERRY-PICKING, RACING AND FISHING

Patents are granted, in Europe and in most patent systems, to the first to file a patent:

> Today more than ever, those engaged in research may be competing to solve a scientific or technical problem. The 'first to file' basis of most patent

[187] 'But whereas the patent system has uniform criteria to judge patent applications, the pattern of technical progress may vary significantly in different fields.' (CIPR Report, 2002, 112).

systems exacerbates the pressure to reach the patent office as soon as feasible.[188]

It is natural that firms will concentrate their efforts upon developing and producing inventions that create the best prospects for returns. If more than one aspirant in the field emerges, rivalries will be created but there can be only one eventual winner. Losers in the race to patent will have spent effort for which there is no reimbursement and this seems to create inefficiencies conflicting with the general good. This 'race to patent'[189], wastage or 'fishing'[190] plays a negative role so far as 'appropriability'[191] is concerned and is brought about because a patent is a 'true monopoly'[192]. The larger the potential profit, the more entrants there are likely to be, resulting in wasted time, effort and resources used up by chasing the patent and which otherwise could have been put to better use elsewhere. It is arguable that these apparent wasted efforts could be offset by greater efficiencies brought about by being involved in the competition between rival firms, and that sometimes there is no rivalry because there is only one applicant. In the cases of Genentech[193] and Amgen[194] much time and many resources were

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[188] Cornish and Llewelyn , '*Intellectual Property: Patents, Copyrights, Trademarks and Allied Rights*'.

[189] 'The third kind of disadvantage is that, paradoxically, the potential availability of patent protection may serve to make meritorious research more, not less, risky. This is because the reward goes to he who arrives first', Laddie, Prescott and Vitoria, '*The Modern Law of Copyright and Designs*', 852.

[190] Y Barzel, 'Optimal Timing of Innovations' (1968) 50 Review of Economics and Statistics, 248.

[191] 'It is then also said that patent protection provides a monopoly to solve the appropriability problem: if a firm cannot recover the costs of invention because the necessary information is available to all at no cost, it can be expected that the level of information will be much lower.' (Bostyn, '*Patenting DNA Sequences (polynucleotides) and Scope of Protection in the European Union*').

[192] Laddie, Prescott and Vitoria, '*The Modern Law of Copyright and Designs*', 852.

[193] *Genentech Inc's Patent (Human Growth Hormone)* [1989] RPC 147, CA.

[194] *Amgen Inc. v Hoechst Marion Roussel, Inc. and Transkaryotic Therapies Inc.* Civil action No 97-10814-WGY United States District Court District of Massachusetts, 19 January 2001.

wasted in costly global legal disputes. Some economic waste is unavoidable in these sorts of competitive situations where there is only one winner but this is acceptable because the competition of itself creates its own benefits. The Biotechnology Directive at least indicates that there is an issue[195] but it fails to address it in any meaningful way.

(2) (E) (II) EXCLUSIONS

The previous chapter illustrated that it stands to reason that if there is insufficient incentive innovation be discouraged leaving areas of important progress outside the patent system altogether. There are also problems for potential consumers excluded from the benefits of patents because only those who can afford the cost of patented inventions can benefit. But to some extent this is a disingenuous suggestion so it should be put into context. It is true that in the realms of health care, economic exclusions brought about by higher costs of patented drugs raise justifiable arguments against patenting; because patenting can exclude those who need remedies the most. Patenting, and all that it means for encouraging preventative, curative, sedative medicines, focuses upon research and development of medication that is initially expensive and that potentially returns the highest revenue rather than that which allows comprehensive access. But the proponents of patenting can argue that funding has to come from somewhere and that patenting is the most efficient method in the long run in the absence of any better alternatives. Everyone benefits from improvements in the

[195] Recital 18 of the Biotechnology Directive states: 'Whereas, since the patent system provides insufficient incentive for encouraging research into and production of biotechnological medicines which are needed to combat rare or "orphan" diseases, the Community and the Member States have a duty to respond adequately to this problem', and Recital 11 indicates a similar attitude to developing countries'.

end, because generics come on the market or alternatives are developed, which may not have been available in the absence of patents.

So the arguments persist and whilst there are merits of each side they reflect the balance that patent law is supposed to achieve. One ensures so far as possible that the strength of patents does not become too great and the other strengthening private interests to ensure appropriate incentives exist for innovation. On occasions there may be concerns that private or commercial interests are too strong. It may be an acceptable side-effect of patent law and economics that there are casualties along the way[196] because of the overall benefits, but is that justification acceptable in all cases? If many are excluded or progress restricted for the sake of commercial gain then the justification for the grant of patents or their relative strength should be questioned.

(2) (E) (III) BOTTLENECKING – STACKS, POOLS AND REACH-THROUGH PATENTS

The patent system allows for improvements to inventions to be patented separately. Some inventions are constructed by using several components, each of which has been separately patented. This could happen horizontally where the invention is created by using several other patented inventions; as in the case of the Indian manufactured drug, Duovir-N'[197] which is used in connection with AIDS and is manufactured from a combination of zidovudine (AZT), lamivudine (3TC) and nevirapine (NVR). Two are patented by GlaxoSmithKline and the third is patented by Boehringer Ingelheim. The combination drug is manufactured in India to overcome patenting hurdles elsewhere.

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[196] 'In the short term future, there are bound to be instances of personal injustice, but resourcing medicine is full of such occasions and in the long-term, reality must take effect', Warren-Jones, 'Patenting DNA: A lot of controversy over a little intangibility', 124.

[197] Médecins Sans Frontières, 'Drug patents under the spotlight', 6.

Vertical examples occur where the original invention is used as a basis for further research and leads to a new but separate invention. In each of these examples inventions have been created and then developed using other patents which may or may not be held by the same inventor.

This characteristic is more prevalent in some industries than in others. In industries which are characterised by a '...linear research...'[198] model the problems posed by multiple patents may be minimal. On the other hand in knowledge-based industries, like pharmaceuticals or biotechnology: '...the process of innovation may be cumulative, and iterative, drawing on a range of prior inventions invented independently, and feeding into further independent research processes by others'[199].

The pharmaceutical and biotechnology industries have the propensity to become involved in these sorts of situations resulting from the increase of complex research and development that characterise their activities. 'In the Pharmaceutical sector, such an invention may for example relate to a product (e.g. a specific molecule), a process (e.g. the process to manufacture this molecule), a medical indication (e.g. a fixed dose combination of two molecules)'[200].

The difficulty that this characteristic creates is that there can be a reduction in availability of material for further research because of patents over earlier work. The

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[198] CIPR Report, 2002, 112.

[199] Ibid., see also IPI Report, 'Patents For Genetic Sequences: The Competitiveness of Current UK Law and Practice', 92

[200] Médecins Sans Frontières, 'Drug Patents Under the Spotlight'.

negative effects of the above were first discussed in *Science* magazine[201] but have been repeated in other observations[202] about the patenting of biotechnology. The reality of the effect of this is looked at later but the following is a summary of the consequences.

'The extent of the protection conferred by a European Patent or a European Patent Application shall be determined by the terms of the claims.'[203] The result is that patentees can word their claims as broadly as they like provided that they come within the patent qualifications and are warranted as justified by the supporting documentation[204]. A patent over an early stage invention such as DNA will cover all uses. Therefore should further innovation occur the second inventor will require either a licence or permission otherwise they will be in breach of the first. This could give rise to what have become known as patent pyramids. Patent holders at the first stage of development, or top of the pyramid, charge licences to second stages and further to the extent that the development continues. The risk is that 'thickets' develop which slow the progress of innovation in cases where 'the vast number of patents currently being

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[201] M Heller & R Eisenberg, 'Can patents deter innovation? The Anticommons in Biomedical Research', (1998) Science 698.

[202] For example, CIPR Report (2002); Bostyn, 'Patenting DNA Sequences (polynucleotides) and Scope of Protection in the European Union'; Gowers Review; IPI, 'Patents for Genetic Sequences: The Competitiveness of Current UK Law and Practice'; Nuffield Council on Bioethics, 'The ethics of patenting DNA'.

[203] Article 69 (1) European Patent Convention 1973, adopted into UK law by s. 125 Patents Act 1977.

[204] The crucial documentation for a patent application is the patent specification (see Cornish page 152 "...the crucial document in the whole process of securing and relying upon a patent is the specification."). The specification is in two parts; the description and the claims. These must disclose the invention sufficiently so that it can be performed by a person "...skilled in the art" to avoid claims of insufficiency (See Patents Act 1977 s 72 (c) and (d)). The claims will also lay out the scope of the claimed monopoly.

issued creates a very real danger that a single product or service will infringe on many patents.'[205]

(2) (E) (IV) PATENT POOLS

A patent pool occurs when two or more patent owners agree to license a grouping of their patents to others or to themselves[206]. Patent Pools have been used in particular in the electronics industry[207].The negative effects of patent stacks or pyramids have been anticipated in certain areas by researchers who in an attempt to mitigate the difficulties have resorted[208] to patent pools[209]. This reaction may appear to be benign and in some instances it may well be especially if the aim or justification for setting up patent pools is to increase access and lower licence fees. After all research groups are to some extent reliant upon each other and require access to available material in order to survive and prosper. The negative side is that pools are traditionally seen as anti-competitive. Pooling resources with which to license is in effect the same thing as forming a cartel and can give rise to particular anti-competitive behaviour such as price fixing.

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[205] Shapiro C, 'Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard Setting, Chapter Four, Jaffe A, Lerner J and Scott S, *Innovation Policy and the Economy'* National Bureau of Economic Research, London page 121

[206] A patent pool is an agreement between two or more patent owners to license one or more of their patents as a package to one another or to third parties willing to pay the royalties associated, either directly by patentees to licensees or, indirectly, through a new entity specifically set up for administering the pool" Somsen H, *'The Regulatory Challenge of Biotechnology: Human Genetics, Food and Patents'* (Edward Elgar, Cheltenham 2007) at page 251.

[207] Grubb P.W., *'Patents for Pharmaceuticals and Biotechnology, Fourth Edition'*, Oxford University Press, 2004, at page 417

[208] "Patent pools have been suggested as an alternative solution for the emergence of patent thickets" Grubb ibid page 147

[209] Research has been carried by Innogen project as part of the ESRC Genomics network including the "Co-operative Management of Intellectual Property Rights" which looked at the use of patent pools and clearing house mechanisms for intellectual property. See http://www.genomicsnetwork.ac.uk/innogen/

(2) (f) Summary

This chapter has examined patent law at different stages of a hypothetical innovation time line. Importantly it has illustrated that the influence or effect of patents changes throughout the time line and that the aims and justifications of patent law are expressed differently within each stage. Thus an incentive at grant stage is created through rewarding inventors at post-grant or exploitation stage. The incentive/reward is balanced against subsequent restrictions of access or higher prices that may result from patent grants but this is justified on the basis that more innovation overall occurs as a result of patents. If the balance between incentive and subsequent restriction in access is weighted too much in favour of the patentee then this could have a negative effect upon innovation. Arguably this is an issue that is directly relevant to patent grants and when considered in the context of biotechnology where restrictions upon access can mean restrictions in further research and access to important treatments it becomes a moral question. The moral questions that have emerged from patent decisions have however revolved around quite different subject material than exploitation and access but because of biotechnology have centred more upon effects or possible effects of inventions. Chapter four will look at morality and patent law in greater detail and the following chapter will examine the ways in which new technology has nuanced traditional views of patent law.

(3) Chapter Three – Biotechnology Patents

Basic patent requirements are virtually[210] the same for all inventions. Particular characteristics of biotechnological inventions have resulted in a number of specific rules relating to bio-patenting[211] along with stricter procedures in respect of basic patent hurdles[212]. Furthermore the Biotechnology Directive, although merely intent on clarifying and repeating previous practice, contains rules which are specific to biotechnology and which have profound implications[213] in respect of what can and cannot be protected. The debate surrounding protection for biotechnology continues. This chapter outlines the characteristics of biotechnology that give rise to this contradiction, discusses their implications and the effects that this has had on patent rules.

(3) (a) Biological Material

Biological material is defined by the Biotechnology Directive, as 'any material containing genetic information and capable of reproducing itself or being reproduced

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[210] There are some specific rules that apply to particular types of invention. For example, some rules relating to inventions stemming from information technology and to biotechnology have been adopted in order to cope with the particular characteristics involved in those particular industries but the same basic principles apply all the same. Furthermore there are possible differences in treatment of biotech inventions as suggested by the OECD, in relation to biotech inventions, in its report in 2004 that 'patent offices may choose or be asked to apply stricter guidelines when interpreting whether an invention is novel, useful or represents an inventive step.' (OECD, 'Patents and Innovation: Trends and Policy Challenges').

[211] As with those within Directive 98/44 of the Biotechnology Directive.

[212] See *Genentech Inc.'s Patent (Human Growth Hormone)* [1989] RPC 147, CA, for example and although this case rested much upon its own facts. There have been some suggestions that patent grant hurdles should be raised, see OECD, 'Patents and Innovation: Trends and Policy Challenges', which suggests applying stricter rules for biotech than other inventions, as does the Nuffield Council on Bioethics report, 'The ethics of patenting DNA'.

[213] Including an increase in specific exclusions from patentability – see below.

in a biological system'[214]. This is not a new phenomenon[215] and neither is the patenting of biotechnological inventions. A variety of inventions can come under this definition and it is important to understand when an invention becomes patentable and when inventions are not classed as patentable.

There is a sliding scale of what is acceptable to patent and what is not[216]. For example cells in the body are not patentable, whilst those that have been isolated[217] are potentially (i.e. they still have to qualify) patentable. Simple isolation of DNA may only be useful for further research which may lead ultimately to treatment or treatments. Thus there is a chain of biological material that may ultimately lead to some public benefit. Each stage relies upon its predecessor and so must take any previous patents into account. This chain is important because of the reliance of later inventions upon earlier ones and the earlier they are the broader they are likely to be. Subsequent inventions may therefore be blocked, subject to licence agreement or infringe patents.

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[214] Article 2 (1) (a) Biotechnology Directive.

[215] Biotechnology has its early origins thousands of years ago with beer brewing and bread making in Mesopotamia. Hence it is by a long stretch not a new phenomenon although the term biotechnology was first noted to have been coined in the 1920s (Grubb, '*Patents for Chemicals, Pharmaceuticals and Biotechnology*').

[216] The development of the law in Europe as to what is patentable has generally favoured a sympathetic approach for patent applicants. For example *CIBA GEIGT/Propagating Material* [1984] OJEPO 112 held that no "general exclusion of inventions in the sphere of animate nature could be inferred from the EPC" and *LUBRIZOL/Hybrid plants* T 320/87 [1990] O.J. EPO 59 followed a similar approach. Both cases related to hybrid seed production but the "effect of these decisions was to place a narrow construction on the Article 53(b) exclusion as applied to plants" (Cook *"a users guide to patents"* Butterworths 2002, at paragraph 812). The decisions were followed in *HARVARD/Onco-mouse* T19/90, see chapter Four

[217] Article 3 (1) (2) Biotechnology Directive.

(3) (b) Biotechnology – The Characteristics

The features of biotechnology patents that give rise to concerns regarding their use and exploitation are emotive and complex. DNA is personal in that everyone is unique; nevertheless we have much in common. 'We are all alike on the inside'[218] so DNA is sometimes described as a form of 'common heritage of mankind'[219]. This arouses arguments that its special status should not result in commercial gain or if there is to be profit it should be for the public benefit rather than private advantage[220]. Biotechnology has a long history but 'modern biotechnology' is relatively new and its potential is not yet fully known.

It can easily be argued that the public must be the main beneficiary, even though it is not jointly or severally, except through its legal and political representatives, a party in relevant patent processes. No doubt the patent system creates benefits for commercial

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[218] Mark Twain. Astute literary comments aside, human DNA varies to a minute degree between people.

[219] Nuffield Council on Bioethics, 'The ethics of patenting DNA', 21. Ownership of human tissue and genes was also described as common heritage of mankind by the Council of Europe's Committee in Legal Affairs and Human Rights, and common heritage has been referred to in UNESCO's Universal Declaration on the Human Genome and Human Rights (1977).

[220] There are examples of the use of benefit sharing mechanisms to address the objection of lack of openness. See in particular UK Biobank which '...is building a national treasure trove of health information, of an impressive scale, to be used by scientists in the future.' UK Biobank website http://www.ukbiobank.ac.uk/assessment/takepart.php See also conference 'Governing Biobanks- What are the Challenges', Cambridge International Conference June 2008. This included discussions on global systems for governance of biobanks and benefit sharing and how to balance this with protection of the relevant interests involved. A vital balance within biobanks is between privacy, family rights and 'public interest' more details from http://www.ggd.org.uk/index.cfm?fuseaction=events.content&cmid=28 last accessed 23rd July 2008

See also http://www.genomicsnetwork.ac.uk/innogen/ which includes studies into the effects of patent pools and open licenses. Guadamuz A. of Edinburgh School of Law researches, inter alia, open source licensing, see: 'Open Science: Open source licenses in scientific research' (2006) North Carolina Journal of Law & Technology Vol. 7 No. 2, pp.321-366 and 'GNU General Public License v3: A Legal Analysis' (2006) SCRIPT-ed Vol 3 Issue 2, pp.130-139

See also Joly Y, Open Source Approaches in Biotechnology: Utopia Revisited, Maine law Review, Vol. 59. No.2p.386. 2007 and Sulston, Staking claims in the biotechnology Klondike, Bull World Health Organ, Vol.84 no 5 Genebra May 2006

interests but those interests drive innovation so the public should always benefit; eventually.

Watchfulness is the key to the success or otherwise of the patent system and it is clear that it is difficult for any system to maintain balance even if, as in this case, the interests of commerce and of the public are to a certain extent mutual. This requires examination, especially as the thrust of this paper is towards maintaining balance; allowing commercial advantage whilst at the same time protecting the public interest.

(3) (c) Reaction to the Characteristics

The reaction to biotechnology in patent law has been felt in the way that patent law has been interpreted and through questions being raised about the purpose of patent law in the innovation process, with emphasis being upon the ethical role of patent law rather than on the access effects of patent grants.

Opposition to biotechnology has been organised and promoted with emotive and often justifiable arguments so that the patent system has been compelled to address issues for which it is not fully equipped. It is important that the biotech industry should progress financially and morally, therefore the role of patent law with respect to both needs to be examined.

(3) (C) (I) THE METHODOLOGY USED TO PROTECT BIOTECHNOLOGICAL INVENTIONS

The controversy surrounding biotechnology and the patenting of biotech inventions is however relatively new[221] in comparison with the technology. There are few differences between the patent rules that govern other types of inventions and those that relate to biotechnology: '...in general, biotechnology is to be treated no differently from any other inventive science that comes forward with patent claims'[222]. Further as the '...legal protection of biotechnological inventions does not necessitate the creation of a separate body of law...'[223] much of the following could be applicable to any form of technology. It may seem that 'The legitimacy of biotechnology patents' is 'beyond doubt'[224]. Years of debate and a short lived contemplation of alternative methods[225] of

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[221] The development of biotechnology can be separated into three stages; stage one being the early traditional fermentation technologies, with the second stage emanating from the discoveries of Louis Pasteur (whose patent for 'yeast, free from organic germs of disease, as an article of manufacture', was the first patent for living technology. Stage three, or modern biotechnology, covers the areas relevant to this work, namely work such as recombinant DNA technology, cloning and stem cell therapy, in particular in relation to human tissue. It is this latter stage where the difficulties and questions have arisen into whether biotechnology is acceptable and in particular whether it should be patentable. See Dutfield, Intellectual Property Rights and the Life Science Industries, and Grubb, Patents for Chemicals, Pharmaceuticals and Biotechnology, for a detailed and interesting account of the history of biotechnology related inventions.

[222] D Beyleveld, R Brownsword and M Llewelyn, 'The Morality Clauses of the Directive on the Legal Protection of Biotechnological Inventions: Conflict, compromise and the patent community', in R Goldberg and J Lonbay (eds) '*Pharmaceutical Medicine and European Law*' (CUP 2000) 157.

[223] Recital (8) Biotechnology Directive.

[224] UK Patent Office 'Guidelines for patent applications relating to Biotechnological Inventions in the UK Patent Office' (November 2003), clause 5 available from < www.patent.gov.uk/patent/reference/biotechguide/background.htm >. 'Patenting such cultured cells is now so well established a practice that it would be almost impossible to turn back', Professor Peter J Whittaker, 'Stem Cells, Patents and Ethics', Centre for Economic and Social Aspects of Genomics (2002), Institute for Environment, Philosophy and Public Policy, Lancaster University. 'It now looks increasingly unlikely that a sui generis approach will be developed', Holyoak and Torremans Intellectual Property Law, 89). The Biotechnology Directive also states at Recital 8: 'Whereas legal protection of biotechnological inventions does not necessitate the creation of a separate body of law...'. See also Cornish et al., 'Intellectual Property Rights (IPRs) and Genetics', 12: 'In recent years there have been projects to create a new form of right in genomic information which typically aims to procure a return from users to discoverers without stopping actual use of the information. These have not so far made significant political headway.'

providing incentive for biotechnological invention, have led to the Biotechnology Directive and patenting of genetic material continues unabated. The controversy[226] over the patentability of human genetic material is not going away and the amount of official, academic and commercial discussion[227] grows and expands.

Biotechnology raises particular issues and in Europe steps have been taken in the form of the Biotechnology Directive to 'clarify' the law and consequently prevent 'differences...offered by the laws and practices of the different member states...' from creating '...barriers to trade and hence impede the proper functioning of the internal market.'[228] Saying that the Biotechnology Directive added little to existing law, '...one can only conclude that the Directive did not really cover a lot of new ground'[229] although it reaffirmed much existing law and practice. That is not to detract from the harmonising effect that the Directive intended and achieved, indeed it provided a framework for biotechnological inventions for some countries which had hitherto not achieved a developed case law on the matter. There are features of biotechnology, though, that have caused patent law to be interpreted in a particular way and unique

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[225] For example copyright – Laddie, Prescott and Vitoria, '*The Modern Law of Copyright and Designs*', Volume 1, Chapter 21, 'DNA and Protein Sequences', 853: 'could copyright be a solution?'.

[226] The Biotechnology Directive was eventually adopted after 10 years of negotiations. A previous draft had failed through disagreement and even seven years since it was first agreed eight signatory states have failed to implement it despite referral to the European Court of Justice. Before it was adopted opposition was strong within the parliament and continued afterwards, both by opposition from environmental pressure groups and from member states. The Dutch government with support from Italy and Norway brought an action before the Court of Justice against the European Parliament and Council of the European Union which was dismissed in October 2001. There will be a fuller discussion on the ramifications of this action later.

[227] See generally, G Kamstra, M Doring, N Scott-Ram, A Sheard and H Wixon, '*Special Report – Patents on Biotechnological Inventions: The EC Directive*' (Sweet & Maxwell, London 2002); Cook, A User's Guide to Patents; Grubb, Patents for Chemicals, Pharmaceuticals and Biotechnology; R Goldberg and J Lonbay (eds), Pharmaceutical Medicine, Biotechnology and European Law (CUP 2000); Bostyn, '*Enabling Biotechnological Inventions in Europe and the United States*':

[228] Biotechnology Directive, Recital (5)

[229] '*Holyoak and Torremans Intellectual Property Law*', 90.

objections have arisen to biotechnology and patenting of biotech inventions that are unlikely to be raised against other forms of inventions. The nature of biotechnology is such that it may appear to relate to natural products which are not new whilst patent law provides protection for inventions which are new. This, admittedly, is a rather sweeping statement but it serves as a simple illustration of the initial difficulties that faced biotech patentees, namely that their inventions had to be distinguished from discoveries and their natural origins. As a result the patent rules were cleverly interpreted so as to adapt to biotechnology. A separate regime, similar, for example, to that chosen for the patenting of plant life, was not created for biotechnology possibly because it was considered unnecessary or wasteful to create further sets of regulations every time a new technology emerges. One consequence of this approach is that the method used to patent becomes entrenched before the policy makers fully understand the particular difficulties that the industry may offer.[230] The result for patent law has been that the rules have been interpreted using an intelligent approach, allowing patents to be granted, but what differences are there between biotech inventions and other inventions that have created problems?

(3) (C) (II) NATURE OF BIOTECH INVENTIONS

Patent law provides protection for inventions that are new and it excludes discoveries. Biotechnology inventions relate to natural material which gives the twin difficulty of

[230] 'Unfortunately policymakers usually do not have sufficient understanding of the path of such technology and the implications for an appropriate intellectual property regime during this nascent stage of development. Policy makers thus are left in the awkward position of either creating a regime before they adequately understand the problem or waiting until the contours of the problem emerge, at which point economic interests have vested, and reform of it if possible at all, is severely constrained.' Menell P S, University of California, Berkeley, 1994.

being a discovery and already in existence. The US Supreme Court[231], by a majority of five to four, set the tone for the future of patents for life sciences in the United States by allowing a patent over artificially produced bacteria. By holding that in the US, '...anything under the sun that is made by man' is patentable, the court decided the issue that because something was alive that did not mean that it was unpatentable. The crucial issue was whether an invention had been made by man. Although this applied only to the US, and indeed the British version of the patent had already been granted[232], the same distinction, namely made by man[233], forms the essence of the patentability of biotechnological inventions as can be seen in the European Biotechnology Directive:

> Article 3
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> 1. For the purposes of this Directive, inventions which are new, which involve inventive step and which are susceptible of industrial application shall be patentable even if they concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used.

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[231] *Diamond v Chakrabarty*, 447 US 303 (1980),

[232] Grubb, '*Patents for Chemicals, Pharmaceuticals and Biotechnology*', 248.

[233] See also T 320/87, *LUBRIZOL/Hybrid plants*, "...where the TBA held that a determination of whether a nonmicrobiological process is essentially biological depends on the extent of human intervention, the result achieved thereby, and the essence of the invention. Human intervention is not enough *per se*; such intervention has to be more than trivial" Campbell P @Patentable Subject Matter in Biotechnology, CASRIP, UW School of Law available from http://www.law.washington.edu/Casrip/Newsletter/Vol14/newsv14i1Campbell.html#IV last accessed 8th July 2008

2. Biological Material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature.

Article 5

1. The human body, at the various stages of its formation and development and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.

2. An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.

Thus naturally occurring substances and elements of the human body may be patentable so long as there has been some technical intervention, isolation or production which creates a new substance. This 'application of human endeavour to produce a technical solution to a previously unresolved technical problem'[234] is the definitive remedy to the hurdle of 'patenting life' and the exclusion of discoveries from patentability.

[234] G Laurie, '*Genetic Privacy. A challenge to Medico-Legal Norms* '(CUP 2002), 305.

There have been similar prevarications in relation to industrial applicability (or in the United States 'utility') of biotechnology patents. In the United States patent applications were rejected over fragments of gene sequences without known utility and in Europe the Biotechnology Directive states that gene sequences without known function cannot be patentable[235]. The point was the subject of a report by the Trilateral Project in their 2003 comparative study on Examination Relating to Nucleotide Polymorphisms (SNPs) and Haplotypes[236][237]. A "specific, substantial and credible utility that could be practiced without undue experimentation" was the USPO approach whilst the EPO's view was that SNPs were likely to fail because of lack of inventive step. The Japanese Patent Office queried the link between claimed function and SNPs.

Biotechnology has gradually fitted into the patent system, albeit with some semantic hurdles. 'Given the commercial importance of the products of biotechnology and the politicized nature of the patent literature, it is not surprising that the problems of interpretation posed by biotechnology have been treated, on the whole, as mere obstacles to be avoided, rather than stumbling blocks to patentability.'[238] The result is a partnership of sorts but not one blessed with harmony.

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[235] Article 5 (3) "The Industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application" This was confirmed by the ECJ in *Kingdom of the Netherlands v European Parliament and the Council of the European Union*, Case C-377/98, [2001] ECR I-7079, the United Kingdom Intellectual Property Office and EPO agree that known function is essential

[236] i.e. combinations of SNPs

[237] Trilateral Project WM4, Comparative Studies in new technologies, "Report on comparative study on Examination Practice Relating to Single Nucleotide Polymorphisms (SNPs) and Haplotypes, June 10-12, 2003, available from http://www.trilateral.net/projects/biotechnology/examination_snp/examination_on_snps_haplotypes.pdf , last accessed 27th June 2008. Part of the aims of the Trilateral Project is to harmonise practice of the patent offices of EPO, Japan and United States

[238] B Sherman, 'Patent law in a Time of Change: Non-Obviousness and Biotechnology' (1990) 10 Oxford Journal of Legal Studies, 278-287, at 286.

The case of Genentech Inc.'s patent[239] illustrates the reining in of patents over biotechnology. The lengthy judgement covers many points, two of which will be noted here. The first is the adaptation of the notional skilled worker to correspond to new perspectives and the second raises comments that question the suitability of patent law for the protection of biotechnological inventions.

The traditional test to define whether a step taken by a patent applicant is sufficiently inventive is whether that step was obvious to a person skilled in the art in question and that person '...is supposed to have an unlimited capacity to assimilate the contents of, it may be, scores of specifications but to be incapable of a scintilla of invention'[240]. This fictional character has been the subject of criticism[241] but the situation remained that the question of obviousness was to be assessed through the mind of someone who could not invent but was aware of the entire prior art. Genentech changed the situation because it was felt by the Court of Appeal that in an industry which was characterised by intelligent people[242] whose job it was to be inventive it would be unrealistic to characterise the notional man as uninventive. Genentech failed to obtain patent protection for their production of human plasminogen activator[243] for a variety of

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[239] *Genentech Inc.'s Patent* [1989] RPC 147.

[240] *Technograph Printed Circuits Ltd v Mills and Rockley (Electronics) Ltd* [1972] RPC 346.

[241] This notional character has been described as 'unrealistic' (Holyoak & Torremans Intellectual Property Law, 67), that he may lead to confusion (*Windsurfing International Inc v Tabur Marine (Great Britain) Limited* [1985] RPC 59) and as being a 'folksy way of explaining the law to a jury' (*Société Technique de Pulverisation Step v Emson Europe Ltd* [1993] RPC 513 at 519).

[242] '...one cannot treat them as dull plodders...some substantial measure of ingenuity is an essential qualification for being engaged in the enterprise.' (*Genentech Inc.'s Patent* [1989] RPC 147, 279–280 per Mustill LJ).

[243] Genentech's patent related to a new method of synthesising t-PA used for preventing blood clotting and as the method allowed substantial quantities to be produced, the value to Genentech in terms of revenue was enormous and to thrombosis patients it was vital.

reasons[244] including non-obviousness, but the important point to note for this work is the new hurdle that was presented to the biotechnology industry by this new test.

It is an oxymoron for a system that provides patent for inventiveness to refuse patents because the industry in question is inventive. Admittedly this is not a bar to patentability, because showing a level of inventiveness above the norm in the industry should suffice to surmount that particular hurdle[245], but nevertheless this change creates an advance in difficulties for the biotech industry. One wonders whether other factors influenced the decision which leads to the second point of underlying concern regarding suitability of patents for biotechnology, and indeed it is clear that Mustill LJ had this consideration in mind when giving judgement:

> If a sufficient reward is not given in those instances where the research bears fruit, the industry will not attract the venture capital which it needs for survival, the research will cease, and humanity will continue to suffer...it may well be that the work done by Genentech seems worthy of a reward greater than a few months' start on the road to a marketable product. Yet I am driven to conclude both that the monopoly claim exceeds any legitimate award and also that for want of inventive step Genentech are not entitled to any reward through the patent system...

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[244] The court found that some of the claims related to discoveries without the necessary application to define them as inventions and because of obviousness.

[245] It is worth noting that Purchase LJ in the *Genetech* case discussed the artificiality of the ordinary skilled man test. See page Genentech [1989] RPC at page 280 – "I believe that this question is incapable of being answered in vacuo. Not only will the standard differ from case to case, but there may well also be differences between the individual members of the teams... There is no single standard...obviousness is a jury question. This question mustbe in the light of a highly artificial test which, although compressed into a few words in the Act, is impossible to elaborate with any degree of precision."

Mustill LJ is pointing to the fundamental issue regarding the patenting of biotechnology; that protection is needed but patent law fails to provide it. 'I believe that the prime reason why these questions are so hard to formulate is that the structure and philosophy of the Act are not appropriate to an enterprise of the kind undertaken by Genentech.'[246]

We can say that things have moved on and that Genentech is an unusual case that rests on its own particular facts but the point is made nevertheless that there is judicial concern about the potential monopoly over certain patent applications and the contribution made. Indeed evidence was presented at the Genentech hearing pointing to the enormous value of their invention[247]. In the United States, in the case of Amgen Inc[248], District Judge Young C.J. commented in order to indicate the potential value of what was at stake, on how 'publicly traded stocks of the litigants would bob or dip in response to some random comment by the court, the trial lawyers, or a particular witness'.

Thus the grant of patents over biotechnology has raised a number of important and new consequences for research, investment and morality issues. The biotech industry would appear to be more reliant upon patents than other industries, the questions of what is being created versus the moral questions of what is trying to be achieved are very different and significantly broader than questions raised for 'traditional' patents

[246] *Genentech Inc's Patent* [1989] RPC at 274 per Mustill LJ.

[247] The estimates were in excess of US$ 1 billion per annum.

[248] *Amgen Inc v Hoechst Marion Roussel Inc and Transkaryotic Therapies Inc* January 19th 2001, No. 97 – 10814 – WGY.

and importantly the answers are not black and white. Furthermore the rewards are also potentially greater and the consequences of success are likely to have a greater effect on society than other inventions. If patent law is to try to achieve a balance then the issues raised need to reflect both the important changes in the manner that patent research is carried out and the difficult ethical questions that are being asked.

(3) (d) Consequences of the Characteristics

The consequences that have arisen out of the quality and potential of biotechnology inventions, the status of DNA and the youth of the 'new' biotechnology industry have given rise to three categories of concern for its promotion and development. The first relates to the expense of completing research in an industry especially when it is always difficult to forecast what the outcome is going to be. But the rewards can be enormous and in certain circumstances arguably at the expense of public interest and possibly to the detriment of further research. The second area of concern relates to possible restrictions to access to further research and the third has to do with the morality of the use and exploitation of biotechnology.

(3) (D) (I) PATENT RELIANCE AND POTENTIAL

Evidence suggests[249] that the biotech industry relies more heavily and at an earlier stage upon the grant of patent rights than other industries:

[249] See below for a brief discussion of some features of the development of the biotech industry. For a fuller discussion, see Grubb, Patents for chemicals, pharmaceuticals and biotechnology, or The Danish Council of Ethics, Patenting Human Genes and Stem Cells (2004). For a critical view of drug development see M Goozner, *'The $800 Million Pill: The True Cost of New Drugs'* (University of California Press 2004).

> Achieving uniformity and clarity in this area of the law has been regarded as a major factor in influencing the climate for innovation and competitiveness for the bioscience sector, which is generally research intensive and strongly dependent upon intellectual property protection.[250]

Two main consequences stem from reliance upon patents. The first consequence is that the distance between basic research and commercialisation has lessened. The second, which has occurred in part because of the first, is an increase in patenting by public sector organisations including universities[251]. Such research may have previously been more likely have been published open for access by any user. One could look on this as a sensible collaboration between universities and business, or a reasonable method to allow universities to raise contributions towards research which would otherwise have had to come from grants or government funding. Alternatively it could be seen as a sinister development that results in tighter information controls and higher end prices. Whatever side of the fence one sits on, there are ramifications for patent law that must be considered. 'But in Europe, too, the trend towards early patenting and concealment of knowledge is posing an obstacle to collaboration and openness in research'[252]. Early stage patents feed through into later work, further research may require licensing and there are cost and access issues that work against the original purpose of the patent

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[250] IPI, 'Patents for Genetic Sequences: The Competitiveness of Current UK Law and Practice'.

[251] 'The prohibition on patenting discoveries is similarly contained within both the UK and European legislation and its social utility is ensuring that a distinction is made between pure and applied research. This is a distinction which was far easier to distinguish before it became apparent that public research was generating patentable inventions, but is still a divide identifiable in most cases by the difference between making an observation and effecting a creation.' Warren-Jones, 'Patenting DNA: A lot of controversy over a little intangibility'. Page 110

[252] The Danish Council of Ethics, Patenting Human Genes and Stem Cells (2004).

system. Are the benefits obtained through the patent system greater than the negative impact and if so what choices does patent law have to counter the problem?

Biotechnological research involves great costs and if the results of research are developed into a new treatment this requires enormous investment. The Nuffield Council on Bioethics in 2002[253] estimated that on average the cost of each development is about £110 million and other estimates have been higher than this[254].

It follows that on these sorts of scales the potential profit for creating a new technical medical breakthrough must be sufficient to justify the risk and expense of development. The market for the enzyme involved in the case of *Genentech Inc.'s patent (Human Growth Hormone)*[255] was estimated to be worth in excess of US$1 billion per year[256]. Yet despite the expense of developing from origins, the ability to copy or reproduce work is relatively cheap.

These characteristics result in an understandable need to protect valuable research as early as possible:

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[253] Nuffield Council on Bioethics, 'The ethics of patenting DNA'.

[254] Nuffield Council on Bioethics, 'The ethics of patenting DNA', page 14. The Nuffield Council on Bioethics gave two estimates of the cost of drug development. The first from the Tufts centre for the study of drug development estimated that the cost for developing a new prescription drug was $802 million whilst US national consumer group, Public Citizen, estimated $110 million. These figures are open to question as a study by Public Citizen argued: 'A new study claiming that the average cost of developing a new prescription drug is $802 million once again significantly overstates real research and development (R&D) costs, according to an analysis by the national consumer group Public Citizen.'

[255] *Genentech Inc's Patent (Human Growth Hormone)* [1989] RPC 147, CA.

[256] Laddie, Prescott and Vitoria, '*The Modern Law of Copyright and Designs*', 852.

> This suggests that without patent protection, some novel medicines might never be invented. It is often conceded that, while patents may not always increase innovation, when they do, it is usually in the pharmaceutical and biotechnology sectors.[257]

Although there is a debate about whether patents actually hinder scientific development and economic growth it is clear that patents have had, and continue to have, a central and established role to play in the biotech industry. This is recognised in Recital 1 of the Biotechnology Directive which states, inter alia: '...the protection of biotechnological inventions will certainly be of fundamental importance for the Community's industrial development'[258]. Although one could perhaps argue that developments may possibly have occurred without the need for patents, success in the biotech industry has evolved through the use of patents and the industry is, as a result, in its present form, largely reliant upon them. This too is recognised in the Biotechnology Directive in Recital 2: '...research and development require a considerable amount of high-risk investment and therefore only adequate legal protection can make them profitable'. The biotech industry developed through small research companies, most of which needed finance and were without internal reserves to draw upon or established capital base to borrow against. They therefore had to

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[257] Nuffield Council on Bioethics, 'The ethics of patenting DNA a discussion paper',, 14

[258] Recital (1) Biotechnology Directive: 'Whereas biotechnology and genetic engineering are playing an increasingly important role in a broad range of industries and the protection of biotechnological inventions will certainly be of fundamental importance for the Community's industrial development.' See also the subsequent reports on the workings of the biotechnology industry, European Commission: 'Development and Implications of patent law in the field of biotechnology and genetic engineering', Report to the European Parliament and the Council, COM (2002) 545 final, and COM (2005) 312 final.

attract venture capital by utilising the patent system[259]. In turn venture capitalists have recognised the value of patents as a method of securing their investment and have come to regard a strong patent portfolio is an essential ingredient to attracting investment[260] 'and the larger the portfolio (usually measured by the quantity of patents rather than their quality), the greater the interest from investors'[261]. It may be appropriate to go as far as to say that a patent is the most important link in the chain of development: 'For many companies the patent becomes the product...' [262], and it seems that the relative strength of a patent can be as important as the feasibility of the end product[263].

Several studies bear out the essential role of patents for biotech. The 1986 Mansfield Study[264] found that 17% of machinery-based products would not have been introduced without patent protection but the same study found that 60% of pharmaceutical (including biotech) inventions would have been absent if patent protection was

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[259] There are many discussions on the background of the growth of biotechnology industry. Generally they describe a system of smaller companies with only a few making it into the big league. These would include Genentech and Amgen Inc., both of which are now organised on the scale of pharmaceutical companies. They also illustrate how the patent system has been vital in encouraging these small companies to grow. These include; Dutfield, '*Intellectual Property Rights and the Life Science Industries*'. See also OECD, 'Patents and Innovation: Trends and Policy Challenges', Report 2002.

[260] 'In many cases, patents are a start-up company's most valuable assets. As such, patents are essential to securing additional capital from investors as these companies and their science grows and develops.' Ernst & Young, 'Beyond Borders: Global Biotechnology Report 2007'.

[261] Dutfield, '*Intellectual Property Rights and the Life Science Industries*', 153

[262] C Fowler, '*Unnatural Selection: Technology, Politics and Plant Evolution*' (Yverdon, Gordon and Breach 1994), 173.

[263] '...the biotech firm Genetics Institute decides which version of a drug to develop partly based on which iteration shows the best results in clinical trials but also according to which version can command the strongest patent protection', KG Rivette and D Kline, 'Discovering New Value in Intellectual Property' [2000] Harvard Business Review, 54.

[264] E Mansfield, 'Patents and Innovation: An Empirical Study',(1986) 32 Management Science, Vol. 32. No.2 (Feb. 1986) pp 173–181.

unavailable. A previous study in 1981[265] claimed that 90% of pharmaceutical innovation was introduced only because of the ability to obtain a patent. A separate survey[266] in the US produced similar results. 'The patents that a firm holds are seen by investors as the most important factor in deciding whether or not to invest in a company'[267]. A more recent study presented evidence[268] to suggest that the regulation regime and the availability of intellectual property protection[269] are the two most important variables in the biotech innovation process. This dependency has developed due to a number of characteristics of the industry. First the biotech industry is extremely risky. Most projects never make it to market. The work is costly and time-consuming. The small size of the typical biotech company has encouraged a reliance on patents to attract investment. Indeed it could be that the existence of patents has encouraged this proliferation of small firms, in place of larger established companies[270]. The results of the work are easily copied in comparison to production from first principles, thus the need for protection. In the event that a success story is made from a research project the potential returns can be enormous and without patent protection those returns would be reduced substantially due to the ease and low cost of

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[265] Mansfield, Schwartz & Wagner, 'Imitation costs and patents: An empirical study' (1981) 91 Economics Journal 907.

[266] F M Scherer, 'The Economics of Human Gene Patents', 17 Academic Medicine, 1348, 1351; Yale-Levin Study 1987 Carnegie-Mellon University survey 2000

[267] Black, 'Regulation as Facilitation: Negotiating the genetic revolution', 53.

[268] Ernst & Young 'Total Value of Information' 2004 available from <www.ey.com/global/content.nsf/US/Health_sciences_-_Articles_-_WEF_2004_-_Innovation_Divide>. Ernst & Young rated innovation variable in accordance to percentages and Intellectual property counted towards 32 % and regulatory environment counted for 29%.

[269] In the case of biotechnology patents.

[270] See, inter alia, Ernst & Young, 'Beyond Borders: Global Biotechnology Report 2007' on the continuing reliance of small biotech companies on patents for investment. 'In many cases patents are a start up company's most valuable assets. As such, patents are essential to securing additional capital from investors as these companies grow and develop.' (ibid. page 6).

copying. The result is an industry that is to a certain extent reliant upon the patentability of its inventions.

There are a number of consequences of this, including more patents which at least is evidence that there is much research taking place[271] and since a patent is only granted for something that is novel, there are more inventions. The negative side to the increase in patenting activity is that as more patents emerge they protect more material because of the protection that patent law affords and the protected products are not necessarily available as an open resource. A balance has to be struck between what must be protected and what ought not to be allowed to become unnecessarily restricted. The biotech industry is reliant upon patenting so changes to the general rules of patent law will have a greater effect on that particular industry than upon other industries. The consequences of these two points will now be examined in more detail.

(3) (D) (II) ACCESS - RESEARCH STRUCTURE

There are new consequences for biotechnology research due to the granting of patent rights over biotech inventions. This is caused by a number of factors which have ramifications for future research and access to patented material. First there has been an increase in academic patenting[272] which has had the effect of helping to increase the amount of patenting activity as well as augmenting patents over early stage interventions[273]. 'Certainly IP has a rising significance that hovers around universities.

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[271] It may also be evidence of more commercial awareness and increase in public sector patenting. The CIPR report, 'Integrating Intellectual Property Rights and Development Policy', (September 2002), suggests: 'This increase appears to reflect growth in the intensity of patenting ...rather than a 50% increase in the number of inventions'.

[272] See OECD, 'Patents and Innovation: Trends and Policy Challenges'.

[273] Universities are encouraged to form patent links with business and take out early patents that often form the basis for further research – i.e. research tools. In other words, patents are encroaching further into the research exemption – one result is the formation of middle companies that promote research

Scientific colleagues, for example, no longer have research results; they have their IPRs.'[274]

As well as the increase in academic patents, patenting over early stage interventions has been increasing because modern biotechnology[275] is a new science which is still in its relative infancy[276]. 'The corresponding distinctions between basic or academic research on the one hand, and applied or commercial research on the other have been somewhat obscured as a result.'[277]

One consequence of this is that patents may be granted which cover uses not envisaged at the time of grant. This can mean that improvements are prevented or hindered due to licence fees payable down the line to holders of early patents. These patent pyramids or stacks have become a feature[278] of biotech patent law and have caused access issues even in cases where the subsequent use was never envisaged[279] by the original patent holder.

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between stages. Danish Council of Ethics, 'Patenting Human Genes and Stem Cells: A report to the Danish Council of Ethics' 2004, at page 55

[274] W Cornish, '*Intellectual Property, Omnipresent, Distracting, Irrelevant*' (OUP 2004).

[275] As discussed earlier biotechnology developed in stages and has a long history, modern biotechnology is still envisaging its potential

[276] 'Patents confer broader protection, especially in new areas. Patent claims in new areas often cover far more than what the inventor actually discovered or invented', OECD, 'Patents and Innovation: Trends and Policy Challenges', 18)

[277] Herder M, Proliferating Problems with Human Embryonic Stem Cell Research, Journal of Bioethical Inquiry, Springer (Netherlands), Volume 3, Numbers 1-2/August 2006 pages 69-79

[278] See below and also Nuffield Council on Bioethics, 'The ethics of patenting DNA' for a further discussion, and IPI, 'Patents for Genetic Sequences: The Competitiveness of Current UK Law and Practice', and OECD, 'Patents and Innovation: Trends and Policy Challenges'.

[279] See discussion below and OECD, 'Patents and Innovation: Trends and Policy Challenges', 18: 'Some of the current patenting practices in new areas may extend protection to a broad range of applications unknown at the time of patenting (e.g. uses of genes)'.

Another consequence for patent law that arises out of the increase in academic patenting is that difficulties occur when deciding what amounts to research, thereby raising a defence to the infringement of a patent, and what falls outside the research exemption. There are advantages in this trend such as creating revenue for further research and universities may adopt a defensive patenting strategy so as to prevent commercial exploitation. Furthermore not every case throws up an aggressive and opportunistic patent holder bent on preventing further research. However great potential for abuse remains so in the absence of some form of check and balance then the potential for abuse, purposeful or otherwise, will continue and probably increase which could have the effect of stagnating research and innovation rather than encouraging it as is intended by the patent system.

In summary the biotech industry is characterised by reliance upon patents, in particular early stage patents that are required to enable further research, a high potential value in the event of success and a likelihood of companies having patent banks. However access to material required for further research is potentially restricted due to the existence of patents thus increasing the research costs and slowing the process down. This rather pessimistic picture must however be put into perspective. Although there are examples of the detrimental effects of blocking, which are discussed below, there is also evidence that in many instances the biotech industry has worked around such problems either through negotiating licence agreements, inventing around patents,

multiple patenting[280] or pooling arrangements[281]. Research carried out on behalf of the European Commission[282] to study 'potential negative consequences of intensive intellectual property protection surrounding the human genome...' including '...inhibitory effects on research innovation and access...' suggests that '...it may be too soon to expect such negative effects to be apparent'. On the one hand the report indicated that granted patents were '...primarily on research tools...' and there was evidence of wide protective patenting which would indicate a potential latent danger building up. On the other hand there was also the intimation that there would be a reduction in the numbers of DNA patent applications due to difficulty of finding novel sequences. The report concluded a number of points:

(1) number of DNA patent applications declining;

(2) US has considerably more patents and pending applications due to size of their market, ease of obtaining a patent in the US and lower cost. Concern was expressed that uncertainty surrounding IP protection in different states may have a negative effect on European biotech companies looking to secure investment to expand abroad;[283]

(3) That there had been a tightening of patent requirements and restriction on scope of patents;

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[280] 'A large minority of private sector assignees held a significant number of patents to ensure freedom to operate', PATGEN Project, 'The Patenting of Human DNA: Global Trends in Public and Private Sector Activity', November 2006, Final Project Report, vii.

[281] See above.

[282] PATGEN Project.

[283] PATGEN Project, 43.

(4) That the negative impact of DNA patenting may not be as bad as was first thought.

Thus potential remains for early-stage patents to cause blocking effects but the full extent of that is not yet tested and this would appear to be the conclusion from other reports[284]. The effect is uncertain but a situation where '...every potential inventor is also a potential infringer...'[285] is not a suitable atmosphere for maximising creativity. Case study three in chapter five contains some examples of how situations can arise whereby the characteristics described above have led to situations which question whether patent protection is a suitable medium in its present form to protect early stage biotechnology inventions. The difficulty is how such situations can be remedied within patent law but without causing other problems as a result.

(3) (D) (III) ETHICS - MORAL DILEMMAS – THE 'COULD BE EQUATIONS'

The issue of the morality of biotechnology is a continuing and controversial one within patent law. The provisions within European Patent Law for excluding inventions from patent protection on moral grounds has attracted attention partly because there are few other methods for opponents[286] to debate the ethical merits of inventions and also because such opposition is a convenient way of opposing the biotech industry. As

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[284] 'This report concludes that IP restrictions rarely impose significant burdens on biomedical research, but there are reasons to be apprehensive about their future impact on scientific advances in this area.' ('Reaping the Benefits of Genomic and Proteomic Research: Intellectual Property Rights, Innovation, and Public Health' committee on Intellectual Property Rights in Genomic and Protein Research and Innovation, National Research Council 2006).

[285] R MERGES and R. Nelson 'On the Complex Economics of Patent Scope', (1990) 90 Columbia Law Review, 839.

[286] 'It is ironic that these ethical questions have not been faced head on, but rather, and then only in an indirect way, by proxy through the patent system, which has had the misfortune to provide the only forum in which such objections can be advanced', Cook, *'A User's Guide to Patents'* page 341 para. 8.14.

patents protect and encourage the industry it may be seen by opposition groups, such as Greenpeace or the Green Party, as an effective tool to promote their cause. A number of issues arise with morality in patent law which are discussed in detail in section three below, but these are in brief:

(1) The morality clause was not intended to cater for ethical views that are split nor is it capable of being used in its present form to properly interpret such views[287].

(2) Moral issues that arise often pit the immorality of not patenting (or the benefit of patenting, e.g. the potential for a new medical treatment) against the immorality of patenting (e.g. objections to research of invention). This may be an important issue but I will argue that[288] it is not one for patent authorities to interpret using the current morality clause.

(3) If it is felt that there is a requirement for moral interpretation within patent law, a clear explanation must be provided to whoever has to interpret it, as to what exactly has to be considered to be immoral before a patent is excluded. Another way of examining the morality question is to enquire at what stages in the creation and exploitation of inventions does immorality have to occur in order for a particular invention to be excluded from patentability – because if research is the pertinent issue then that occurs pre grant and raises very different issues to those regarding inventions per se. Equally the use of patents

[287] See chapter four

[288] See chapter four

to exploit inventions can also raise important and difficult moral issues but one which are unconnected to specific inventions.

As I have discussed previously in chapter two, just as the patent system can be divided into different periods where issues of patentability and/or exploitation must be considered separately, so we have seen that different moral considerations arise at different periods and must also be treated accordingly. These points will be considered in the next chapter.

(4) Chapter Four – Moral Exclusions to Patentability

This chapter considers the application of morality within European Patent Law as a means to exclude inventions from patent protection. Historically European patent law has enabled inventions to be excluded from patent protection for moral reasons. The scope of the exclusions, and thus the potential for removing particular inventions from the ambit of patent protection has changed gradually over time but has noticeably altered in scope in recent years because of opposition to biotechnology. Holding patent law complicit in the perceived wrongs of science causes interaction and conflict between two different systems of regulation[289], raising the question of where the boundary lies between the two systems.

Much has been said about whether and if so to what extent morality should be a matter for patent offices and patent law. Traditionally the view is, as expressed by Armitage and Davies[290], is that patent offices are ill-equipped to answer complex moral questions and would be overburdened with additional administration and delay if such a role was to burden it. Indeed both Armitage and Davies were involved in the preparation for the Strasbourg Convention and point out that morality was not part of the early drafts of the Convention[291]. On the other hand the advent of biotechnology has meant that new moral issues are already facing patent law within the rules of the European Patent Convention and Biotechnology Directive and arguably these must be

[289] i.e. between patent law and rules that relate to science

[290] Armitage E and Davies I, '*Patents and Morality in Perspective*', Common Law: Institute of Intellectual Property, London, 1994

[291] Ibid note 281

faced head. Such a view was advocated by D Beyleveld and Brownsword[292] who argued that the European Convention on Human Rights provides appropriate standards with which to follow when assessing morality within patent decisions. Morality standards would be, in this view, rights based rather than a utilitarian equation of relative benefits. The relative arguments for and against morality expression within patent law are examined shortly.

The tension between regimes which regulate science and the patent system, which encourages innovation, has been heightened as a result of the Biotechnology Directive, the stated aims of which are harmonisation[293] and encouragement of biotechnology[294] through the provision of necessary[295] incentives of legal protection. However disharmony has arisen because the Directive expressly expands the extent of the morality clause through the addition of four categories[296] of specific examples of inventions which are '...in particular...considered unpatentable' and because

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[292] See Beyleveld and Brownsword, '*Mice Morality and Patents*', London: Common Law institute of Intellectual Property, 1993. See also Beyleveld D, 'Why Recital 26 of the E.C. Directive on the Legal Protection of Biotechnological Inventions should be implemented in National Law' [2001] IPQ No1, pp1-26

[293] Recital (3): 'Whereas effective and harmonised protection throughout the Member States is essential in order to maintain and encourage investment in the field of biotechnology...'.

[294] Recital (1) '...protection of biotechnology will certainly be of fundamental importance for the Community's industrial development'.

[295] Recital (2):, 'Whereas, in particular in the field of genetic engineering, research and development require a considerable amount of high-risk investment and therefore only adequate legal protection can make them profitable...'

[296] Article 6 (2) Biotechnology Directive - Processes for cloning human beings, processes for modifying the germ line identity of human beings, uses of human embryos for industrial or commercial purposes, processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial benefit to man or animal and also animals resulting from such processes'.

subsequent European Patent Office interpretation[297] has come into conflict with the practices of signatory states.

The position of moral exclusion is complicated within Europe because of the multiple legal systems and cultural differences that exist there. At the international level each state is a signatory to the Agreement on Trade Related Aspects of Intellectual Property (TRIPS), Article 27 (2) of which provides, inter alia, for a minimum standard of patent protection but allows the option for individual states to refuse patents on moral grounds. The aim is to allow for specific national objections to be taken into account. At the European level, the European Patent Convention (EPC) is an international treaty which has a broader signatory base than the European Union and is subject to interpretation according to Law of Treaties. The EPC contains a morality clause preventing the grant of patents if contrary to *ordre public* or morality and this is interpreted at the time of grant by the European Patent Office (EPO). The Biotechnology Directive[298], on the other hand, is a directive of the European parliament and is interpreted by the European Court of Justice but has been included as part of the EPC.

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[297] See inter alia; *Wisconsin Alumni Research Foundation Case* T 1374/04; *Edinburgh Patent* (EP 0695351) (November 2005); O Mills, *Biotechnological Inventions: Moral restraints and Patent Law* '(Ashgate 2005) and A Plomer, 'Stem Cell Patents: European Patent Law and Ethics Report', FP6 'Life Sciences, genomics and biotechnology for health', SSA LSSB-CT-2004-005251.

[298] Directive 98/44 of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions ('Biotechnology Directive').

On a national level, EPC states agree to recognise patents that have been granted by the EPO[299] and the enforcement of patents granted by the EPO remains the responsibility of each state. Each separate country can also grant patents through its own national patent office, valid within that specific jurisdiction, and is able to exclude inventions for moral reasons pertinent to their beliefs. Those reasons may or may not be in sync with morality as interpreted by the EPO. Clearly there are different national laws in relation to research, use and exploitation of inventions and these rules may not necessarily[300] be parallel with the interpretations of morality by the EPO or national patent offices.

The following illustrates that the EPO interpretation of morality is sometimes at odds with national interpretation and that the EPO's interpretation has become broader in scope. This expansive interpretation of morality raises a number questions, two of which will be discussed in this section. What should be the role of the European Patent Office in relation to morality in patent law and what should the role of morality in patent law be?

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[299] Article 2 of the EPC: 'The European patent shall, in each of the Contracting States for which it is granted, have the effect of and be subject to the same conditions as a national patent granted by that state…'.

[300] Exploitation under the various morality clauses is not to be deemed immoral merely because it is illegal.

(4) (a) The Morality Clause(s)

This section is not concerned with entities that by definition are not inventions such as discoveries, scientific theories, mathematical methods and so on[301] but with those that are inventions (i.e. they are novel, involve inventive step and have utility or industrial application) but are not patentable because they are excluded from patentability as a result of moral objections. Many countries' patent systems contain a 'morality clause' enabling exclusions from patentability for moral reasons and the World Trade Organisation Agreement of Trade Related Aspects of Intellectual Property (TRIPS) permits signatory states to accommodate moral objections.

It is more accurate to say morality clauses[302] because within European patent law there are several slightly different versions[303]. The morality clause contained in Article 6 of the Biotechnology Directive states as follows:

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[301] Section 1(2) of the Patents Act 1977 (UK) lists non-inventions.

[302] There are slight differences between morality clauses within Europe as follows. Under Art. 53 of the EPC, European patents should not be granted in respect of:

(a) inventions the PUBLICATION OR EXPLOITATION of which would be contrary to 'ordre public' or morality, provided that exploitation shall not be deemed so contrary merely because it is prohibited by law or regulation in some or all of the contracting states

Under Section 1 (3) of the Patents Act (UK): A patent shall not be granted for an invention the commercial exploitation of which would be contrary to PUBLIC POLICY OR MORALITY; and Section 1 (4) For the purposes of subsection (3) above the exploitation shall not be regarded as contrary to public policy or morality only because it is prohibited by any law in force in the United Kingdom or any part of it.

TRIPS – Members MAY exclude inventions which the commercial exploitation of which is necessary to protect ordre public or morality, provided that such exclusion is not made merely because the exploitation is prohibited by domestic law

[303] There are continuing moves towards harmonising European Patent Law and the EPC 2000, which came into force at the end of 2007, brings the wording of EPC 1973 into line with TRIPS and the Biotechnology Directive by changing the wording 'publication and exploitation' to 'commercial exploitation'.

(1) Inventions shall be considered unpatentable where their commercial exploitation would be contrary to *ordre public* or morality, however, exploitation shall not be deemed so contrary merely because it is prohibited by law or regulation.

(2) On the basis of paragraph 1, the following in particular, shall be considered unpatentable:

(a) processes for cloning human beings

(b) processes for modifying the germ line identity of human beings

(c) uses of human embryos for industrial or commercial purposes

(d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial benefit to man or animal and also animals resulting from such processes.

It is worth noting that Article 6 (2) (a)-(b) are a non-exhaustive list of exclusions, and two further examples were added to the recitals of the directive; processes to produce chimeras from germs cells or totipotent cells of humans and animals[304].

Interpretation of morality within European Patent Law is made more difficult because of European institutional complexity which allows for a variety of conflicting sources at the same time. Inventors can apply for a patent either through national patent offices or through the European Patent Office. The European Patent Convention is an international treaty that includes signatory states which are not European Members,

[304] The legal position of recitals within the Biotechnology Directive has been analysed at length in Beyleveld D, 'Why Recital 26 of the E.C. Directive on the Legal Protection of Biotechnological Inventions should be implemented in National Law' [2001] IPQ No1, pp1-26 and is discussed below at pages 208 - 209

whilst the Biotechnology Directive is a European Commission Directive. The European Parliament has adopted a resolution[305] attempting to restrict the EPO in interpretation of morality relating to the patentability of human embryonic stem cells. There are thus two frameworks[306] in which the interpretation of morality can take place within Europe, the European Union and the European Patent Convention[307].

In the case of *Kingdom of the Netherlands* v *European Parliament and Council of the European Union*[308], the ECJ stated that the provision in Article 6 of the Directive '...allows the administrative authorities and courts of member states a wide scope for manoeuvre in applying this exclusion.'[309] The discretion however is limited by the proviso that '...commercial exploitation is not to be deemed to be contrary to *ordre public* or morality merely because it is prohibited by law or regulation...' and because of the four examples of processes which are not patentable. Although described as a

[305] P6_TA (2005) 0407 European Parliament Resolution on Biotechnological Inventions, although supporting biotechnology and stem-cell research, rejected research on human embryos which resulted in the destruction of embryos (resolution point 3) and to limit patents on DNA to 'purpose bound protection' (resolution point 4). The resolution (points 11 and 12) calls on the Commission to file a notice of opposition under Article 99 (1) of the European Patent Convention, to EP 1257168. This patent was awarded to XY Inc. of Colorado in February 2005, and relates to a 'Method of cryopreserving selected sperm cells'. The Commission opposed the patent on the grounds that the patent covered 'non-patentable human germ cells'.

[306] Attempts are ongoing to harmonise patent law throughout Europe and the London Agreement relating to languages and EPC 2000 are evidence of progress. The experts attending the EPO Conference on Patenting Biotechnology, in Brussels in November 2007, felt that harmonisation had not been achieved as intended by the Biotechnology Directive. See 'Patenting biotechnology inventions: Little harmony in Europe' available from < www.epo.org/topics/news/2007/20071121.html > for more information.

[307] See Plomer, 'Stem Cell Patents'.

[308] Case C-377/98.

[309] Paragraph 37

'...general guide...'[310] by Recital 38 of the Directive, the exclusions amount to a patentability test in their own right. Courts are required to assess whether an invention is invalid under each exclusion[311] and if not then the general morality test is to be considered[312].

The Patents Act (UK), as amended by Regulation 1(3)(a) of the Patents Regulations 2000 in response to the Biotechnology Directive, contains the following morality clause with slightly different wording, replacing '*ordre public*' with 'public policy'[313]:

> Section 1 (3) A patent shall not be granted for an invention the commercial exploitation of which would be contrary to public policy or morality:
>
> Section 1 (4) For The purposes of subsection (3) above the exploitation shall not be regarded as contrary to public policy or morality only because it is prohibited by any law in force in the United Kingdom or any part of it.

Three relevant questions arise from the issue of morality in European Patent Law for discussion here. How should morality be interpreted? How should diverging moral views be accommodated within Europe? In what way can the impact of moral issues in patent law upon regulatory systems be addressed? Much depends upon the purpose of

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[310] The four specific examples are described in Recital 38 of the Directive as providing '...national courts and patent offices with a general guide to interpreting the reference to ordre public and morality...'.

[311] Whether this amounts to a two-stage test or a one-stage test with two questions is irrelevant (Case Number T 0315/03).

[312] *HARVARD/Transgenic Animals,* Case Number T 0315/03 – 3.3.8.

[313] There is no equivalent wording for ordre public in United Kingdom law.

morality provisions and whether they are to be interpreted broadly or narrowly; the wider the interpretation the greater the impact upon other systems and the greater the conflict between EPO and national interpretations. Clearly it would be of benefit to find greater reconciliation but is it possible, on the one hand, to have a central determination of morality whilst on the other to have a system that encourages national moral choices?

(4) (b) Historical Perspective

The relationship between law and morality has provided much philosophical discussion[314] that is beyond the scope of this work, but there are few examples where morality is expressly incorporated into the legal decision process[315]. 'Morality is an old legal concept [and is] ...one of the fundamentals of our legal system and at the same time forms the basis for the inclusion of extra-legal principles of ethics in the law'[316]. The choice between providing one person with rights of exploitation over an invention to the exclusion of others, or refusing their application, involves a moral balance but the addition of a specific morality clause has not been employed to address the unique monopoly situation that a patent provides. Instead morality has been adopted to

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[314] For example: Natural Law theory which proposes that if the law is not morally correct then it is not law, legal positivism where morality enters the legal arena if the law expressly states so, and moral utility where morality is implicit when interpreting the law. For a further discussion, see R Brownsword, 'The Ethics of Patenting: A Legal Perspective', Sheffield University, Bioethics Today, 7 October 2003.

315 The TRIPS Agreement provided that such exclusion is not made merely because the exploitation is prohibited by domestic law. Article 27 (2) of TRIPS permits a state to include a morality provision but does not make it compulsory. The United States is one country that has not included a morality clause within its patent law. Although the United States patent rules make no provision for exclusion on morality grounds, courts have interpreted the Utility requirement to enable exclusion of some inventions that were morally controversial on the grounds that they were not useful. However the Supreme Court in the case of Diamond v Chakrabarty in 1980 amended this 'moral utility doctrine' and declared that anything under the sun is patentable as long as it is 'made by man'.

[316] *MICHIGAN STATE UNIVERSITY/Euthanasia Compositions* [2005] T 0866/01, paragraph 6.12

question inventions per se, which has created tensions between patent law and other regulatory systems.

The origins of morality in patent law give no hint of the functions that are being created for it at present. An exception for patents on the basis of morality has long been a part of European Patent Law but its original conception is quite different from the position today. Certainly it never played a major role within the patent decision process and was originally aimed at publication of patent claims which may be obscene or contain instructions to make articles that could be used against public order. The narrow role within Europe:

> ...was to recognise two legitimate government concerns. One was that governments should not have to publish obscene documents, and the other was that they should not have to publish instructions on how to perform acts leading to a breach of the peace or breakdown of morals.[317]

In the UK exclusions from patentability for reasons of morality originated in The Statute of Monopolies (inventions must not be '...contrary to law or mischievous to the State'[318]) and the 1883 Patents and Designs Act provided the Comptroller-General with the ability to refuse a patent if its use would be '...contrary to law or morality'. Two cases[319] arose under this power, both relating to the patenting of improved contraceptive devices and in both cases the patents were disallowed not because their

[317] Mills, '*Biotechnological Inventions*'.

[318] Section 6 of the Statute of Monopolies.

[319] *In the Matter of an Application for a Patent by A and H* (1927) 44 RPC 298 and *In the matter of an application for a patent by Rufus Riddlesbarger* (1935) 53 RPC 57

use would be contrary to public policy or morality (under the above power) but because publication could be prevented by royal prerogative[320].

Interestingly, morality was later differentiated from law so illegality of an invention is not of itself sufficient to cause it to fall foul of the morality clause. Illegality may be a factor to consider but an invention must not be declared immoral '...merely because it is prohibited by law or regulation in some or all of the contracting states.'[321] It would seem absurd that '...one law may grant patents that serve as a reward to persons for providing the means of violating any other law'[322], but that is possible under current patent law.

> This qualification makes clear that the assessment of whether or not a particular subject-matter is to be considered contrary to either 'ordre public' or morality is not dependant upon any national laws or regulations. Conversely and by the same token, the board is of the opinion that a particular subject-matter shall not automatically be regarded as complying with the requirements of Article 53 (a) EPC merely because its exploitation is permitted in some or all of the contracting states.[323]

The reasons for accepting the possibility of illegal inventions were outlined by the Advocate General thus:

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[320] As was enabled under section 102 of the Patents Act 1949. A more detailed historical analysis can be found in Mills, '*Biotechnological Inventions*'.

[321] Article 53 (a) EPC.

[322] S. Thambisetty, 'Understanding Morality as a ground for exclusion from Patentability under European Patent Law' (2002) 12 Eubios Journal of Asian and International Bioethics, 48–53.

[323] *PLANT GENETIC SYSTEMS/Glutamine Synthetase Inhibitors* [1995] EPOR 4, at paragraph 7.

> ...that the reason for that provision is that restrictions or limitations may be temporary in nature so that the patent will acquire value once they have been removed. Moreover the patented invention so restricted may be the basis for further patents which do not fall within the restrictions: there is in that case no reason to deprive the holder of the first patent of licence-fees etc to which the link between the two inventions might entitle him.[324]

The Advocate General used the example of genetically modified organisms to indicate that a further reason for the distinction between morality and illegality is that a manufacturer may wish to make the prohibited invention in a country which prohibits its exploitation but not its manufacture for export to a country where the exploitation is acceptable. Interestingly this distinguishes law regarding the physical invention and the law that governs patents. It also highlights different legal attitudes towards inventions per se and their exploitation. The separation of patents from the inventions they protect is emphasised by Article 14 of the Biotechnology Directive which reiterates that it is for '...national, European or International law...' to regulate '...the monitoring of research or the use or commercialisation of its results'.

European governments had been under commercial pressure[325] to standardise patent law for the sake of consistency and this led to the Strasbourg Convention 1963 which formed the basis of the European Patent Convention of 1973. The question of morality

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[324] Opinion of Advocate General Jacobs, '*Kingdom of Netherlands*' case, 14 June 2001.

[325] See Mills, '*Biotechnological Inventions*', for a detailed discussion of the background to the development of European Patent Law.

barely featured in the discussions leading up to the Strasbourg Convention[326] but was added to reflect views of individual states regarding obscene documents and to prevent the publication of instructions relating to acts that were morally offensive. The European Patent Convention discussions '...recognised that there was no European definition of morality and unanimously agreed that interpretation of the concept of morality should be a matter for European institutions'[327] The Nuffield Council on Bioethics described the status of the morality clause prior to the growth in the biotechnology industry as follows:

> In June 1978, when the Patents Act 1977 came into force, biotechnology was in its infancy. Thus the 'immoral' inventions which the legislation contemplated at that time included such things as instruments of torture and letter bombs – which were so clearly immoral as to require little detailed consideration of the meaning of the exclusion.[328]

The increased exercise of the morality clause in European Patent law has arisen from two different sources. First there is wider public awareness of science and methods of economic protection. This fuels groups such as the Green Party or Greenpeace to campaign against forms of progress that they feel are objectionable or immoral. Secondly technology has taken great leaps forward with enormous potential

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[326] '...the morality provision did not feature in the early drafts of the Convention', Mills, '*Biotechnological Inventions*', 26.

[327] Mills, '*Biotechnological Inventions*', 32. See also Ladas S P, '*Patents Trademarks and Related Rights, National and International protection, Harvard University press*' (1990), pp. 1685 – 1686, Morality "...reflects customs and habits anchored in the spirit of a particular community."

[328] Nuffield Council on Bioethics, 'Human Tissue: Ethical and Legal Issues', 1 April 1995, chapter 11 paragraph 11.16 page 89.

accompanied by possible latent dangers. To a certain extent the fear of the unknown can be misinterpreted as immorality, but '...very often fear of the unknown is couched in moral terms...'[329]. There are also clear moral concerns regarding biotechnology of such a significant nature to bring governments into the patent debate through opposition procedures and the European Court of Justice[330].

Nevertheless, historically the morality clause had a narrow interpretation and role. 'From the historical documentation relating to the EPC it appears that the view was that 'the concept of patentability in the European patent law must be as wide as possible'[331]. Accordingly the exceptions to patentability were narrowly construed: '...In the Board's view, this approach applies equally in respect of the provisions of Article 53 (a) EPC.'[332]' Conversely and as the discussion below indicates case law of the European Patent Office including the Edinburgh Patent and the pending appeal WARF cases as well as the comments from the former President of the European Patent Office Alain Pompadour the morality clause is to be used to question events which have occurred prior to patent application such as research leading to the invention and thus also question the wider industry rather than just the specific invention.

The lack of case law until the advent of biotechnology inventions would support this. This absence of judicial interpretation though could be '...explained by the very

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[329] Thambisetty, 'Understanding Morality as a Ground for Exclusion'.

[330] Relevant examples include: Kingdom of the Netherlands case; *Wisconsin Alumni Research Foundation case; Edinburgh Patent* (EP 0695351) and notice of opposition under Article 99 (1) of the European Patent Convention to EP 1257168.

[331] (see document IV/2071/61-E, page 5, point 2, first paragraph)

[332] *PLANT GENETIC SYSTEMS/Glutamine Synthetase Inhibitors* [1995] EPOR 4.

existence of an express statutory prohibition. This may mean that inventions likely to be hit by it were not presented as deserving of patent protection in the first place...'[333]. It is more likely that the increase of public awareness coupled with the contentious nature of biotechnology and mixed with fear of the unknown and/or misunderstanding of the technology has given rise to the increase in use of the morality clause. Thus although morality has been a part of patent law for many years it was never designed for nor was it originally intended that it should be used as a vehicle through which it should interpret complex moral questions regarding biotechnology. That does not mean that it is not capable of being introduced to cope with a broader role, only that such a role was not envisaged. Before considering how the role has been interpreted and extended it is of interest to examine the arguments for and against the use of a morality clause in patent law, in part because the arguments expose the strengths and weaknesses of a morality clause as an instrument of regulation.

[333] Thambisetty, 'Understanding Morality as a Ground for Exclusion'.

(4) (c) Should Patent Law account specifically for moral concerns?

The following are some of the major arguments for and against the inclusion of morality within patent grant procedure. Two general comments are pertinent to make before this analysis starts. First, arguments relating to the suitability of morality within patent law are usually presented simply as for and against, rather than exploring how morality should be expressed within patent law or whether the criticisms against the inclusion of a morality clause can be answered through changes in interpretation of morality rather than by ignoring morality altogether. Secondly, as the cases below indicate, there is ambiguity surrounding the objective of the morality clause and what should be immoral in order to achieve that aim. This work takes the view that there are justifications for retaining morality within patent law but that there should be changes to the way and method in which it is interpreted at present. In some respects morality is too narrow and in others too broad. Further the morality clause does not take into account, and therefore does not make use of, the time frame within which innovation occurs.

There are three main categories in which arguments have been presented for and against patent morality; the efficacy of using morality within patent law, the symbolic nature of the patent grant and the difficulty in defining what is morality.

(4) (C) (I) PURPOSE AND EFFECT OF PATENT GRANTS

Attempts to prohibit inventive behaviour by prohibiting patents are unlikely to be effective. Patents provide patentees with the power to prevent others from making selling and distributing patented inventions and do not grant rights to manufacture, research, distribute or use inventions which could be prohibited by law[334]. The refusal of a patent cannot stop particular activities and so if society is opposed to something then it should be made illegal and not attacked indirectly through the patent system which is '...is not the appropriate vehicle for regulating the use of particular technologies on ethical grounds'[335].

On the other hand patents clearly provide incentives and rewards, so grants of patents must be complicit in the immorality of each invention in the sense that we could say it is wrong to create incentives for activities that may be considered immoral even if they are not illegal or controlled by legislation.

These points illustrate a recurring problem within morality interpretation for patent authorities and those who seek to question innovation for moral reasons; what is it that the morality clause is intended to do and what should be immoral in order to achieve

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[334] This point is made in the Biotechnology Directive in Recital 14 which states: 'Whereas a patent for invention does not authorise the holder to implement that invention, but entitles him to prohibit third parties from exploiting it for industrial and commercial purposes, whereas, consequently substantive patent law cannot serve to replace or render superfluous national, European or international law which may impose restrictions or prohibitions or which concern the monitoring of research...'. See also Kingdom of the Netherlands case: 'The conditions of exploitation or use of patented inventions are, as discussed above, outside the scope of patent legislation, falling to be controlled by other means' (paragraph 214).

[335] House of Representatives Standing Committee on Industry, Science and Technology Report, 'Genetic Manipulation: The Threat or the Glory', February 1992, paragraph 7.99.

that aim? The assumption behind these arguments is that morality is aimed at immoral inventions and the object is to prevent or hinder proliferation of such innovation. Clearly patent law is a weak instrument to achieve that. The European Patent Office[336] has had difficulty with this point. It is true that the morality clause specifically links morality with 'exploitation' but is that because the exploitation is immoral or because the invention itself is immoral and therefore so is exploitation? Whether or not a patent is granted does not necessarily affect exploitation, as we have seen, so the charge of inefficacy can arise. Thus the validity of the efficacy argument depends upon the ultimate aim of exclusion and when that is felt within the innovation time line.

(4) (C) (II) SYMBOLISM

The provision of a patent over a particular invention can be interpreted as being a badge denoting general approval for wider technology relating to the invention[337]. The patent office is a government body and given that a patent can be used to attract finance its symbol is important and raises possible concerns in that it equates inventions per se with the monopoly given by a patent. Patent law clearly distinguishes[338] inventions from patent monopoly so general regulation should address issues relating to the former. By the time that inventors patent their inventions the relevant research will most likely have been completed and the inventions created so it will be too late to make attempts to halt them by using the patent system: 'The genie

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[336] See the case studies in chapter five relating to *The Edinburgh Patent* and *WARF* patents regarding the patentability of stem cells.

[337] "...the symbolism in the grant of a patent is not an insignificant one..." Thambisetty S, 'Understanding Morality as a ground for exclusion from patentability under European Patent Law' (2002) 12 Eubios Journal of Asian and International Bioethics 48.

[338] Article 14 of the Biotechnology Directive, see also above.

cannot be put back in the bottle'[339]. Yet patents because they are granted by a government organisation, can be seen as a form of government approval even though the grant of a patent '... does not authorise the holder to implement that invention...'[340]

The validity of the argument against a specific moral exclusion within patent law based upon patent grant amounting to a symbol of approval depends upon the regulatory position relating to the area of technology in question, within national law; i.e. whether that is prohibitive, permissive or silent. Within Europe there are varying degrees of what is acceptable to research, develop and exploit and therefore the reasonableness of refusing patents based upon such arguments will meet with varying degrees of success.

Regulation does not have to be black and white i.e. prohibiting or encouraging; there are other forms of regulation that can be effective. For example a particular line of science may be tolerated but not encouraged by being excluded from patentability. Thus it may be true to say that using exclusion from patentability for moral reasons as a method of objecting to particular activities is limited in scope but that does not mean that it should be ignored altogether. The possible scope of the interaction of patent laws with regulation is discussed below but the limits of the interaction should also be appreciated. The only influence patent law has is to remove incentive (which applies not to the applicant but to other inventors and potential patentees) and deprive the applicant of reward. The effects of refusal of patent grants are thus felt in different areas of the innovation time line: disincentive for others at innovation stage and no

[339] Laurie, '*Genetic Privacy*', 307.

[340] Recital 14 Biotechnology Directive

monopoly for the applicant in exploitation stage. Another result of patent refusal is that material that would otherwise be subject to the grant of a patent is available for open research, which for many is the real reason for opposing patent grants – that is, it might result in more research not less.

(4) (C) (III) MORAL PURPOSE

(4) (C) (III) (A) CHANGING VIEWS

Every societies views change through time[341] sometimes very quickly, so that which is accepted as abhorrent now may not be deemed to be so a few years hence. The change of attitude towards patents for contraception[342] is one example of this, so it is not considered to be either helpful or constructive to refuse patents on moral grounds, because applicants could be prejudiced in later years as moral perceptions change. Historical attitudes to advances in science have impacted upon earlier law and there may be examples of this again, but patent law is not designed to address changes in legal issues that relate to sensitive moral questions and its independence should be defended. On the other hand law should reflect as best as possible morality at a given

[341] The Reports from The European Commission's Directorate-General for Research – the latest one being, 'Eurobarometer 64.3 Europeans and Biotechnology in 2006: Patterns and Trends', May 2006 – provide an insight into the changing views among Europeans regarding biotechnology and the variances within Europe.

[342] 'To show how standards of 'morality' change a similar principle was implied by common law in the UK and was once the basis for rejecting patents for contraceptives', Cook, *'A User's Guide to Patents'*, Page 340 para. 8.14. The reasons for refusal however related not to opposition to contraception per se but because of concern about possible side effects such as insanity, tuberculosis and diabetes, to name a few. See also *Riddlesbarger's Application* (1936) 53 RPC 57 and A Wells, 'Patenting New Life Forms: An Ecological Perspective' [1994] 3 EIPR 111 at 113.

time and, as has happened in the past, the law has been changed to reflect moral attitudes.

(4) (C) (III) (B) DIFFERING EUROPEAN MORALS

Views about what is acceptable and what is not vary across Europe. This may be an obvious comment and it relates to a complication that European legislation has had to deal with for many years. However diverging views on controversial innovation cause unnecessary complications and uncertainty in patent applications within Europe. Decisions taken on morality of patent applications within the European Patent Office will naturally be based upon the interpretation by the examiners, at the time creating a Europe-wide imposition of what is morally patentable but one that does not necessarily reflect a Europe-wide consensus. The different views of what is acceptable across Europe are shown by the European Commission on Patterns and Trends and it is accepted by Recital 39 of the Biotechnology Directive that the morality clause in the Biotechnology Directive is intended to provide for these diverse views[343]. It '...is therefore inevitable that article 6 will be interpreted and applied divergently.'[344] Here lies the problem; there cannot realistically be, on the one hand a Directive reflecting divergence of views when at the same time the European Patent Office can dictate what the views should be. It is accepted that enforcement occurs at national level so interpretation can eventually be determined within the national arena but that still leaves two problems. First, when a patent is granted by the EPO it is valid in all

[343] Recital 39 of Directive 98/44: 'Whereas ordre public and morality correspond to a particular ethical or moral principle recognised in a member state, respect for which is particularly important in the field of biotechnology in view of the potential scope of inventions in this field and their inherent relationship to living matter whereas such ethical or moral principles supplement the standard legal examinations under patent law regardless of the technical field of the invention.'

[344] Opinion of Advocate General Jacobs, *Kingdom of the Netherlands case*, 14 June 2001, paragraph 94.

applicable countries, so if there are valid national objections they are not reflected in the initial grant. Secondly if the EPO refuses a patent for moral reasons then that decision also applies throughout applicable countries regardless of whether the invention is considered immoral within each one. Those countries that wish to push ahead with research considered immoral in other countries are thus held back. Research companies that would otherwise base themselves within Europe may be discouraged from doing so on the basis of the uncertainty that this situation creates. The problem arises through applying morality at the time of grant through the EPO, giving a blanket moral policy that may not reflect the morality of individual states.

Separate applications could be made within individual countries. One of the aims of the European Patent Convention and the Biotechnology Directive was to simplify the patent application process so encouraging patentees to go the national patent office route is self-defeating. Tension between moral positions of each country can only be addressed (in absence of ignoring moral views altogether in patent law) through adoption of a mechanism or facility that enables cultural differences to be taken into account at the time of grant of patent or through the life of each patent. Such a mechanism will be considered in due course but difficulties are posed by any option and a perfect answer to reflecting moral concerns within patent law is unlikely to exist.

Ignoring morality altogether also disregards the fact that the grant of patents carries moral consequences at each stage of innovation. Trying to address these at the time of grant through the European Patent Office raises the conflict, discussed above, between moral attitudes and leaving moral questions until after grant leaves open the

symbolism of patent grant to be taken as acceptance of the practice of the science within the patent in particular within countries which are regulatory silent[345] but morally against the practice in question. Despite this shortcoming there is much to be said for the flexibility that such a route presents and this will be discussed in due course.

(4) (C) (III) (C) MORALITY IS INDEFINABLE

Another argument that provides support to the view that the patent system should avoid moral judgements is the difficulty of assessing moral standards. There are many different standards and opinion. Patent offices are already overstretched because of the volume of new research and they are ill-equipped and inappropriate to deal with contentious ethical issues. Given the views of patent examiners, expressed in an open letter dated 13 April 2007, any further increase in complexity it not likely to be welcome:

> Consequently, we, the undersigned representatives of patent examiners, join together in declaring that the combined pressures of higher productivity demands, increasingly complex patent applications and an ever expanding body of relevant patent and non-patent literature have reached such a level that, unless serious measures are taken, meaningful protection of intellectual property throughout the world may, itself, become history.[346]

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[345] I.e. where a country has strong moral views against particular research or innovation but has not regulated against it. See further discussion below in Chapter five

[346] 'Open letter from a coalition of Patent Examiner Representatives' including USA, Germany, Canada, EPO and Austria, dated 13 April 2007 to Directors of USPTO, EPO, and the German, Canadian and Austrian patent offices.

It has been said that patent offices need only to recruit more examiners in order to deal with difficult moral problems: 'If patent examiners lack moral expertise, they should be replaced by persons who have it...'.[347] But given what the examiners have said above this makes little sense, indeed it is arguably unjustifiable to employ staff to assess ethical issues with the additional cost in time and finance necessary especially as most relevant cases should be regulated by law. It is suggested that attempting to predict whether commercial exploitation of an invention is going to be immoral or not involves a certain amount of supposition at the time of grant. This implies that the current morality clause is deficient in that it is interpreted in absence of pertinent facts.

(4) (C) (III) (D) MORALITY AND ECONOMIC DISADVANTAGE

Arguments against moral interference in patent decisions can[348] also be based upon disincentive caused if patents are unavailable so tempting inventors into jurisdictions which are more encouraging. Patents are tools to encourage economic investment and we have seen that they have important roles to play in the way in which the biotech industry develops. Refusals of patents for inventions on moral grounds could place any authority at an economic disadvantage as compared to other countries not constrained by such issues.

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[347] Beyleveld, Brownsword and Llewelyn, 'The Morality Clauses of the Directive on the Legal Protection of Biotechnological Inventions', 157.

[348] See Thambisetty 'Understanding Morality as a Ground for Exclusion' and Beyleveld, Brownsword and Llewelyn 'The Morality Clauses of the Directive on the Legal Protection of Biotechnological Inventions'

On the other hand economic factors should not presumptively eclipse moral views or positions. It will be suggested that the relative strength of such arguments depends upon how morality is expressed within the patent system and the ethical rules of science in general and that we should strive for consistency between what is permitted and what is promoted.

(4) (C) (III) (E) UTILITARIAN APPROACH TO MORALITY

The grant of a patent involves moral issues. It is in the nature of patents that they favour some parties over others, so choices involve at least issues of fairness and thus morals are never far away from all patent processes. There may be moral arguments that support the grant of patents as well as those that suggest patents should not be granted; for example, supporting development of life enhancing treatments could outweigh the moral difficulties of allowing a perceived offensive patent. In the 'Oncomouse' case, for example, the applicants argued that the benefits of the invention, in the form of research for treatment for cancer, outweighed the animals' suffering[349]. In any event they suggested that although mice, the subject of the invention, suffered, there would be fewer mice required for the purposes of other research as a result[350]. The balance is arguably unfair in that the invention used as outlined in the patent claims will cause harm to animals but it may only lead to the *opportunity* for a cure for some forms of cancer.

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[349] *HARVARD/ONCO-mouse* v 0006/92 03 April 1992 page 3

[350] ibid page 3

(4) (d) European Patent Morality

Given the weaknesses and strengths of the arguments for and against a morality clause in patent law it can be seen that a morality clause can be beneficial, but this depends upon its purpose and upon the effects of exclusion of particular inventions. Arguing that inventions should be refused patent protection because of objection to specific characteristics of inventions may be an ineffective method of addressing those concerns. On the other hand if objections are raised against the granting of monopoly rights to particular inventions, then refusal of patent grant will be effective as against the objection in question. Proponents of open source material would argue that the real moral issue for patent law is that patents restrict innovation both through blocking of research and restricting availability of inventions. In the realm of health care[351] there are strong arguments to support[352] a more open environment. The changes in wording of the moral provisions in Europe towards linking morality with 'commercial exploitation' of inventions would suggest that morality of how inventions are exploited is the central issue. This has not been how commercial exploitation has been interpreted and economic effects of patent grants are not considered to be a matter for the EPO[353]. It is suggested that such a focus may make the above criticisms more difficult to justify. In order to obtain such focus it is suggested here that the important targets are the direct consequences of patent grant.

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[351] The restrictions on patents on medical treatments have been justified on the basis that patent grant should not hinder treatment but this exception has narrowed over time.

[352] The discussion in chapter five below outlines these and provides working examples where patents have been used as methods of encouraging openness.

[353] *NOVARTIS/Transgenic Plant* G1/98 [2000] EPOR 303; [2000] 3 OJEPO 111, and see below

The expansion of patentable subject matter (in effect the granting of patents over biotechnological inventions) has also extended the basis for excluding inventions from patentability for moral reasons. This development of moral provisions has occurred on several levels. First it relates to the subject matter, biotechnological inventions, which continue to challenge patent mechanisms. Historically the purpose of the moral provisions was to exclude inventions whose sole purpose was immoral. This is intrinsically different from recent cases which concern inventions that are beneficial but may also have an immoral consequence. The second is in respect of the timing of objections or period in which they arise whether that is pre-grant or post-grant, for example. Third, moral provisions are gradually being utilised for wider purposes such as influencing research.

The reasons for the expansion are understandable but perhaps some objections are misdirected so there are arguments that the basis for expansion has been motivated by attempts to regulate particular aspects of the biotechnology industry rather than for reasons connected to the grant of a patent.

> It is clear that the EU Biotechnology Directive wants to take action in view of 'ordre public' and morality. It is not clear, however what exactly is envisaged in article 6. Should only inventions of which the *commercial exploitation (= commercialisation? = application*) is considered. Or should

inventions which are believed to be contrary to 'ordre public' and morality be denied patent protection?[354]

These different views of whether the grant of a patent involves a moral issue or not may have arisen in part because there has not as yet been a decisive parameter placed around that moral question nor what it should be focused upon. Part of the difficulty in assessing moral questions within patent law is that they arise within different periods of innovation and relate to widely diverse areas and this thesis suggest that if morality is to play a role within patent law then patent law must reflect this situation through taking account of when moral issues arise and the effect of addressing them through patent law.

(4) (D) (I) COMMERCIAL EXPLOITATION AND PUBLICATION OF INVENTION

The moral provisions within Article 6 (1) of the Biotechnology directive, Article 53 of the European Patent Convention, the UK Patent Act 1977 and TRIPS all relate exclusion from patentability for moral reasons to 'commercial exploitation'[355] of inventions. Commercial exploitation is therefore the key issue in determination of *ordre public* and morality and case law confirms this.

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[354] European Group on Ethics in Science and New Technologies, 'Study on the patenting of inventions related to human stem cell research', Report to the European Commission (Office for Official Publications of the European Communities, 2002), 71.

[355] The EPC 1973 referred to: 'inventions the publication or exploitation of which would be contrary to ordre public or morality'.

For example in the case of *HARVARD/ONCO-mouse*[356], sixteen different groups filed opposition proceedings against the patenting of a 'method for producing a transgenic eucaryotic animal having an increased probability of developing neoplasms'. The evidence was clear that the genetically engineered rodent would be of benefit to research and that fewer animals would be required for research purposes as a result. The initial decision[357] in the Examining Division of the EPO refused to grant the patent application but on appeal to the Technical Board of Appeal the matter was referred back to the Examining Division and the patent subsequently granted.

Among the questions for consideration was the interpretation of Article 53 (a) of the European Patent Convention which states: 'European patents shall not be granted in respect of: (a) inventions the publication or exploitation of which would be contrary to 'ordre public' or morality...'. In the board's opinion it was '...only possible to read the words 'contrary to *ordre public* or morality' as qualifying 'publication or exploitation'. Accordingly, the Article raises no question of the morality of patenting a particular invention or of the morality of that invention'[358].

Equating exploitation with morality was the interpretation of Article 53 of the EPC by the Technical Board of Appeal in *MICHIGAN STATE UNIVERSITY/Euthanasia compositions*[359] which refers to 'publication or exploitation' [360] rather than

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[356] T 0315/03 Decision 6 July 2004; [1991] EPOR 525.

[357] [1990] EPOR 4.

[358] T 0315/03 para. 4.2.

[359] *MICHIGAN STATE UNIVERSITY/Euthanasia compositions* T 0866/01 3.3.02 decision of the Technical Board of Appeal, 11 May 2005.

[360] The EPC 1973 has been amended by EPC 2000 to include, inter alia, a different reference for morality so as to bring it into line with TRIPS, thus the new EPC morality clause will refer also to

'commercial exploitation': 'It is, in the Board's opinion, only possible to read the words 'contrary to *ordre public* or morality' in Article 53 (a) EPC as qualifying the objective facts, namely 'publication or exploitation' of the invention.'[361]

The text of Article 53 (a) of the European Patent Convention 1973 prevents patents in the event that the '...publication or exploitation ... is likely to be contrary to ordre public or morality...'One of the original purposes of the moral provisions was to prevent patents publicising obscene material or material that may give rise to public order offences.

The term 'commercial exploitation' is pertinent to the aims and purpose of the patent system and relevant to the monopoly power that a patent provides. But enquiries into the economic repercussions are not part of the remit of the European Patent Office. According to the Enlarged Board of Appeal in the case of the NOVARTIS II patent grant:[362]

> The EPO has not been vested with the task of taking into account the economic effects of the grant of patents in specific areas of technology and of restricting the field of patentable subject matter accordingly....[363]

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commercial exploitation rather than publication or exploitation. The EPC 2000 will enter into force on 13 December 2007 at the latest.

[361] *MICHIGAN STATE UNIVERSITY/Euthanasia compositions.*

[362] *NOVARTIS/Transgenic Plant* G1/98 [2000] EPOR 303; See also Guidelines for Examination in the European Patent Office December 2007, 4.4 Economic effects. The EPO has not been vested with the task of taking into account the economic effects of the grant of patents in specific areas of technology and of restricting the field of patentable subject-matter accordingly (see G 1/98, OJ 3/2000, 111, reasons 3.9). The standard to apply for an exception under Art. 53(a) is whether the commercial exploitation of the invention is contrary to "ordre public" or morality.

[363] [2000] EPOR 303 page 318 note 3.9.

> Although the positions adopted in society on genetic engineering are controversial...there is no consensus in the Contracting States condemning genetic engineering in the development of plants under the above criteria.[364]

The lack of European consensus is critical in the interpretation of morality. A European consensus clearly exists against the typical examples of immoral inventions such as letter bombs and anti-personnel mines but in relation to the particular areas of biotechnology discussed above no such consensus exists. This illustrates that a consensus exists that particular inventions should not be patentable but exclusion of particular inventions from patentability is only one moral issue at stake; how they are exploited, for example, is another.

(4) (D) (II) USE OF INVENTION

An invention may have several uses, some of which could be moral whilst other uses may be immoral. The Advocate General in the *Kingdom of the Netherlands* case[365] used the example of a complex copying machine that could be adapted to produce counterfeit bank notes which would be contrary to *ordre public* or morality. Use of the copier for other printing purposes would not be immoral. Patent law cannot distinguish between, immoral use and use that does not offend. Separate legislation may outlaw the former but patent law can only grant or refuse a patent.

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[364] Ibid. 318 note 3.9.

[365] Case C – 377/98 Opinion of Advocate General Jacobs, *Kingdom of Netherlands V European Parliament and Council of the European Union*

(4) (D) (III) INVENTION

On a narrow reading of Article 6 (2), the word 'commercialisation' would suggest that inventions per se are not the intended target of the morality clauses, but there is sufficient indication elsewhere that could impute a broader interpretation. Article 6 (2) of the Biotechnology Directive includes a list of inventions which, '... in particular shall be considered unpatentable...' and Recital 38, to which Article 6 relates, speaks of an '...illustrative list of inventions excluded from patentability...'. This implies that in order to interpret Article 6 (1) one must look to the invention and not the commercialisation of the invention. The Article 6 (2) exceptions are not exhaustive and several other examples of excluded inventions are provided within Recital 38. A further issue relates to what form of invention is to be covered by the specific exclusions within Article 6 (2). The reading itself refers to processes but does not include the products. Is it to be taken by the absence of reference to products that they are not excluded? Unfortunately there does not appear to be any satisfactory answer to these questions and rather than making the interpretation of morality easier the specific examples have had the opposite effect.

(4) (D) (IV) PATENT GRANT

It was, inter alia, argued in the case of *MICHIGAN STATE UNIVERSITY/Euthanasia compositions*[366] that the act of granting a patent may be considered immoral on the basis that there is a risk of infringement of Article 2 of the European Convention of Human Rights. The Technical Board of Appeal rejected these assertions as follows:

[366] T 0866/01 3.3.02 decision Technical Board of Appeal 11 May 2005.

'Neither the invention per se nor the act or conditions of patenting the claimed invention fulfil the condition of being part of the exploitation of the present invention'[367]. Yet the act of granting a patent carries moral issues, such as the symbolic effect discussed above, and the MICHIGAN STATE case suggests this is irrelevant and that morality attaches to the broader effect of the grant of patents rather than the act of granting per se. But the broader effect is not defined in a way that makes it clear what immoral act will fall foul of Article 6.

(4) (D) (V) RESEARCH LEADING TO INVENTION

Patent law aims to promote and encourage research and development. It is not surprising, therefore, that objections have been raised by opponents in relation to the morality of the research lying behind particular inventions. There are difficulties with equating the perceived wrongs of research with the granting of patent rights; not least that patent law is a completely different form of regulation to the rules that govern scientific exploration, as we have seen:

> Patent law and biomedical research regulations largely legislate the same issues, but from a different angle. Biomedical research regulations try to outline the type of research which is considered legitimate...Patent law deals with the same subject matter, but mainly focuses on the research applications and the ethical implications the exploitation might entail.[368]

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[367] T 0866/01 3.3.02 decision Technical Board of Appeal 11 May 2005, 66.

[368] European Group on Ethics in Science and New Technologies to the European Commission, Study on the Patenting of inventions related to human stem cell research, 2002, pp 66-67

In *MICHIGAN STATE UNIVERSITY/Euthanasia compositions*[369], the Board agreed and answered the opponents' suggestion that animal experiments were used in the research that led to the invention in question as follows: 'These experiments were carried out during the making or development of the invention and as such do not fulfil the condition of being part of the exploitation of the present invention'[370].This clearly separates the interpretation of morality within Article 6 from research. Clearly research can be moral or immoral but according to MICHIGAN STATE UNIVERSITY Case the morality of research is not relevant for the question of patent law.

The relevance of research in respect of patent grants, however, takes on a different importance under the Biotechnology Directive and the four specific exclusions. Two cases relating to the patentability of human embryonic stem cells have opted for a broad interpretation of morality exclusion.

In the *Wisconsin Alumni Research Foundation* case, the Examining Division[371] based their judgment upon looking behind the patent and the invention and held that the patent was invalid because human embryos had been used as starting material. Although the patent did not cover human embryos or methods of obtaining stem cells from embryos, the Examining Division held that the invention as claimed was equivalent to using embryos for industrial and commercial purposes for the purposes of Rule 23 D (c) of the European Patent Convention and therefore prohibited. The actual patent claimed related to cell cultures[372], no claim was made in respect of the

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[369] T 0866/01 3.3.02 decision Technical Board of Appeal 11 May 2005.

[370] T 0866/01 3.3.02 decision Technical Board of appeal 11 May 2005, at page 65

[371] 18th *Wisconsin Alumni Research Foundation*, Case T 1374/04, November 2005.

[372] 'A cell culture comprising primate embryonic stem cells which (i) are capable of proliferation in vitro culture…' (EP 0770125).

process for the production of the cells, but this was considered to be irrelevant because there was only one method of originating cells and that was through the use – and destruction – of human embryos, which equated with industrial and commercial use of embryos.

The main consideration was the way in which the morality clause set out in Article 23 (d) in particular the specific exclusion to patentability in Article 23 (d) (c) should be interpreted? If a narrow interpretation was to be used then this would correspond with previous decisions within the European Patent Office. A narrow interpretation would not extend further than what is stated in the claims and so would not exclude the patent because the only source was human embryos, whereas a broad interpretation would include looking behind the product to the process, in effect equating the invention with the research. Similar reasoning was applied in the *Edinburgh Patent* case[373] and both cases are under appeal. This current approach is at odds with all previous case law on the morality clause where the '...boards of appeal have repeatedly found that such exceptions are to be narrowly construed'[374].

These two cases raise important issues relating to the research of inventions, and the borderline between patent law and the regulatory bodies that govern science. In particular the views of A Pompidou, the ex-president of the European Patent Office, suggest that morality will play a greater role in relation to controversial areas of research.[375] They also raise issues relating to the relationship between EPO and

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[373] EP 0695351.

[374] *HOWARD FLOREY/Relaxin*, V 0008/94 OD at para. 6.2.2, [1995] EPOR 541, 547.

[375] See case study one below

national patent authorities. Their importance is of sufficient weight to be discussed in a separate case study in the following section.

(4) (e) Moral Definition

The previous paragraphs indicate that there are different interpretations of what morality in patent law actually refers to. Equally important and debatable is the question what amounts to immorality in European Patent Law. This has not been entirely straightforward, although it is fair to say that the trend, until recently, is that a narrow interpretation should prevail. The way in which morality, couched in narrow terms, was interpreted varied. 'There was no European definition of morality'[376]. The EPO Guidelines state the purpose of the morality clause is to:

> ...deny protection to inventions likely to induce riot or public disorder, or to lead to criminal or other generally offensive behaviour....This provision is likely to be involved only in rare and extreme cases. A fair test to apply is to consider whether it is probable that the public in general would regard the invention as so abhorrent that the grant of patent rights would be inconceivable.[377]

A difference in interpretation of morality is apparent and the case law of the European Patent Office reveals various approaches. It is possible that the importance of investment in biotechnology may have influenced the approach taken by the EPO and it looked at one stage as though the morality clause was going to be interpreted so narrowly that the clause became meaningless. Some examples of the approach of the EPO are outlined below:

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[376] EPC Working Party, Document IV/2767/61-E, page 7.

[377] EPO Guidelines, December 2007, paragraph 4.1

The European Patent Office, in the *HARVARD/ONCO-mouse*[378] objection dealt with under Article 53 of the European Patent Convention, came to the conclusion that the applicant's cancerous rodent was patentable and not contrary to *ordre public* and morality on the basis of a balance between the achievement of the invention against the harm that it may cause. The Technical Board of Appeal accepted that although the animal would be harmed that fact was to be offset against the potential benefit that may result towards research for treatment for cancer. The test resulting from this decision was:

> The decision as to whether or not Article 53 (a) is a bar to patenting the present invention would seem to depend mainly on a careful weighing up of the suffering of animals and possible risks to the environment on the one hand, and the invention's usefulness to mankind on the other.[379]

A narrower test was inserted into Article 6 (2) (d) of the Biotechnology Directive, which renders inventions unpatentable in the event that they involve: '...processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes'.

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[378] T 19/90.

[379] T 19/90, paragraph 5.

In the *PLANT GENETIC SYSTEMS/Glutamine synthesase inhibitors* case[380] in 1995, the Technical Board of Appeal rejected a claim by Greenpeace that a patent should not be granted in respect of transgenic plants resistant to the applicant's weed killer, 'Roundup'. Although it was alleged that harm to the environment could be caused, the Board held that this had not been proven and so the balance of harm test in the *Onco-mouse* case was inappropriate. Instead the question of morality came down to what the public would find acceptable:

> Accordingly, under Article 53 (a) EPC, inventions the exploitation of which is not in conformity with the conventionally-accepted standards of conduct pertaining to this culture are to be excluded from patentability as being contrary to morality.[381]

A further alternative to the 'public acceptability' test came in the case of *HOWARD FLOREY INSTITUTE/Relaxin*[382] which further narrowed the scope of the morality clause by imposing a test where the grant of a patent had to be so 'abhorrent' to the public that 'the grant of patent rights would be inconceivable'.[383]

The above cases were heard under the EPC 1973 and related to morality in the general sense, rather than to dealing with particular examples of morally unpatentable inventions that were added by virtue of Article 6 of the Biotechnology Directive. A

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[380] 1995 WL 1081384, [1995] EPOR 357.

[381] [1995] EPOR 4, at paragraph 6.

[382] [1994] EPOR 388.

[383] see also *Lubrizol Genetics Inc* [1992] EP – B1-122 791 (opposition Division) unreported and *Human Stem Cell/BIOCYTE* also unreported regarding patent number EP 03432317

number of important issues have arisen from the way in which the specific exclusions have been interpreted because the EPO has applied a broad interpretation to the exclusion, thus clearly distinguishing these from the approach adopted in relation to the general exclusion. The justification for the change in direction by the EPO may be due to the nature of the technology, human embryonic stem cells, or because specific exclusions were felt necessary. So if the European Parliament and the Council considered these to be appropriate, at the time of drafting, it is reasonable that they should give a broad interpretation to them. Whatever the justification, the result has been to illustrate that tensions exist between rules that regulate science and those that encourage innovation. This highlights the lack of European consensus in relation to those products and processes that are acceptable and the way in which morality should be interpreted.

The European Court of Justice confirmed in the *Kingdom of the Netherlands* case that the four Article 6 (2) exceptions were not discretionary[384]. This was reiterated by the Technical Board of Appeal in *MICHIGAN STATE UNIVERSITY/Euthanasia Compositions*[385] stating: '...if a case falls within one of the four categories of exceptions set out in Rule 23d EPC...then it must ipso facto be denied a patent under Article 53 (a) EPC'.

That is not the end of the matter, though, because an invention '...not falling within the limited exclusions of Rule 23d EPC...must then be considered under Article 53(a)

[384] Paragraph 38 '...the scope for manoeuvre left to member states is not discretionary...by giving four examples of processes or uses which are not patentable.'

[385] [2005] T 0866/01

EPC. There are thus in effect two quite different Article 53 (a) objections'[386]. Each must be considered separately and it seems from the EPO interpretation that the specific exclusions are to be interpreted broadly as in the *Wisconsin Alumni Research Foundation* case[387], and the *Edinburgh Patent*[388] exemplify. Article 6 (2) (c) states that inventions that use human embryos for industrial or commercial purposes are unpatentable and in both cases the claims in relation to human embryonic stem cells were disallowed under this section. The case of *California Institute of Technology* (T 522/04)[389] also followed the broad interpretative approach when considering the patentability of stem cells:

> The relevant question is whether the claimed cells comprise human embryonic cells since then the invention involves the use of a human embryo.[390]

The Examining Division of EPO is currently following this interpretation thus 'applications are currently being refused if the invention inevitably involves the use of a human embryo, even if such uses are not specifically claimed'[391]

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[386] [2005] T 0866/01

[387] Case T 1374/04, November 2005

[388] EP 0695351.

[389] *California Institute of Technology Case* T 522/04 CIT [2003] ED EP 93921175.1

[390] Ibid at para 2.3.3

[391] Webber P, Patentability of human embryonic cells under the EPC, Pharmalicensing, Bioscience Law Review, 2008, page 5, available from http://pharmalicensing.com/public/articles/view/1119630334_42bc33fe14906 last accessed 8th July 2008

Appeals are pending[392] although the *Edinburgh Patent* has been withdrawn[393]. In neither of the cases did the patent claim '...uses of human embryos for commercial purposes' which would clearly not be patentable under Article 6 (2) (c) but would also be disallowed by Article 5 (1) which states: 'The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions'.

Both inventions did, however, use human embryos in the creation of the stem cells which were the subject of the patent application. Furthermore, in order to recreate the invention using the same technique, embryos would have to be utilised and destroyed. Importantly, though, use of the invention did not require human embryos and given the self-replicating nature of the stem cells further lines could easily be created without use of embryos, thus giving a ready supply. Therefore human embryos did not form any part of exploitation of the invention. The EPO felt that because others who may recreate the invention from first principles would have to use and destroy embryos, and because use and destruction of embryos was necessary in the initial work of the applicants, the invention was considered immoral[394]. The effects of this are discussed

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[392] The appeal of the WARF case is due to be heard on 24th 25th June 2008 see 'Enlarged BoA to review WARF stem cell case' available from www.epo.org/topics/news/2008/20080617.html last accessed 8th July 2008

[393] 'Edinburgh Patent appeal withdrawn', European Patent Office news release, available from <www.epo.org/topics/news/2007/20071120a.html>.

[394] See also comments of Alain Pompidou, former President of EPO, in Open Letter of the President dated 28 September 2006 at page 3, available from <www.cipa.org.uk/download_files/epo_warf.pdf>: 'Hence, where the skilled person wishing to perform or reproduce the invention cannot succeed unless he follows the steps of some specific technical means or methods disclosed in the application which form an integral part of the technical contribution to the prior art, those technical means or methods are to be taken into consideration for the purposes of Rule 23 d (c) EPC'

in the following section but clearly this is a broad interpretation and one which did not follow the views of the Commission's European Group on Ethics empowered under Article 7[395] of the Biotechnology Directive to evaluate all ethical aspects of biotechnology. Their report concluded:

> As to the patentability of processes involving human stem cells, whatever their source, there is no specific ethical obstacle, in so far as they fulfil the requirements of patentability (novelty, inventive step and industrial application).

The EPO decision was closer to the dissenting opinion of Professor Gunter Virt who disagreed with the patenting of 'process and products using materials resulting from destroyed human embryos' because:

> This use as material contradicts the dignity of an embryo as a human being with the derived right to life. If the condition for patentability is the industrial and commercial use and if the use of human embryos for industrial and commercial purposes is not patentable, then every exception, which cannot exclude industrial and commercial purposes, is against the ethical sense of the directive.[396]

Although the appeals are pending, the former President of the EPO, Professor Alain Pompidou, has responded to an invitation to comment upon the *Wisconsin Alumni*

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[395] Under Article 7 of the Biotechnology Directive: 'The Commission's European Group on Ethics in Science and New Technologies evaluates all ethical aspects of biotechnology'. Their conclusions are advisory and are not binding upon the EPO.

[396] European Group on Ethics in Science and New Technologies, 'Ethical aspects of patenting inventions involving human stem cells', Report to the European Commission, number 16, 7 May 2000, page 19

Research Foundation case[397] and has underlined the broad interpretation as the appropriate course to follow. In particular he states:

> Article 52 (1) EPC does not enshrine a general principle of narrow interpretation of exclusions. A presumption in favour of a narrow interpretation of exceptions to patentability would unduly limit the significance of the moral jurisdiction under Article 53 (a) EPC and Rule 23 (d) EPC, the purpose of which is the incorporation of higher ranking legal and moral principles into European patent law, and would thus be in conflict with the general objectives of said norms.[398]

This interpretation of the moral provisions within patent law adds a new dimension to patent exclusions and creates a conflict with national patent office policy[399] and the policies of the practices of member states[400]. Linking morality to the research leading to the invention rather than to the 'commercial exploitation' of the invention is an attempt to control or influence the direction of research within member states. Given the reliance of biotechnology companies[401] upon the patenting of their inventions clearly prohibition of patents over particular inventions will affect the direction of research, or at the very least it will ensure that such research is carried out elsewhere.

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[397] Case T 1374/04, G 2/06.

[398] Pompidou, 28 September 2006, at page 34.

[399] The United Kingdom patent office takes a different approach, see case study one

[400] Some countries, for example, the United Kingdom encourage human embryonic stem cell research

[401] See Chapter three

(4) (f) Moral Problems

Patents, the inventions they protect, and public perceptions have changed immeasurably in recent times. The morality clause was never intended to be interpreted as widely as the examples outlined above illustrate. There is no accepted, clear and agreed role, scope or aim for the use of morality in patent law to exclude inventions which would otherwise enjoy protection. The role of morality is becoming increasingly invasive as a result of the human embryonic stem cells cases and because of the direction that the EPO appears to be following.

It is ineffective to continue to try to address pre-grant moral concerns relating to inventions through the patent system. This gives the impression that patent law is the bastion of morality; it provides a false picture and could leave a legal vacuum. The expanding interpretation of morality is also invasive because such a role enables the European Patent Office to construe its own morality in EPO countries whether or not the relevant research is acceptable and funded within the affected states.

If regulation is negative, in other words if the relevant invention is illegal, then the advantages in obtaining the grant of a patent depend upon extraneous circumstances such as potential future changes to regulation, the regulatory position of other countries[402] and difference between regulations relating to research and those relating to exploitation[403]. If regulation is facilitative so that regulation includes specific provision to make possible an invention then it is obtuse to refuse a patent upon the

[402] Subject to the caveat of Article 53 (not deemed immoral merely because prohibited), see the comments in Opinion of Advocate General Jacobs, Kingdom of the Netherlands case.

[403] In the case where research may be disallowed but use of the invention is not.

invention because of objections to permitted research. On the other hand if regulation is silent then patent law could be the only method available of attesting to the acceptability of the work in question. Three variances in regulatory attitude are thus apparent:

1. Permissive or facilitative Regulation
2. Prohibitive Regulation
3. Absence of Regulation

(4) (F) (I) PERMISSIVE OR FACILITATIVE REGULATION

Most people would agree that human embryonic stem cell research raises controversial issues. It is wholly appropriate to question the extent, if any, to which such research should be permitted. Certainly a line should be drawn between what is acceptable and what must be justified within scientific and ethical principles. In the United Kingdom the demarcation is in accordance with the Human Fertilisation and Embryology Act which, inter alia, regulates research on human embryos. Lengthy debate[404], litigation[405] and Parliamentary scrutiny[406], have created precedent to enable research within tightly controlled licences.

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[404] Including Nuffield Council on Bioethics, 'Stem Cell Therapy: A Discussion Paper' (2000) and Department of Health, 'Stem Cell Research: Medical Progress with Responsibility' (2000), Report of the Committee of Inquiry into Human Fertilisation and Embryology 1984, 'Warnock Report' Cm 9314.

[405] See for example *R (on the application of Quintavalle) v Secretary of State for Health* [2003] 2 AC 687.

[406] Report of the Committee of Enquiry into Human Fertilisation and Embryology (the Warnock Report) 1984 Cmnd.9314 , House of Lords Stem Cell Research (HL Paper 83 (i) 2002) and see current debate regarding Bill to amend the procedures relating to consent and use of material for human embryonic stem cell research http://services.parliament.uk/bills/2007-08/humanfertilisationandembryology.html last accessed 25th January 2008

It would be at odds with a permissive regime of regulation if patent law were to interpret morality so that inventions which have been scrutinised in such detail were to be excluded from patent protection. It is submitted that in such cases patent law should only take a moral stance if there is some additional factor present that makes granting of a patent immoral and that additional factor must relate only to the added value that a patent provides. It follows that in such circumstances it is wholly incorrect to refuse a patent because of an objection to the technology. Objections to such inventions being exploited through a monopoly or to the manner of exploitation may be reasonable, but these are separate matters and are discussed below.

(4) (F) (II) PROHIBITIVE REGULATION

Clearly the way to control specific objections to innovation is by the general legal system rather than by using alteration of innovation rewards. There may be reasons for the two, i.e. patent law and regulatory provisions, to diverge as outlined by the Advocate General[407] but, of course legal prohibition must be an indication, if not the only clear indication[408], of what view society adopts. Consistency is important, and is one of the aims of European Patent Convention, of the ongoing attempts at harmonisation of European patent provisions and the Biotechnology Directive, but harmonisation will be impossible without greater congruence between the two.

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[407] Opinion of Advocate General Jacobs, *Kingdom of the Netherlands case,* see also above page…

[408] 'Indeed, legal prohibition in a realm such as embryo research is likely to be a much more balanced and accurate measure of an invention's unacceptability to citizens within a particular jurisdiction than is the application of the exclusions of Article 6 EC Directive or Article 53 (a) EPC by a patent office.' G Laurie, 'Patenting Stem Cells of Human Origin' [2002] EIPR 59.

(4) (F) (III) SILENT REGULATION

Patent law may be looked upon as the last bastion of legal protection when the regulation system is silent:

> Experience has shown, that in cases where appropriate research legislation is missing, high expectations are raised and many claims are laid on the patent authorities and on the patent legislator to address controversial issues and offer guidance in ethically delicate matters, which have not effectively been treated by bio-ethical research laws.[409]

Yet this too is problematical. Patent law for several reasons, does not have nor should it have a mandate to direct what society permits or ought to permit. There may be particular inventions which a clear consensus exists against them, and examples have been discussed in cases[410], but outside the obvious how far should patent law be permitted to draw the boundaries of acceptability?

Furthermore patent law merely grants or refuses patents, which has little effect upon inventions per se. So and if (a) inventions are sufficiently dangerous or objectionable, and (b) no formal legal action is available to address the concerns, there is a dangerous vacuum in regulation which ought not to be filled by patent law which is inappropriate and ineffective for that purpose.

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[409] European Group on Ethics in Science and New Technologies Report, 'Study on the patenting of inventions related to human stem cell research', 67.

[410] Nail bombs, land mines, letter bombs etc

The use of the morality clause in the European context is of greater concern because it results in moral policy being determined centrally by the European Patent Office which, however hard it tries, cannot be reflective of the diverse European perceptions of morality in relation to research, the morality of which is subject to divided opinions. Furthermore, states that do not take it upon themselves to regulate issues that they are opposed to cannot leave it up to the EPO to fill the gap. The morality clause can be harmful in certain circumstance because prospects of a morality challenge within European Patent law will deter innovation[411] within Europe and potentially draws attention away from creation of regulations aimed more directly and, therefore, more effectively at ethical concerns about innovation.

The reasons behind the concerns which have led to expansion in the scope, but not the competence, of the morality clause may be justified and the scrutiny welcome, but I believe that broadening the range of the current morality provisions, in the way envisaged by the European Patent Office, is excessive and at the same time insufficient. Different moral issues arise at each stage of an innovation process so the focus of objections to patents for moral and access reasons at grant stage is ineffectual.

[411] For example through encouraging innovation transfer to the United States.

(4) (g) Moral Options

The above cases suggest that there is a conflict within European Patent Law between retaining integrity on the one hand and influencing public policy on the other and this is reflected in the debate between supporters and opponents of biotechnology. Tensions between the EPO interpretation of morality and the practices and views of individual EPC states are disharmonious and act against the initial aims of the Biotechnology Directive and the European Patent Convention. One option open to the EPO is to keep the current interpretation and leave applicants to apply to individual states for patents in cases where EPO morality would exclude them but national interpretation would not. This would fail the aims of harmonisation and simplification of European Patent Law. Alternatively the moral interpretation of individual states could be ignored. This too is unsatisfactory because of the uncertainty for potential patentees who may not appreciate the likely position taken by the EPO and would also be a failure to take account of strongly felt views of Member States.

Morality could be removed from patent law altogether, but this is unlikely because there are particular inventions for which a uniform view on morality exists and exclusions from patentability of these are unlikely to cause any controversy or confusion[412]. The crux of the initial question therefore is what way should morality be addressed in relation to inventions for which no European consensus exists?

[412] Such as letter bombs, landmines etc

One option is to enable patents for inventions only for those states which do not object to particular products or processes. But the EPO is unlikely to be able to mount investigations into every controversial invention within each individual country and such a scheme is likely to give rise to administrative overburdening. A more appropriate option is to grant patents and leave objections in relation to morality to be dealt with by individual patent offices at the time of enforcement as advocated by the PATGEN Project[413].:

> Having reviewed the options in circumstances where there is no uniform European view on morality, the report concludes that the jurisprudence of the EPO interpreting the EPC, is that in absence of a European wide moral norm the patent should be granted. Member States may thereafter exercise their right to invalidate the patent to reflect distinctive national moral considerations precluding the grant of the patent.

In this way moral objections can be raised during exploitation and the national patent office can decide upon morality in accordance with the moral principles that apply therein. Another advantage of assessing the morality of inventions during the exploitation of patented inventions is that it enables patent offices to appreciate whether or not the 'commercial exploitation' of inventions has been contrary to *ordre public* or morality.

Importantly different moral issues relating to patents and the inventions they protect arise at each stage of innovation:

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[413] PATGEN Project, 'The Patenting of Human DNA: Global Trends in Public and Private Sector Activity' Final Project Report, November 2006, Priority: FP6-2003-Lifescihealth-II, AT PAGE 133

	Innovation or Incentive Stage	Grant Stage	Exploitation Stage	Generic Stage
Regulation	Ethical and legal rules that govern the envelope of research e.g. HFEA. Any other legal requirements – e.g. Health and safety/environmental regulations etc – consent from participants. Human Tissue Act 2004 **Regulation relating to research**	Different regulation may be relevant i.e. from that which governs particular research to that which is pertinent for resulting inventions. **Regulation relating to invention resulting from research**	(a) Strength of market demand (b)licensing practices (c) Competition Law **Regulation relating to method of exploitation**	Generics still under regulations – i.e. will still have to comply with any regulatory requirements re safety etc
Moral Concerns	Unnecessary blocking effect of patents already granted – a direct cause of patent grant Research – danger to environment/animal cruelty/unknown potentially hazardous outcomes – not caused by grant of patents	Encouraging or rewarding particular immoral innovation. Symbolism of acceptance in event of absence of regulation	Stacks/reach-through licences – potential blocking – research – restrictive licenses caused by patent grants	Other IP – Trade secrets/

Table Six – Regulation and Morality

The following chapter examines patent law within the stages of innovation with particular emphasis upon pre and post-grant so as to observe how patent law operates within each stage so as to achieve the aims of incentive etc as well as how patent law reacts to or addresses the moral influences discussed in this chapter such as controversial research. Three case studies will be utilised in the following chapter; two of which relate to objections to patentability that arose before the grant of patent and the third of which arose during exploitation. The aim is to appreciate, in greater detail, the way in which morality is addressed at different stages within an innovation time line.

(5) Chapter Five - Patent Law and Regulation

'...the power of science for good and evil has always troubled man's mind'.[414]

The introduction[415] outlined the complexities of regulation and how the operation of patent law illustrates a variety[416] of regulatory attributes[417]. This chapter examines these qualities in greater detail in particular the regulatory strategies utilised by patent law at the various stages of the innovation time line. The first part of the chapter examines the manner in which patent law 'regulates' what may be considered as traditional aims of patent law, i.e. creating incentive to innovate. The second section discusses how patent law responds to pressures outside the traditional picture of patent law. The third section examines three case studies, two relating to pre-grant issues and one relating to post-grant concerns:

1. Examples of Specific Exclusions from Patentability – pre-grant
2. Consent to use of human material – pre-grant
3. Defeat of the Patent Paradox – post grant

The relevance of this exercise is to illustrate that patent morality cannot be addressed with a simple on/off switch at the time of grant. In other words the different moral

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[414] *PLANT GENETIC SYSTEMS/Glutamine Synthetase Inhibitors* [1995] EPOR 4, page 12 para.17.1

415 See 'A Regulatory Chameleon' above

416 There is no clear definition of regulation but in its broader sense it relates to any form of government intervention, 'a specific set of commands...deliberate state influence...all forms of social control or influence...' Baldwin and Cave Understanding Regulation: Theory, Strategy and Practice (OUP 1999) 2. This definition includes patent law within its ambit

417 Incentive based regime, market harnessing, control of information for example

factors at each stage should be taken into account and patent decisions makers should be equipped with more flexible options. Morality has provided a gateway through which patent examiners can respond to wider concerns than the technical questions of patentability of inventions. Ethical questions, as we have seen, have far greater ramifications than questioning the patentability of inventions and are no longer limited to inventions that are clearly and universally abhorrent. Inventions derived from research using human embryonic stem cells (HESCs), for example, may save lives and benefit many, and cannot be compared to letter bombs or anti-personnel mines. On the other hand there are important ethical questions that arise from research into human embryos, the use and exploitation of HESCs derived from such research, and there will be other equally controversial technologies that will challenge the patent system[418]. So the question arises: what is the role of patent law in relation to the different ethical concerns that arise at each stage of innovation?

A letter bomb, for example, is immoral at all stages; it is immoral to research, invent, use and exploit. HESCs, on the other hand, are created through research which is considered unethical to some, but HESCs per se do not raise the same ethical concerns and exploitation of HESCs may raise different issues. The actions of some European states illustrate these different attitudes to concerns at each stage. For example, Germany prohibits research relating to human embryos to establish HESC lines but permits the importation of HESCs created through such processes for research

[418] Controversial issues raised by nanotechnology, for example, or the results of cytoplasmic hybrid research, licences for which were granted by the Human Fertilisation and Embryology Authority ("HFEA") to Newcastle University, Newcastle Upon Tyne, in May 2007, may eventually come to be considered by EPO.

purposes[419]. This section considers the effects of granting patents at each stage of the innovation process vis-à-vis different ethical questions. The results suggest that it is doubtful that patent law can address morality on a holistic basis and moral questions for patent law should be more specific and linked to the effect of excluding inventions rather than being motivated by reaction.

Regulatory effect can be separated into policy objectives or regulatory target, and the means of determining them[420] or regulatory strategy.[421] The objective describes the question, 'What is regulation aimed at?' (purpose) and the strategy answers, 'How that is to be achieved' (method).

European patent law can be understood in two planes; traditional patent law, blind to the wider issues, and new patent law which excludes inventions from patentability for policy reasons. The objective of traditional patent law is inter alia[422] to stimulate economic growth and it applies regulatory strategies[423] to achieve this end. 'New' patent law on the other hand utilises exclusion of inventions but the purpose and

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[419] A Plomer, 'Stem Cell Patents: European Patent Law and Ethics' Report, FP6 'Life Sciences, genomics and biotechnology for health', SSA LSSB-CT-2004-00525: 'Nevertheless, it is prohibited to extract hESC from embryos, thus making it impossible to establish hESC lines in Germany. It is, however, possible to research on imported pluripotent hESC in accordance with the German Stem Cell Act'.

[420] See C Scott, 'Rethinking regulatory governance for the age of biotechnology', in Somsen, *'The Regulatory Challenge of Biotechnolog'y*. See also Baldwin R and Cave M, *'Understanding Regulation: Theory, Strategy and Practice'* (OUP 1999).

[421] R Baldwin and M Cave, *'Understanding Regulation: Theory, Strategy and Practice'* (OUP 1999).

[422] Section two indicated that patent law is also intended to increase the availability of information through publication of patent specifications by inventors. There may be some disagreement as to what patent law achieves; promotion of private interest against the public interest, rewarding inventors or stimulating the economy, promoting the knowledge-based economy rather than increasing access to health care (See B Williams-Jones, 'History of a gene patent: Tracing the development and application of commercial BRCA Testing', (2002) 10 Health Law Journal, 124). However the ultimate aim of patent law is to provide incentives to innovate.

[423] Such as creation of rights and liabilities and through incentive

strategy is unclear. The following examines the regulatory strategy of traditional and new patent law to appreciate the purpose and method of each.

(5) (a) Traditional Picture[424] of Patent Regulation

The way patent law achieves its 'traditional' aims illustrates the effects of patent law upon innovation at different stages of innovation:

	Innovation or Incentive Stage	**Grant Stage**	**Exploitation Stage**	**Generic Stage**
Patent Theory	Utility Theory/incentive Fund raising	Disclosure/information control	Reward or Natural Right theory – Democratic tax theory	Distribution to all funded by prior higher prices
The Patent Effect	The prospect of a patent provides an incentive to commence research and development. Patents may also encourage commercialisation so distinguish between incentive to research and incentive to commercialise the results of research	Assess inventive quality – novelty/inventive step and Utility – Morality Priority date (application) Publication within 18 months – nb section 21 applications representations by 3rd parties Max. time to grant 4.5 years NB – EPO 9 months for 3rd party to oppose patent grant	Monopoly Publication – encourages (a) further research (b) inventing around patent (c) compulsory licenses (d) research exemption	Open competition

Table Seven – Patent Effect

The following examines in more detail how patent law uses regulation, so as to help understand whether the refusal of patent grant, to address broader issues, is effective.

[424] See also section one which discusses the patent system in greater detail. It is the intention here to indicate the regulatory forms used in traditional patent application.

(5) (A) (I) INCENTIVE REGULATION

The obvious starting point is to recognise patent law as an 'incentive-based regime'. This form of regulation normally aims to induce relevant persons to '...behave in accordance with the public interest'[425] by incentives or tax relief or provision of public grants. Incentive regulation is apparent in the first stage of the innovation time line. Patent law is an unusual illustration of this form of regulation for a number of reasons:

(1) The incentive is not of a defined amount. There is no direct monetary reward such as a grant or tax deduction. Instead the reward is in the form of a negative right[426]; the ability to prevent potential rivals from making, disposing of, offering to dispose of, using or importing the patent holder's invention[427]. The value of this will vary from case to case and will be significantly influenced by other factors[428].

(2) The benefit of a patent once obtained achieves expression through two other forms of regulatory strategy; self-regulation and creation of rights and liabilities. Self-regulation is characterised usually by rules that are administered via industries' own trade organisations. This can be seen in the insurance industry, some media sectors and advertising in the UK. Patent law in some

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[425] Baldwin and Cave, '*Understanding Regulation*'.

[426] Recital 14 Biotechnology Directive describes the right as 'Whereas a patent for invention does not authorise the holder to implement that invention, but merely entitles him to prohibit third parties from exploiting it for industrial and commercial purposes...'.

[427] Section 60 (1) (a) Patents Act 1977.

[428] See the sub-section 'Interplanetary Alignment' in section one above.

respects[429] resembles a self-regulatory system but it is different in that there is no central body that takes the decision to enforce patent rights. It is the members, i.e. inventors, who apply for and are granted a patent to decide whether to take any action in the event that they believe their patent is infringed. There are patent courts and patent offices which constitute the mechanism of the system, but at the end of the day it is up to the inventor/patent-holder to take proceedings in the event of perceived infringement. Patent law functions because the grant of a patent creates an individual right to litigate for infringement and a consequent liability for proven infringers. There are parallels in other legislation where regulatory aim is achieved through creating rights. Health and safety law, for example, enables injured parties to claim damages through the courts in the event of negligence as one of a number of strategies[430] of encouraging safer working environments.

(3) Financial reward does not come directly from the public purse but from those who purchase patented inventions. The patent incentive is one step removed from direct government finance, instead of payment from general taxation the earnings are generated by those who actually fund patented inventions by purchasing them. If there are moral concerns regarding particular inventions then it may argued that the market should decide; the public can express their views through deciding whether they are happy to purchase the particular invention or not.

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[429] I.e. it is in the control of the members (the inventors or patent owners) to take action in respect of infringement

[430] Fines and criminal penalties may be imposed in relation to serious breaches of health and safety regulation thus using a more command and control oriented regulation strategy

If patents are refused over particular inventions for reasons relating to objection to the invention or for wider concerns relating to research the outcome is difficult to predict. On the one hand refusal to grant may encourage others to enter the particular market thus having the opposite effect to that intended by the refusal in the first place. On the other hand it may signal a removal of incentive to others who may be involved in a similar area and so removing the incentive for that particular area. Incentive regulation (and the opposite regulating through disincentive) is therefore not foolproof. The disincentive from working with a particular invention and a disincentive from working in a field generally are two entirely different matters and the effect of using the refusal of a patent to influence either occurs at different stages (invention specific in exploitation stage and invention general in incentive stage).

(5) (A) (II) REGULATION THROUGH CREATION OF RIGHTS AND LIABILITIES

Awards of patents create rights to patentees to prevent competitors or anyone else from infringing their patents. In the event of infringement the holders may obtain damages and/or an injunction. Thus a patent is a reward that directly affects others, including inventors who have made the same invention independently but failed to file their patent application in time[431]. Once a patent is granted there are strong incentives upon others not to infringe. This section of the operation of the patent system occurs during the enforcement or commercialisation stage whereas the incentive element is relevant

[431] The first-to-file rule applies in UK patent law whilst in the United States, the patent is granted to the first to invent.

mainly at grant or pre-grant stages. Patent law therefore relies upon patentees to police the system so if a patent is not granted then the relevant invention is no longer part of the system and is thus open to all comers.

(5) (A) (III) MARKET HARNESSING CONTROLS

The award of a patent creates interference in the free workings of the market economy. Market harnessing controls are usually in the form of methods of preventing monopolistic behaviour or increasing competition. The reward of a patent to an inventor brings the opposite as it allows him to exploit prices by restricting supply and preventing competition. The result of refusing a patent over a particular invention is that anyone can enter the relevant market.

The basic economic rationale for the grant of a patent breaks down in the event that patent rights are excessive and stifle further innovation or restrict access to such an extent that society fails to benefit. Such a scenario is perhaps more acute in the case of medical innovation because the result of restricted access is restrictions on health care. Patent law is an instrument of public policy and its aim is to benefit the public through greater innovation, it should not enable innovation to be smothered, yet there are instances[432] where this could be the case. Here patent law is faced with a dilemma; should the law ignore the minority of cases where this may occur or should steps be taken to control the extent of the monopoly? There are dangers in either course; inaction may result in specific restrictions in relation to the patent in question whilst the proactive approach may reduce the overall incentive for other innovation and thus have a subsequent deterrent effect for others entering the market. Whether that would

[432] Discussed below

occur and if so to what extent is difficult to tell, but one could envisage circumstances whereby gross inequality in rights of individual patentees against the public interest should have a remedy within patent law if the inequity arose as a result of the grant of a patent[433]. Clearly this is a moral argument as well as an economic one and one in which patent law is well placed to have an impact, but strong patent rights are seen as essential for the proper working of the patent system and any qualification to those rights is likely to be met with strong opposition, regardless of the merits of individual cases. It will be suggested[434] that this attitude requires revisiting and it is in the area of market harnessing regulation, which is apparent in the exploitation stage of innovation where this is likely to be effective, rather than within the incentive stage.

(5) (A) (IV) INFORMATION DISCLOSURE

Information control as a form of regulation normally takes the form of compulsory disclosure as with ingredients of food and drinks[435]. Part of the patent bargain between inventors and the patent office is the supply of information. The workings of inventions must be fully disclosed by defining the invention, and outlining the extent of the claim enables copying once a patent expires and enables competitors to improve upon inventions. The level of information should be equivalent to the monopoly provided, in other words, patent protection only covers what is delineated within the patent claims and must be disclosed to allow every working of the invention. In this

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[433] Patent law in certain restricted circumstances may grant a compulsory licence after three years from grant in the event that there is a need for the particular invention and the patentee is not satisfying that need. These licenses are discussed further below but the aim with such licenses is to encourage patented inventions to be commercialised.

[434] See below chapter six

[435] Baldwin and Cave, '*Understanding Regulation*', chapter four

way it should be clear what others can add to it and to what extent they can invent around it. In the absence of the requirement of disclosure, it is likely that many inventions and fundamental information about them would remain outside public knowledge. In the event of use of refusal of a patent to remove incentive relating to a particular form of technology one result may be to encourage secrecy as inventors seek to protect inventions in other ways.

(5) (A) (V) DIRECT ACTION OR PUBLIC COMPENSATION

Patent law can be seen[436] as a form of fund raising – it rewards innovation paid for retrospectively by those who purchase patented products or processes. It is similar to a voluntary tax but is payment for the specific purpose of funding innovation. Much innovation arises as a result of venture capital loaned or invested in the belief or hope that the fruits from finance will be protected through patent rights. It is consumers' choice whether to pay for particular inventions and if a moral question arises with an invention per se then whether it is patented or not is irrelevant – if they are offended they wont buy it and if not they might. Likewise if a patented invention is expensive it is the consumers' choice whether or not to buy. A mixture of demand and supply determines price of a product and if supply is reduced to maximise returns, which a monopolist can influence, then the existence of a patent influences a patentees ability to control supply in his favour. I am not suggesting here that patent law should take positive steps to influence such a situation[437], but using this as an example to show that patents can do little to influence inventions per se but can influence the supply.

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[436] As discussed above in chapter two

[437] Indeed the ability for patentees to set supply to maximise return is the reward for innovation

Each of these types of regulation operates at different stages of innovation and it is reasonably clear how and why patent law is structured in the way it is. Once excluding inventions for policy reasons is examined the regulatory strategy is no longer as clear.

(5) (b) Wider Perspectives of Patent Regulation

In relation to traditional aims of patent law the 'why' (economic incentive) and the 'how' (application of regulation strategy) can be understood in terms that illustrate a complex but coherent system. The regulation strategy can be summarised in the following table:

	Innovation or Incentive Stage	**Grant Stage**	**Exploitation Stage**	**Generic Stage**
Patent regulation strategy	Incentive regulation	Creation of rights and liabilities Information Control	Market Harnessing Direct Action Self regulation	Public Compensation

Table Eight – Regulation strategy

Chapter four discussed generally morality issues that have arisen against patenting, in particular the increase in moral issues because of biotechnology and it illustrated that different moral issues arose at each stage of innovation. This can be expressed within the innovation time line as follows:

	Innovation or Incentive Stage	Grant Stage	Exploitation Stage	Generic Stage
Moral Concerns	Consent Morality of particular research Cruelty to animals	Grant of patent Encouraging or rewarding particular immoral innovation. Symbolism of acceptance in event of absence of regulation	Commercial exploitation -	Other IP – Trade secrets/

Table Nine – Morality

Each objection can be reflected within different stages of the hypothetical innovation time line. The theoretical objections may be of a different nature (ethical or accessibility, for example) or object (research, physical inventions or exploitation of inventions). The morality clause does not distinguish between them, but yet the medium of such objections is through the morality clause. The remainder of this chapter examines the wider effects of opposition to patents for pre-grant and post-grant objections so as to obtain some regulatory logic or purpose to the exclusion of specific inventions. A patent system can only accept or refuse patents[438] so the consequence of a successful opposition to particular patents is to broaden the range of a priori exclusions. Given the different type of opposition which arises in different stages of innovation the aim is now to understand the consequences from a regulation perspective of excluding particular inventions from patentability. Motivation for excluding inventions may be different for gamekeepers and poachers[439].

[438] Subject to provisions for compulsory licences in restricted circumstances, see below. It should be noted that patent systems will allow for amendment of claims. For example the UK Patents Act 1977 allows for amendments before grant (s19), after grant (s 27) and during infringement or revocation proceedings although amendments shall not include added matter (s76)

[439] If gamekeepers are considered as supporters of biotechnology and poachers as those who oppose it on occasions they may both advocate exclusion from patentability for particular inventions but for very

Regulatory strategy (in the case of specific patent exclusion) should be seen in the light of other regulation and whether objections to patents are related to pre- or post-grant issues. The strategy that is used by patent law interacts with other regulation (which may relate more directly to the object of objection – for example research or consent). The interaction has been expressed by Dutfield G as:

> One of its[440] successes is that international policy making and diplomacy increasingly treat intellectual property relating to biological and genetic material and the regulation of biodiversity control, access use and exchange as interrelated topics for negotiation.[441]

The above quotation is of interest because it illustrates a new and apparently accepted relationship between patent law and other regulation. 'The patenting process stands at the confluence of science and technology, on the one hand, and law, on the other.'[442] Clearly regulation out-with the patent system is the appropriate place to deal with '...regulation of biodiversity control, access use and exchange...', but equally clearly, intellectual property has established a role also. What that role is or what it should be is not clear.

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different reasons – this apparent paradox has been alluded to in the introduction and is discussed further below

[440] I.e. opposition to biotechnology groups.

[441] Dutfield, '*Intellectual Property Rights and the Life Science Industries*', 211: 'National intellectual property offices and politicians are beginning to listen to alternative voices'.

[442] Mills, *Biotechnological Inventions*.

The three case studies below examine interaction of patent law with different rules that relate to research, those of consent to use body material and those which relate to the commercial exploitation of inventions. The first two relate to events that concern pre-grant issues during innovation stage whilst the third relates to post-grant.

(5) (B) (I) INNOVATION STAGE

This section examines the interaction between patent law and regulation during the period leading up to the grant of a patent – the innovation stage – with the purpose of illustrating the effect of using patent invalidity as a means of directing or helping to direct research within legal or acceptable parameters. Concern has been mentioned above[443] regarding invalidation of patents for this reason including: 'There is a disturbing trend to consider patents as invalid under Article 53 (a)[444] EPC, not for anything to do with the *use* of the invention but because of what the inventor did before filing the application'[445].

Such concern is understandable not least because of the uncertainty and unfairness to inventors who may encounter difficulties that they were not aware of when they embarked upon the relevant research. Furthermore a regulatory strategy involving the refusal of patent grant to address events carried out prior to patent applications, would appear to be ineffective if applied retrospectively – the invention having been created,

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[443] See above, Introduction, 'Stimulate or stipulate'.

[444] Article 53 (a) is the EPC version of what has become know as the 'morality clause' and states as follows: 'European Patents should not be granted in respect of (a) inventions the publication or exploitation of which would be contrary to ordre public or morality provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the contracting states'. Annex X lists the different versions of the morality clause as provided for by the various instruments and the differences will be discussed in due course.

[445] Grubb, *'Patents for Chemicals, Pharmaceuticals and Biotechnology'*, 286.

the horse has bolted, the genie cannot be put back in the bottle[446]. There is however a subtle relationship between patent law and regulation, so this section will continue with this in mind.

Case Study One – Example of a Specific Exclusion:

Article 6 (2) (c) Biotechnology Directive '...uses of human embryos for industrial or commercial purposes...'

CS (1) CONFLICT IN EUROPE...

The Biotechnology Directive was intended to harmonise biotechnology patent law. However, there has been a divergence of views between signatory states in relation to how morality is to be interpreted, in particular with reference to the patentability of human embryonic stem cells ("HESCs"). This may not be surprising given that the interpretation of morality is intended to reflect the views pertinent within each state at the time so as to allow interpretation accordingly. 'It is common ground that...' Article 6 of the Biotechnology Directive '...allows the administrative authorities and courts of the member states a wide scope for manoeuvre in applying this exclusion'[447].

The contradiction between harmonisation and the respect of interstate autonomy is reflected in practice both in implementation of the Directive and with the interpretation. The Austrian and Dutch Patent Acts, for example, do not include the second and arguably limiting section of Article 6 (2) (c) of the Directive and exclude

[446] Laurie, *Genetic Privacy. A Challenge to Legal Norms.*

[447] *Kingdom of the Netherlands* case at paragraph 37.

uses of embryos per se rather than uses of embryos for industrial or commercial purposes. The specific differences may be invalid[448] but may also be aimed at reflecting the national regulations: 'In, some cases, the legislative measures implementing the Directive make a direct link to national laws on human embryo research'[449]. The United Kingdom translated the wording of Article 6 of the Biotechnology Directive into the Patent Act 1977[450] but changed the wording so as to exclude "...among others..." from Article 6 giving the impression that the list of exclusions appears exhaustive. Furthermore as we shall see the UK Intellectual Property Office interprets the meaning of Article 6 differently to the EPO.

CS (1) ...OR PEACE IN OUR TIME?

There are cases where a standard of morality is accepted[451] within all states as described in the *Plant Genetic Systems*[452] case:

> The concept of morality is related to the belief that some behaviour is right and acceptable whereas other behaviour is wrong, this belief being founded on the totality of the accepted norms which are deeply rooted in a particular culture. For the purposes of the EPC, the culture in question is the culture inherent in European society and civilisation. Accordingly, under Article 53 (a) EPC, inventions the exploitation of which is not in conformity with the

[448] Case C-456/03, *Commission v Italy* [2005] ECR 1 – 5355.

[449] Plomer, 'Stem Cell Patents'.

[450] Schedule A2 Section 76 A of Statutory Instrument 2000 No. 2037

[451] Examples given in papers and cases include letter bombs and antipersonnel mines.

[452] [1995] EPOR 4, Case T-356/93

conventionally-accepted standards of conduct pertaining to this culture are to be excluded from patentability as being contrary to morality[453].

The Biotech Directive presupposes, on the one hand, an allowance for different moral aspirations and, on the other, for Article 6 to be interpreted in accordance with common standards. Therefore there must be room for individual interpretation of morality in the absence of a common standard. Although a common standard is not defined, the four Article 6 (2) exclusions are taken as reflecting that standard and, as they have been inserted by the European Parliament, allow no derogations.

The difficulty for European patent law is how wide an interpretation should be applied to the Article 6 (2) exclusions. The narrow interpretation applied to the morality cases, outlined in chapter three, would confine interpretation to the specific meaning within each exclusion, whilst a broader reading would encompass a range of activities connected to the specific.

The two examples below illustrate this interpretative conflict. Although the examples relate to patentability of HESCs and Article 6 (2) (c), it is suggested that the same issues[454] apply to any of the Article 6 (2) exclusions. For example Article 6 (2) (a) excludes '...processes for cloning human beings...' but this does not differentiate between 'therapeutic cloning' and 'reproductive cloning' the latter is universally accepted as immoral but the former is lawful and encouraged in some states including the United Kingdom. Different opinions exist regarding the source of embryos chosen

[453] ibid.

[454] i.e. that there is no European Consensus as to the interpretation of the specific moral exclusions

for research; whether they are left over from IVF, donated specifically for research purposes or created through parthenogenesis[455]. This creates a separate, but just as emotionally charged, argument about whether we have the right to create life solely for the purposes of destruction and will create the similar conflict in interpretation of morality as under Article 6 (2) (a).

The Article 6 (2) exclusions are limited in quality and scope as they are reflective only of four elements of specific technology considered immoral at the time the Directive entered into force. They do not include all immoral inventions[456] and they are not reflective of changes in morality and advances in understanding of the specific excluded technology. They do not account for advances in science and curiously are differentiated from other immoral inventions outlined in Recital 38[457]. Attitudes may change and the general provision of morality within Article 6 (1) allows moral interpretation to reflect the situation at the time of elucidation but the specific exclusions do not. Biotechnology is still in its infancy and as time goes on and knowledge expands, views on what is acceptable will change.

> Perhaps the time will come when the germ line modification of humans to eradicate genetic disease in entire families will be deemed to be ethical, and

[455] Uniparental sexual reproduction: 'Parthenogenesis is defined as the development of an ovule without there having been any fertilisation by a spermatozoid' (IPI, 'Patents for genetic sequences: The Competitiveness of Current UK Law and Practice').

[456] Recital 38 '....whereas this list obviously cannot presume to be exhaustive...'

[457] Such as '...processes to produce chimeras from germ cells or totipotent cells of humans and animals...'

maybe even imperative; but that is clearly not yet the view of the legislator or, according to Recital (40) society...[458]

Given the differences in the views within Europe at present it would not be surprising if moral views changed within each state at different rates. That said. the example of the interpretation of Article 6 (2) (c) illustrates the current state of confusion relating to the Article 6 (2) exclusions.

CS (1) EMBRYOS EARNING THEIR KEEP: EQUATING RESEARCH WITH INVENTION

The morality exclusions outlined in Article 6 (2) (c) have come to be interpreted by the EPO because HESCs, which can only be obtained by using human embryos that are destroyed in the process, are believed to be vital in order for research to progress into treatments in respect of serious illness, disease or injury which result in destroyed or damaged tissue. 'The hope is that ESCs can be turned into specialised cells for repairing damage in a wide range of tissues'[459], so potentially many terrible afflictions can be treated: multiple sclerosis, diabetes, spinal injuries[460], auto-immune diseases, degenerative diseases such as Parkinson's disease, and many more.[461] Patents which claim HESCs or which use HESCs will relate to inventions that have been created through use and destruction of embryos. The secret is to obtain types of cells that will

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[458] G Kamstra et al., '*Patents on Biotechnological Inventions.*'

[459] 'Great Expectations – Embryonic Stem Cells could work wonders if we knew how to get them', New Scientist (28 May 2005), 5.

[460] A Goho, 'Embryonic Hope', New Scientist (5 July 2003), 19: 'The findings add to a growing number of studies that suggest embryonic stem cells could have a valuable role to play in treating spinal injuries'.

[461] Corrigan et al., 'Ethical, legal and social issues in stem cell research and therapy', Briefing Paper from Cambridge Genetics Knowledge Park, 2nd Edition March 2006.

grow in accordance with specific instructions, but not all stem cells are capable[462] of doing this.

Stem cells can be classified in groups according to their origins or their elasticity, the differences mean that they do not all carry the same ethical baggage; some are more objectionable to opponents of the processes than others. Human stem cells can be derived from various sources including adults' nasal linings[463], umbilical cords, foetal cells[464] and human skin[465]. It is possible that non-embryonic stem cells, the use of which is not so contentious, could be as efficient at producing significant medical breakthroughs, personalised[466] for the patient concerned[467]. This may be from skin cells[468], cells from the nasal linings, or bone marrow or umbilical cord, and thus experimentation will not raise the same emotive issues. Theoretically any type of adult cell can be reprogrammed through 'transdifferentiation'[469] which means 'transforming an already specialised or differentiated type of adult cell, such as a skin cell, into a

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[462] Scientists have reengineered skin cells to act like embryonic stem cells and this may provide an alternative to the use of HESCs. Opinion is divided as to whether there is a need for HESC research 'It is important that this breakthrough should not prevent work on therapeutic cloning' according to Dr Lyle Armstrong, North East England Stem Cell Institute: 'This is a very exciting advance'. Available < http://news.bbc.co.uk/1/hi/health/7103787.stm >. Last accessed 3rd January 2008

[463] R Nowak, 'Do nose cells know how to bridge the spinal gap?' New Scientist (13 July 2002), 18, see also Goho, 'Embryonic Hope', 19: 'Human trials of some treatments, such as using nose cells, have already begun'.

[464] A Coghlan, 'Baby Cells patch up Mother's Brain', New Scientist (20 August 2005), 8.

[465] A Coghlan, 'How to turn your Skin into Bone', New Scientist (2 July 2005), 16.

[466] Pharmacogenomics, sometimes called 'personal medicine', relates to the tailoring of the intake of drugs to the particular genetic makeup and disease variant of the individual patient. Pharmacogenomics also means that clinical trials can be targeted at a specific group of patients whose genetic make-up responds closely to the drug, which reduces time and cost in trials.

[467] For example, 'Organs on demand, no embryo needed' New Scientist (7 October 2006), 8, claims that embryonic stem cells have been created from skin cells of mice, see also 'Human Embryonic stem cell lines derived from single blastomeres', Nature, doi: 10.1038/nature05142.

[468] See 'Development Biology: Field Leaps Forward with New Stem Cell Advances' Science Now (23 November 2007), 1224: 'Two groups report this week that they have reprogrammed human skin cells into so-called induced pluripotent cells…'.

[469] S P Westphal, 'Transformers', New Scientist (12 October 2002), 39.

completely different type, such as a nerve cell'. Claims have also been made to derive stem cells from interspecies cloning[470]. Such theories are not, so far, supported by practical results so the most likely sources of obtaining useful stem cells are from human embryos.

Stem cells can also be classified according to their potential to metamorphose but the boundaries between categories are not so obvious. Human totipotent cells have the potential to develop into any human cell and could ultimately reproduce into 'an entire human body'[471]. Human pluripotent stem cells arise after a further subdivision of totipotent cells. The distinguishing factor between pluripotent and totipotent stem cells is that pluripotent cells are not capable of transforming into an embryo[472] and thus are not capable of forming an entire human body. This characteristic distinguishes their patentability status in the United Kingdom in that the '...Patent Office is ready to grant patents for inventions involving such cells provided they satisfy the normal requirements for patentability'[473]. Whereas 'the Patent Office will not grant patents for human totipotent cells'[474] because the human body at its various stages of its formation and development is excluded from patentability by Para 3(a) Schedule 2 of the Patents Act 1977. Multipotent stem cells are cells which do not have an unlimited capacity for diversifying into new cells but which can be multiplied and kept in culture[475]. They are

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[470] P Cohen, 'Rabbit-Human Stem Cell claims provoke controversy and doubt', New Scientist (23 August 2003), 14.

[471] The Patent Office, 'Inventions involving human embryonic stem cells' (2003) available at < www.patent.gov.uk >,

[472] Nuffield Council on Bioethics, 'Stem Cell Therapy, the Ethical Issues, a discussion paper' (2000) < www.nuffieldfoundation.org/bioethics >, page 4. Last accessed 3rd January 2008

[473] Patent Office, 'Inventions involving human embryonic stem cells'.

[474] Ibid.

[475] Nuffield Council on Bioethics, 'Stem Cell Therapy, the Ethical Issues'.

present throughout life but are not ubiquitous in adults. Their capacity for renewal is limited although research is ongoing.[476]

The status of cells is not the priority for the EPO as a criterion for the test of morality for patentability; EPO's concern instead is the source of cells. If they originate from the destruction of human embryos then inventions relating to such cells are unpatentable for moral reasons, as illustrated by the following cases:

CS (1) The Edinburgh Patent, number EP 0 695 351

The patent titled, 'Isolation, selection and propagation of animal transgenic stem cells' owned by the University of Edinburgh, originally claimed to include human or animal embryonic stem cells but was amended in July 2002[477] after opposition proceedings brought by, inter alia[478], Greenpeace. The Opposition Division held that the patent failed to comply with, inter alia[479], Rule 23d(c) EPC, which mirrors Article 6(2) (C) Biotechnology Directive, which states that 'uses of human embryos for industrial or commercial purposes' are not patentable for moral reasons.

A broad interpretation of Rule 23d(c) EPC is as follows. Article 5 of Biotech Directive excludes the human body at its various stages of development from patentability, and

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[476] Ibid.

[477] The patent was filed in its original form in April 1994 and was granted in December 1999. The EPO allows a period of nine months for opposition proceedings to be filed by any third party and oppositions were filed in March 2000. Although there were some initial definitional hurdles which were resolved, three days of public hearings led to a decision by the Opposition Division.

[478] Fourteen different parties lodged formal oppositions including the German, Dutch and Italian governments.

[479] It also held that the patent failed for want of disclosure in accordance with Article 83 EPC.

as an embryo is one of the stages of development of the human body it is not patentable by virtue of Article 5. If Rule 23d(c) EPC was to be construed narrowly then Article 5 would in effect make Rule 23d(c) redundant as human embryos would be excluded twice. Therefore Rule 23d(c) had to be interpreted broadly[480], excluding inventions created using human embryos as well as those involving human embryos.

The patent did not claim patent protection for human embryos. However in the process of obtaining the cells, embryos were destroyed. The Opposition Division's decision was based upon objections to acts that were not part of the patent claims. Article 69 EPC states that: 'The scope of protection conferred by a European patent or patent application shall be determined by the terms of the claims'. The decision was appealed but the appeal was withdrawn prior to hearing.[481]

The motive behind the above interpretation is unclear and it has been suggested that it may have been to force interpretation from Enlarged Board of Appeal ("EBA"):

> The above rulings represent such an extreme turnaround from previous EPO jurisprudence in this area that it leads us to wonder if the issue is not being forced from within the EPO itself to ensure that a body with standing such as the EBA brings full and final resolution to the issue[482]

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[480] See *Edinburgh Patent* case

[481] 'Edinburgh Patent Appeal Withdrawn', EPO press release (28 November 2007)

[482] MacQueen H, Waelde C & Laurie G, '*Contemporary Intellectual Property*', Oxford University Press, 2007,

The later comments in relation to this case and the case below from the former President of the EPO Alain Pompidou[483] suggest a broader motive and one which it is submitted herein, that is fundamentally flawed.

CS (1) Wisconsin Alumni Research Foundation (WARF) Patent for 'Primate Embryonic Stem Cells'

A similar patent application by WARF was also refused and the decision has been referred to the Enlarged Board of Appeal (EBA) to consider, inter alia, whether the destruction of spare embryos in the preparation of human embryonic stem cells should invalidate the patent claim to 'primate embryonic stem cells'. Although it cannot be predicted what the EBA will decide, the indications from EPO are that the applicants will be disappointed. The Technical Board of Appeal[484], in referring the case to the EBA, commented upon the questions referred and their view supported the broad interpretation of Rule 23d(c) EPC. The former President of EPO, Professor Alain Pompidou, answered requests from EBA to comment and he too has favoured exclusion of the WARF patent. The positions of the various authorities are summarised below.

***CS (1) Technical Board of Appeal* (7 April 2006):**

Four questions were referred to the EBA but the second question is pertinent for this discussion:

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[483] See below

[484] T-1374/04 – 3.3.08, Interlocutory Decision of Technical Board of Appeal, 7 April 2006.

> If the answer to question 1[485] is yes, does Rule 23d(c) EPC forbid the patenting of claims directed to products (here: human embryonic stem cell cultures) which – as described in the application – at the filing date could be prepared exclusively by a method which necessarily involved the destruction of the human embryos from which the said products are derived, if the said method is not part of the claims?

The answer depends upon whether the exclusion within Rule 23d(c) EPC should be read narrowly or given a broad interpretation. Previous case law suggests that a narrow interpretation should be adopted[486] but the Board has emphasised that the rule that exceptions to patentability should be interpreted narrowly '...does not apply without exception.'[487] The only EBA case where the narrow interpretation rule was addressed is the decision in case number G1/04, on 16 December 2005:

> It is true that there are exclusion clauses from patentability provided for in the EPC. It is also true that the frequently cited principle, according to which exclusion clauses from patentability laid down in the EPC are to be construed in a restrictive manner, does not apply without exception.[488]

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[485] Question 1 asks 'Does Rule 23d(c) EPC apply to an application filed before the entry into force of the rule?'.

[486] See Section three above, and also Boards of Appeal Cases, *PLANT GENETIC SYSTEMS/Glutamine Synthetase Inhibitors* [1995] EPOR 4, Case T 356/93, [1995] OJ EPO, 545; *HARVARD/ ONCO-mouse* T 0019/90, [1990] OJ EPO, 476.

[487] T 1374/04 at Paragraph 33

[488] G1/04 16 December 2005 at reason 6 page 20. The EBA however applied the narrow rule to the case in question relating to Article 52 (4) 'Diagnostic methods'.

The EBA did not provide an opinion either way but suggested that all relevant matters are to be included in interpreting the exclusion and that it should be read according to Articles 31 and 32 of the Vienna Convention on the Law of Treaties[489].

***CS (1) Professor Alain Pompidou* EPO (28 September 2006)[490]:**

The opinion of Professor Pompidou likewise suggests that a broader interpretation is relevant in the circumstances:

> Article 52 (1) EPC does not enshrine a general principle of the narrow interpretation of exclusions. A presumption in favour of a narrow interpretation of exclusions would unduly limit the significance of the moral jurisdiction under Article 53 (a) EPC and Rule 23d(c) EPC, the purpose of which is the

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[489] Article 31, General rules of interpretation:

1: 'A treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose'.

2. The context for the purpose of the interpretation of a treaty shall comprise, in addition to the text, including its preamble and annexes: (a) any agreement relating to the treaty which was made between all the parties in connection with the conclusion of the treaty; (b) any instrument which was made by one or more parties in connection with the conclusion of the treaty and accepted by the other parties as an instrument related to the treaty.

3. There shall be taken into account, together with the context: (a) any subsequent agreement between the parties regarding the interpretation of the treaty or the application of its provisions; (b) any subsequent practice in the application of the treaty which establishes the agreement of the parties regarding its interpretation; (c) any relevant rules of international law applicable in the relations between the parties.

4. A special meaning shall be given to a term if it is established that the parties so intended.

Article 32, Supplementary means of interpretation:

Recourse may be had to supplementary means of interpretation, including the preparatory work of the treaty and the circumstances of its conclusion, in order to confirm the meaning resulting from the application of article 31, or to determine the meaning when the interpretation according to article 31: (a) leaves the meaning ambiguous or obscure; or (b) leads to a result which is manifestly absurd or unreasonable.

[490] Open Letter from Professor Alain Pompidou, former President of EPO (28 September 2006) page 34, available from < www.cipa.org.uk/download_files/epo_warf.pdf >.last accessed 3rd January 2008

> incorporation of higher ranking legal and moral principles into European patent law...

He goes on to say:

> ...where the skilled person wishing to perform or reproduce the invention cannot succeed unless he follows the steps of some specific technical means or methods disclosed in the application which form an integral part of the technical contribution to the prior art, those technical means or methods are to be taken into consideration for the purposes of Rule 23d(c) EPC.

If the appeal of the WARF patent follows these principles then the method of creating the stem cells within the claims of their patent will be included in the consideration of validity. Whether some states permitted research upon human embryos was irrelevant for the purposes of interpretation of Article 53 (a).

The result of these two decisions is to remove HESC inventions from patentability in EPO. Separate patents could be applied for through individual State patent offices but that involves greater administration for individual patent applicants and would be at odds with the basis for the Biotechnology Directive which was to harmonise the situation in Europe. The effect of the decision is unclear and appears to be aimed at both the specific patentee, hence the invention concerns and other potential patentees who are in the field of human embryonic stem cells research. The effect upon the former is in the exploitation stage of their innovation time line and on the latter in their

incentive stage. The effect is uncertain but would appear to be aimed at steering the direction of research away from human embryonic stem cells.

CS (1) Opinion of the European Group on Ethics in Science and New Technologies:

The European Group on Ethics in Science and New Technologies (EGE) (the opinion of which was effectively ignored by Professor Pompidou and the TBA in the above cases as being 'strictly advisory and not legally binding[491]') adopted a classification relating to how far subject material has been separated from the source, i.e. embryos, to define the morality of patents relating to HESCs. Its view was that:

> ...isolated stem cells which have not been modified do not, as a product, fulfil the legal requirements...to be seen as patentable. In addition, such isolated cells are so close to the human body, to the foetus or to the embryo they have been isolated from, that their patenting may be considered as a form of commercialisation of the human body.[492]

In addition they said that unmodified stem cells are unpatentable for not having '...a specific use but a very large number of potential undescribed uses...'[493], but that modified cell lines capable of industrial application could be patentable and that processes involving human stem cells from any source are patentable if they fulfil the patent requirements.

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[491] There was no legal reason for him to follow the EGE opinion nevertheless the EGE as the group intended to assess ethical questions relating to patenting biotechnology inventions under the Biotechnology Directive, one would have thought that it may carry some influence

[492] European Group on Ethics in Science and New Technologies, 'Study on the patenting of inventions related to human stem cell research', Report to the European Commission (Office for Official Publications of the European Communities 2002), page 15.

[493] Ibid., page 15, paragraph 2.3,

This is very different from the interpretation presented by the EPO. The EGE opinion is not binding upon the EPO but it has a mandate for providing advice by virtue of Article 7 of the Biotechnology Directive[494]. The EPO interpretation links morality with the source of the cells, not in relation to their isolation and modification.

CS (1) Dissenting Opinion of Professor Gunter Virt EGE:

The dissenting opinion of Professor Gunter Virt was closer to the EPO interpretation than the EGE in that he argued that patenting products and processes resulting from destroyed human embryos was unacceptable[495].

The real reason for the decisions and Professor Virt's opinion may lie more with opinion against research rather than interpretation of the Article. Removing the incentive relating to the creation of human embryonic stem cells may encourage alternative research:

> Patenting is an incentive. Patentability of human embryonic stem cells and stem cell lines would push research towards embryonic stem cells and thus undermine the priority of research using non embryonic stem cells.[496]

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[494] Article 7 Biotechnology Directive 'The Commission's European Group in Science and Ethics and New Technologies evaluates all ethical aspects of biotechnology'.

[495] See Chapter four

[496] European Group on Ethics in Science and New Technologies, 'Study on the patenting of inventions related to human stem cell research', Report to the European Commission, Office for Official Publications of the European Communities, 7th May 2002, at page 19

The EGE also discussed concerns regarding access to patented genetic material as 'the basic ethical dilemma':

> ...patents can encourage scientific progress which can be used to the benefit of better health care, and at the same time, patents can also impair access to the health care due to the need of a licence to use them and to the fees that will have to be paid to the patent holder.
>
> It is then necessary to secure the right balance between the inventor's interests and the society's interest...[497]

Two different views emerge from the EGE opinion regarding the purpose of the patent system. The first, Professor Virt's, relates to the use of the patent system to direct research in a particular direction. Setting aside the question of whether or not HESC research should be acceptable, the issue for patent law should be whether it should be involved in such a question at all. I submit that it should not be because of uncertainty with the regulatory method used – i.e. the negative use of incentive against two different regulatory targets with different aims and applied in different zones of the innovation time line:

(1) Regulatory Target – or who is the regulation[498] aimed at? The justification for objecting to HESC, from Professor Virt's point, is objections to the research that led to

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[497] European Group on Ethics in Science and New Technologies, 'Study on the patenting of inventions related to human stem cell research', Report to the European Commission, Office for Official Publications of the European Communities, 7th May 2002. at pages 14 - 15

[498] Regulation being, in this case, the withdrawal of incentive

creation of HESCs. However there are two effects on two quite different targets. The first target is the specific inventor and the second is the group of inventors in the field in general. The specific inventor has already created the invention, the cells, and so removing incentive because of objections to the research will not affect that research. The effect upon inventors in the field in general, as we have seen, creates conflict and uncertainty in result without consistency[499] in regulation.

(2) Regulatory Aim - Furthermore the regulatory aim is different as between the specific and the general inventors. For the specific the aim of excluding the patent is quasi- punitive – the non-reward for research. The effect is not upon research but to an invention. The objections to the particular research no longer hold valid as against the invention which in the case of HESCs may provide relief and/or life to many.

(3) Innovation Period – The effect of excluding an invention upon the specific inventor falls in the inventor's exploitation stage whilst the general falls in the incentive stage. It is submitted that the two regulatory aims are inconsistent. The general aim is towards research of others whilst the specific is directed at research, which has already taken place, but effects the invention, which in the case of HESCs is of enormous positive potential[500]. Therefore taking a stance against the general research has a resulting negative effect upon the specific invention regardless of its substantial merit.

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[499] Vis-a-vis patent law and regulation of science and also, in the case of European Law, between individual States

[500] As mentioned above some States allow importation of HESCs but forbid the production of them. Indeed the justification for the rider to the morality clause ("...exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation" – Article 6 Biotech Directive) is that it enables one country to produce an invention for export to another even if illegal to use the invention in the former

The second view in the latter quotation from the EGE opinion refers to patent law as a gateway through which it can either assist better health care or impair access to health care depending upon the '...right balance' between interests of inventors and society. This view I submit is more a consistent approach for the aims and justifications of patent law and the third case study below examines the reasons why in more detail. The second case study relating to consent is of interest because although consent relates to a pre-grant issue the Biotechnology Directive treats the relevance of consent to patenting in a different, and I submit a preferable way, than it addresses research.

Case Study Two – Consent

Human biotechnology patents rely upon basic materials obtained from a human source. The original material is unpatentable by virtue of Article 5 of the Biotechnology Directive[501] but isolated elements or those produced by a technical process may be patentable even if identical to the natural element[502], provided it qualifies and industrial application is disclosed in the patent application[503]. Clearly there is a link between the source material and the isolated material but the latter must be considered 'new'[504] by the Directive in order to be patentable. The link between the original material and the 'new' material is expressed within the Biotechnology Directive in Recital 26, as follows:

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[501] Article 5 Biotechnology Directive, 'the human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.

[502] Article 5 (2) Biotechnology Directive.

[503] Article 5 (3) Biotechnology Directive.

[504] Article 3 Biotechnology Directive.

> Whereas, if an invention is based on biological material of human origin or if it uses such material, where a patent application is filed, the person from whose body the material is taken from must have had an opportunity of expressing free and informed consent thereto, in accordance with national law.

It is not intended to discuss the complexities of national rules and regulation in relation to the obtaining of consent, but it is important to indicate that the complexity of obtaining consent has provided courts in the United Kingdom (and indeed elsewhere) with a rich case history[505], caused public scandals[506] and created much debate in parliament[507] and elsewhere[508]. It is submitted that similar investigations by the EPO are unlikely and unwelcome. As stated by the European Court of Justice:

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[505] There are numerous cases involving refusal of consent, for instance, for religious reasons, such as in *Re T (adult) (refusal of medical treatment)* [1992] 4 All ER 649, (1992) 9 BMLR 46, CA and *Re C (adult: refusal of medical treatment)* [1994] 1 All ER 819, (1993) 15 BMLR 77. The law has tended towards respecting patients' autonomy. On obtaining consent from those without mental capacity, see for example, *Marshall v Curry* [1933] 3 DLR 260 Canadian Case (consent considered unnecessary for removal of diseased testicle without consent for protection of patient's life and unreasonableness to delay for later date); *Williamson v East London and City Health Authority* (1998) 41 BMLR 85 (damages awarded for mastectomy performed without consent even though treatment required, as patient would not have consented). Consent relating to new born child, see *Wyatt (a Child) (medical treatment: parents' consent)* [2004] Fam 866 and for minors, *Gillick v West Norfolk and Wisbech Area Health Authority* [1986] AC 112, [1985] 3 All ER 402 HL.

[506] For example, the issue of the unauthorised removal, retention and disposal of human tissue at the Alder Hey Children's Hospital between 1988 and 1995.

[507] Including The United Kingdom Parliament, Select Committee on Science and Technology, Fourth Report (20 March 2001), Chapter 7, paragraph 7.8, and the UK Government's consultative report, 'Human Bodies, Human Choices' (2002).

[508] A good illustration and discussion of the consent debate can be found in JK Mason and GT Laurie, '*Mason and McCall Smith's Law and Medical Ethics*' (7th edition, OUP 2006), chapters 10, 18 & 19. The requirement for consent arises out of self determination: 'The seriousness with which the law views any invasion of physical integrity is based on the strong moral conviction that everyone has the right of self determination with regard to his body...'. See also G Laurie, 'Patents, patients and consent: Exploring the interface between regulation and innovation regimes' in Somsen (ed.), '*The Regulatory Challenge of Biotechnology*': 'Consent, therefore, is not an end in itself, but rather a means to an end – it is a means to respect people' page 216

> Reliance on this fundamental right is, however, clearly misplaced as against a directive which concerns only the grant of patents and whose scope does not therefore extend to activities before and after that grant, whether they involve research or the use of the patented products.[509]

This raises the question of how Recital 26 is to be addressed if a challenge relating to failure to obtain proper consent emerges. There is a clear parallel between this question and research into HESCs in that both are pre-grant issues being questioned by a Directive after the event and which has no control over either issue.

Cases have not yet arisen that would assist in interpreting Recital 26, but in the United States the case of *Moore* v *Regents of the University of California*[510] is of interest because the plaintiff[511], whose cells were removed and isolated into an essential element in a patent which was used to develop a multimillion dollar treatment, had no claim either to the cells as altered or to the patent (which remained valid) that protected them. His only claim lay in an action for damages in respect of the failure to obtain appropriate consent. If the same set of circumstances arose in Europe under the Biotechnology Directive, it is arguable that Recital 26 could invalidate any similar patent either by virtue of Recital 26 or through its expression within Article 6[512].

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[509] *Kingdom of the Netherlands* case.

[510] 793 P 2D 479 (1990).

[511] John Moore suffered from hairy cell leukaemia and underwent a splenectomy. The surgeon in charge, Dr Golde, established an immortal cell line from Moore's T-Lymphocytes and obtained a patent. He later provided exclusive access rights to Genetics Institute in return for shares and an annual contract.

[512] See discussion in Beyleveld, 'Why Recital 26 of the E.C. Directive…'.

There is no requirement within the rules of the EPO or the United Kingdom Patent Office to furnish proof of consent at the time of patent application and in an effort to ascertain the effect of Recital 26 I contacted both offices and the following are responses to my question[513] regarding the necessity of proof of consent, the first being from the United Kingdom Patent Office:

> In accordance with the 1977 Patents Act, the UK-IPO[514] does not require evidence of consent when dealing with inventions based upon human origin; this is also consistent with practice under the European Patent Convention. The Recitals of a Directive set the context for and are referred to in the interpretation of the Articles of the Directive; they do not form stand-alone legal requirements. There are other legal provisions in place in the UK to provide some protection to an individual from whom tissue samples have been taken, such as the Human Tissue Act 2004, but the practice of the UK-IPO does not fall within the scope of such provisions[515].

Secondly, the following is the EPO's response:

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[513] 'I write to ask whether the Intellectual Property Office UK requires evidence of consent of donor in relation to inventions based on human origin. If not what is the office policy in relation to consent?' Dr Rowena Dinham, Senior Patent Examiner (Biotechnology and Pharmaceuticals) responded to this query. A similar query addressed to the European Patent Office received no response.

[514] The United Kingdom Patent Office has been reorganised under the umbrella of the UK Intellectual Property Office

[515] Dr Rowena Dinham, Senior Patent Examiner, (Biotechnology and Pharmaceuticals),UK-IPO, Concept House, Cardiff Road, Newport, NP10 8QQ by email Monday 18th June 2007

> Rule 23b (1)...aims in particular to ensure that the recitals of the Directive preceding its provisions, although not legally binding, are also taken into account and to promote a uniform Europe-wide interpretation of the relevant provisions. [Quotes Recital 26]
>
> There is however nothing in the legally binding Articles of the Directive – the 'operative part' as Recital 38 calls it – which seeks to give effect to this. There is thus no general patentability requirement within European patent law that the donor of the biological material has to be given the opportunity to give free and informed consent. Recital 26 is rather to be seen as an encouragement to seek prior informed consent. Legal consequences to the non-respect of this encouragement therefore lie outside the ambit of European Patent law, i.e. civil administrative or penal law of the EPO Contracting States.
>
> As highlighted by the European Court of Justice (ECJ) in its judgement in CASE C-377/98, the Directive concerns only the grant of patents and its scope does not therefore extend to activities before and after the grant, whether they involve research or the use of patent products[516].

The EPO response is interesting not least because of the treatment of recitals as 'not legally binding'. In some circumstance recitals may not create legal obligations upon states but, if subject to other obligations, such as being connected to an Article within

[516] Christof Friedrich, EPO, letter and email dated 27th September 2007

the relevant Directive[517] or another Directive or Convention[518], then such a recital must be binding at least to the extent of the related obligation. If it is accepted that Recital 26 does not create a binding obligation upon signatory states, which some would argue is not correct[519], it must still be arguable that the failure to obtain consent is immoral[520] and so Recital 26 must be read in conjunction with Article 6 and thus creates a moral obligation breach of which will result in invalidity of any such patent.

In the event of an application being made before the EPO, or in national patent offices, regarding failure or inadequacy of consent, the standard of consent is based upon whether or not consent has been obtained in accordance with national law. It must be presumed that this relates to the country in which the consent was obtained or where the opportunity to give consent was made (as opposed to where the case is brought or where research is carried out). Therefore it is irrelevant if the manner of obtaining consent is manifestly inadequate according to the rules of the country of patent (or where the application is brought) or the views of the EPO.

The Biotechnology Directive could have been made conditional upon states adopting certain standards upon research or obtaining consent or use of particular human material etc. But it did not, and given the ten years of discussions, drafts and redrafts to

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[517] For example, Recital 16 (dignity and integrity of the person) and is given expression in Article 5, and Recitals 36–39 refer specifically to ordre public and morality and reflect the obligations within Article 6 although differing in a number of ways, including the addition of two other inventions which are '…Obviously also excluded from patentability…'.

[518] For example, Recital 43 refers to the European Convention of Human Rights and Fundamental Freedoms 1950 (ECHR 1950). And Recital 55 refers to Decision 93/626/EEC (OJ L 309, 31.12.1993, p. 1) and to the Convention on Biological Diversity (5 June 1992).

[519] Beyleveld, 'Why Recital 26 of the E.C. Directive…'.

[520] Ibid.

arrive at the final compromise, it was hardly likely that such issues would be addressed. As there is no common standard and the EPO is not charged with or capable of providing a common standard, the approach of interpretation of consent on a national basis is eminently sensible. In one respect this appears disharmonious, but in the absence of a common standard throughout the EPO Member States the local standard must prevail. The previous case illustrated the confusion of adopting the approach of EPO in attempting to direct individual member states, which operate research policy in different ways, and it is suggested here that a similar approach to that of consent should be taken in respect of morality.

The first case study illustrates the weakness of, and complications which arise from, using patent law to address moral issues that occur before the grant of patent. The complications arises through tensions created between the European Patent Office and National Policy and between patent law and regulation (in these examples regulation relating to research) suggest that interventions by patent law into areas of regulation unconnected to the 'traditional' view of patent law should be avoided, at least in so far as pre-grant issues are concerned. Tensions that may exist between States relating to moral differences between what may be immoral to patent and what is acceptable are difficult to reconcile in a situation where a central body such as the EPO assesses morality on a uniform basis where in situations where there is no consensus. The second case study, relating to consent, leaves the interpretation of what amounts to appropriate consent in the hands of National institutions and National Law and it is suggested that this is a more appropriate way to look at the issue of morality within

European Patent Law. In this way patent practice would coincide with national regulation.

(5) (B) (II) POST- GRANT STAGE

'You can never plan the future by the past.'[521]

Subsequent to an award of patent the inventor begins to exploit the invention commercially. This third stage in the innovation time line also signifies the creation of a disincentive to others, who cannot then trade or use the invention outlined in the patent claims. This part of the balance discussed earlier also marks the trade-off between incentives and restriction, thereby giving rise to the patent paradox. This section examines cases where the balance is weighted so far in the patentee's favour that the patent paradox fails. It is not possible to balance the patentee's reward in such a way that it equates with the contribution but in some cases it is arguable that interference in the patent monopoly would be justified.

The first case study looked at using patent law as a broader regulatory instrument to raise objections and to influence inventions per se or research. Instead of asking whether an immoral invention should be exploited, this section enquires whether exploitation is immoral. Clearly exploitation can be immoral even if its invention is moral, if it occurs in a way that is so restrictive that there are few beneficiaries and further research is inhibited. The European Patent Office has however indicated that such questions are economic and not moral and that it is not the place for patent law to decide upon such points: 'The EPO has not been vested with the task of taking into

[521] Edmund Burke, 'Letter to a member of the National Assembly (1791)', quoted from The Oxford Dictionary of Quotations (5th edition, OUP 1999), 162.

account the economic effects of the grant of patents in specific areas and of restricting the field of patentable subject-matter accordingly'[522].

I submit that there are compelling reasons why patent law should consider such a role. Patent law could manage the monopoly it provides in better ways than by attempting to control inventions, through appeals to morality, which earlier discussion has shown to be flawed. Furthermore a patent grants a monopoly so it is reasonable that the granting mechanism should take some responsibility for that. Indeed the following study illustrates that there can be negative effects from patent grants which suffocate the contribution and that patent law can have a direct and effective role in such control. There may be reluctance to interfere in the patent monopoly in case this results in weakening the powerful incentive effect of patent grants[523]. Yet this objection relies upon the weakening effect of the incentive brought about by the interference in patent monopoly being much greater than that of the advantages gained from reducing the scope of particular patents. Whether such a calculation would always be the case is a moot point.

The next case study examines several cases, including the Myriad Genetics patent over the BRCA 1 and 2 genes, which raised genuine concerns about the ramifications of patents in particular cases. The relevant concerns in this section are about the commercial exploitation of inventions and whether they can be contrary to morality if a patent grant has been abused, for example, with the result that the patent paradox no longer applies.

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[522] *NOVARTIS/Transgenic Plant* [2000] EPOR 303.

[523] Indeed this has been the experience of compulsory licenses

CS (3) Case Study Three – Defeat of the Patent Paradox: Ethical aspects of exploitation

This case study examines the exploitation stage of innovation and the potential of patents to hinder the aim of promoting access and instead discourages innovation. It examines the effects of several patents upon areas of innovation of the field in question. The possibility of patents hindering further progress is, as discussed, likely to be more prevalent in biotechnology patenting because of the 'cumulative innovation paradigm'[524] caused by 'upstream' gene patents blocking research further along the innovation process. To address this within the context of the morality clause it is necessary to raise the question of whether commercial exploitation has been contrary to morality. It is impossible to guess whether exploitation will be contrary to morality at the time of grant and it would seem that if commercial exploitation is to be a criterion for refusal of patent grant it would be required to be a continuing process.

The difficulty is to assess how morality is to be decided in this context. We have seen how morality can be interpreted in different ways at different times by different people. The basic tenet, it is suggested, is that it is immoral for the grant of a patent to be used in such a way that there is an overall reduction in access to resources. For example a patentee can argue quite validly that was it not for his contribution the world would not have access to his new invention. Thus by virtue of inventing the world is enriched and whatever way he exploits the invention is irrelevant because there will still be an increase in what was available. This argument does not always hold true. For example

[524] S. Basheer, 'Block Me Not: Are Patented Genes "Essential Facilities"?', University of Oxford, Berkeley Electronic Press, 2005, available from < http://law.bepress.com/expresso/eps/577 > at page 2.

if the particular invention is exploited in a way that prevents further innovation or access to the invention is restricted by other terms which affect access to other resources then that is arguably immoral. If such a situation arises by virtue of the grant of a patent then it is submitted that it is immoral for the patent to be continued to be used in such a way. The following cases reveal a number of circumstances whereby similar situations have arisen and thus reveal a danger that at present patent law has no effective control of.

Several studies[525] have examined the effects of patent grants for biotechnology related inventions upon further research and a number of common conclusions emerge. The potential blocking effects of biotechnological patents still gives cause for concern that they '...can cause a tension between private profit and public good. Not least, they can hinder the free exchange of ideas and information on which science thrives'[526]. Despite this there does appear to be, in many cases, evidence of cooperation which has resulted in avoiding blocking effects through working practices and licence agreements although this is not seen as occurring in every case. 'However difficulties arose in agreeing licences in many cases'[527].

[525] Including, Intellectual Property Institute, 'Patents for Genetic Sequences: The Competitiveness of Current UK Law and Practice, A study by the Intellectual Property Institute (IPI) on behalf of the DTI' (May 2004), available from <www.dti.gov.uk>; The Royal Society, 'Keeping Science open':, and the Gowers Review.

[526] The Royal Society, 'Keeping Science open'.

[527] IPI, 'Patents for Genetic Sequences: The Competitiveness of Current UK Law and Practice'.

A number of submissions to the Australian Law Reform Commission formed a similar conclusion[528]. One stated that although gene patents do not appear to have an adverse impact on research currently, 'this appears to be because patents are not being enforced rather than because they either encourage or inhibit biotechnology research'[529].

Problems of access created by early-stage patents were discussed in the 2004 report by the Intellectual Property Institute (IPI) on behalf of the Department of Trade and Industry[530]. IPI carried out empirical research into the negative research consequences of patenting, specifically related to genetic sequences. Although it seemed that reach-through licensing was accepted as 'reasonable business practice where appropriate contribution has been made to the end product'[531] a number of issues arose including:

(1) Discovering who owns a key patent

(2) US practices being more restrictive

(3) Royalty stacking resulting in multiple negotiations with different parties and uncertain outcomes

(4) Lack of universally accepted confidentiality clause

(5) Avoiding certain areas where there is a thicket of patents.

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[528] The quote pertains to Australia, where similar issues have arisen to those in Europe, and relates to the potential for aggressive IP practices to reduce innovation in the absence of control enabling research in the face of protected material.

[529] C Dent, P Jensen, S Walker and B Webster, 'Research Use of Patented Knowledge: A Review', STI Working Paper 2006/2 (OECD 2006), 25.

[530] IPI, 'Patents for Genetic Sequences: The Competitiveness of Current UK Law and Practice'.

[531] Ibid. 126.

Not all the respondents have faced difficulties and some had only minor problems but foresaw greater hurdles ahead.

Cases in which such concern arises tend to relate to early stage innovation where results provide a base or vector for further research. If the results are patented then further research requires a licence. The consequence is that knowledge is disseminated through licence agreements[532] rather than publication, which gives rise to deliberate or incidental blocking effects or 'patent thickets'. 'The ideal IP system creates incentives for innovation, without unduly limiting access for consumers and follow-on innovators'[533]. The following examples illustrate that particular circumstances can give rise to the situation where access becomes unduly limited and that the patent system is restricted in its ability to react and remove the resulting restraints.

[532] It has generally been the case that licenses were used to disseminate knowledge but as licenses come at a cost then an increase in patenting prior to publication means that there is additional cost and because licenses relate to signatory parties the dissemination is significantly narrower than through publication

[533] Gowers Review, foreword.

CS (3) Myriad Genetics patents on genes BRCA 1 and BRCA 2

The four Myriad patents[534] over two genes linked to the susceptibility to breast and ovarian cancer[535] caused 'unparalleled legal challenge in the European Union'[536] and although the patents were amended after opposition proceedings, the issues raised continue to be significant for patent law. Curiously the grounds of opposition[537] and the basis for invalidating (or at least amending) the patents conceal the true motivation behind the numerous[538] objections to the patents. The opposition proceedings were founded upon principles of technical patent law, that the claimed invention lacked inventive step, novelty and industrial application and was insufficiently disclosed, rather than moral grounds. The patents were amended as a result of the technical opposition and, in the case of EP 699754, were revoked on the basis of novelty and failure to disclose the invention fully. The motivation for raising the objections was quite different and related more to the manner in which the patents enabled Myriad to exploit the inventions:

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[534] EPO granted three patents to Myriad in relation to BRCA1 (EP 0699754, EP705902 and EP 0705903) and one over BRCA2 (EP 0785216).

[535] In October 1990 Mary-Claire King discovered that breast cancer was hereditary and she progressed to finding the location of the breast cancer gene. Sensing the commercial potential, rival groups competed to isolate the gene with the aim of using it to test for the predisposition to develop breast cancer. Commercially, for the first to isolate the gene it would be significant to obtain patents in order to prevent others from offering the same tests and, in 1994, Dr M Skolnick of Myriad Genetics isolated BCRA 1 & 2 and obtained patents on the 'composition of matter' over the isolated gene and a 'method of use' patent for diagnosis and treatment. See M Rimmer, 'Myriad Genetics: Patent law and Genetic Testing' [2003] EIPR 20.

[536] J Paradise, 'European opposition to exclusive control over predictive Breast Cancer Testing and the inherent implications for U.S. Patent Law and Public Policy: A Case Study of the Myriad Genetics' BRCA Patent Controversy' (2004) 59 Food and Drug Law Journal, 59.

[537] The opposition proceedings are not the main point of interest for this work but more the motivation behind them and that the opponents had really only that route to take against the patents in question. The thesis suggests that a alternative procedure could be used in such cases which would be tied more to the real reasons for such opposition. This is discussed in chapter six .

[538] Opposition proceedings were filed against BRCA1 by several organisations including, Switzerland's Social Democratic Party, German Greenpeace, the Netherlands Ministry of Health, Institut Curie (France), The Belgium Society of Human Genetics and the Austrian Federal Ministry of Social Security.

> Underlying the technical grounds for opposition were deeper ethical and policy concerns. In addition to the continuing questions about patenting inventions derived from the human genome, the Myriad case raised concerns about the potentially limiting effects of the patents on further research, on the development of new tests and diagnostic methods.[539]

The debate surrounding technical patent issues, whilst providing a solution to those who opposed Myriad's patents, is arguably a means to an end rather than exhibiting the real reasons for opposition:

> Much of the debate surrounding the Myriad case, however, concerned not the validity of the patents as such – similar patents held by other entities have not attracted the same criticism – but rather the ethics of how the patent rights were exercised commercially.[540]

These objections should be addressed because both the protagonists and antagonists in the debate on the protection of genetic invention have much to lose. The patent antagonists wish to restrain broad rights but the method that may be adopted will not appeal to the supporters of strong rights[541]. The European Parliament for example

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[539] A von der Ropp and T Taubman, 'World Intellectual Property', Global IP Issues Division, WIPO magazine 2006, Issue 4.

[540] Ibid.

[541] The cases led to a change in French Patent Law requiring compulsory licensing of diagnostic tests (see B Williams-Jones, 'History of a Gene Patent: Tracing the Development and Application of Commercial BRCA Testing', Health Law Journal). In Canada, the provinces of Alberta, Manitoba and Ontario carried out their own BRCA 1 & 2 testing, in direct contravention of Myriad's patent, and in

called upon the European Patent Office to ensure that the Human Genome is freely available for research purposes. The Nuffield Council urged that human gene patents should become '...the exception rather than the norm'[542], the point being that in order to address objections to the methods of exploitation, the policy appears to favour restrictions upon what is patentable rather than the curtailment of exploitation: '[s]eriously taking into account these concerns is the only approach that will be beneficial to industry in the long run'[543].

Three main objections against the methodology of exploitation; reduction in the quality of patient health care, decrease in access and increased cost to patients, and restrictions on further research[544], underlie the reasons for such antagonistic opposition against the Myriad patents. Under the terms of the Myriad patents, all DNA samples taken for breast cancer screening had to be sent to Myriad's laboratories in Utah in the United States. This was, according to Institut Curie, 'contrary to our conception of public health...'[545]. The French Minister for Research said that Myriad had 'an abusive monopoly in the exploitation of predisposition screening for breast cancer'[546].

Europe, the EPO amended Myriad's BRCA1 patent to remove diagnostic methods from protection and reduced the scope of the BRCA2 patent.

[542] Nuffield Council on Bioethics, 'The ethics of patenting DNA', 70: 'In the light of these conclusions, we conclude that in the future, the granting of patents that assert rights over DNA sequences should become the exception rather than the norm'.

[543] Somsen, *'The Regulatory Challenge of Biotechnology'*, Overwalle G V, Reshaping bio-patents: measures to restore trust in the patent system' p 244.

544 Paradise, 'European opposition to exclusive control over Predictive Breast Cancer Testing'.

[545] Dr Dominique Stoppa-Lyonnet, Institut Curie, quoted in R Watson, 'France Challenges patent for genetic screening of breast cancer' (2001) 323 BMJ 888.

[546] Ibid.

Opposition groups argued that the Myriad testing was inferior to other methods because it carried a low predictive value of testing, offering only a 'general estimated chance'[547] in those women who had a family history of breast cancer and even lower estimates for those that did not have such a history. The Myriad testing also failed to detect 10–20% of mutations. In the event that a positive result emerged, Myriad's marketing and business set-up, which separated the diagnosis from treatment and counselling, resulted in failure to provide psychological support for patients and families. Myriad's aim, it was alleged, was to maximise profits without concern for the consequences for patients[548] and this was permitted and enabled because of the hold that the patent had given them.

Myriad's testing was expensive compared with other tests. The cost of sending results to Myriad's laboratories in Utah was three times that of French testing[549] and the result was that either an alternative and sub-standard method was used or no testing took place.

Research was potentially hampered by the Myriad patents because researchers were restricted in the use of the genes under the Myriad patent and the requirement to send all samples to its Utah laboratory enabled Myriad to build the only database in respect of results from breast cancer testing and allowed it a monopoly over further research upon that material.

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[547] Paradise, 'European opposition to exclusive control over Predictive Breast Cancer Testing', 147.

[548] Ibid.

[549] Ibid. Myriad's test cost 2744 Euros whilst a similar French test cost approximately 914 Euros.

> To allow the exclusive monopoly over human genes to continue in dereliction of healthcare and scientific research runs contrary to the public interest and the goals of the patent system, both in Europe and in the United States.[550]

Although the end result may have satisfied some of the objections, the underlying issue that caused the concern in the first place is still at large. Accepted that the case is evidence that '...the checks and balances within the patent systems have proved to work rather well in revoking a patent which happened to lack inventive step...', it also demonstrates that if the technical faults are not found to be present there is nothing that patent law could do in order to redress the true objections to the patents: 'What is happening today can happen again tomorrow with any patent based on a genetic sequence'[551].

I submit that there is a gap within patent law which has been exposed by these cases and which is also illustrated, in differing degrees, by the cases outlined below. It is asserted that if a patent is used in the manner described above then an issue arises as to the morality of the exploitation. The factors that may give rise to such a situation include:

- Absence of alternative

[550] Ibid., 154

[551] Dr Jean-François Mattei, Professor of Medicine and Genetics and deputy in the French Parliament, quoted in Watson, 'France Challenges patent for genetic screening of breast cancer'.

- Essentiality of invention – the BRCA patents covered what would have been for many the difference between life and death
- Unreasonable terms of licences – Myriad insisted that all tests be referred to their laboratory at high cost to patients
- Further research was hampered
- The above criticisms were enabled because of the grant of patent
- Revocation of patent would be an effective remedy

The main thrust of the objections against the Myriad patents was related to the manner of exploitation but restitution was achieved by attacking patent validity and not through addressing the commercial exploitation of the Myriad. If the Myriad patents had been held to be valid, and similar cases may arise in the future where invalidity may not be called into question, then there is no other forum open in which to address the situation. It is submitted that the manner of exploitation adopted by Myriad using the BRCA raises a moral issue that patent law would be able to effectively address if it had the mandate to do so and that patent law is flawed by not possessing such a mandate.

> Myriad have manifestly illustrated this tendency and have demonstrated the potential negative effect of patents on the supply of diagnostic testing services. According to Matthijs[552], other hindering patent seem to be

[552] Matthijs G & Halley D, "European-wide opposition against the breast cancer gene patents", European Journal of Human Genetics 10, 783-784 (2002)

emerging as well, like the one on Haemochromatosis. Such blocking patents are worrisome and have to be watched closely.[553]

CS (3) MSP-1 Protein – Patent Stacks

This second example illustrates how further research can be hampered due to a plethora of patents and patent law is unable to provide a remedy, instead researchers having to rely upon a mixture of the goodwill of other patentees and hard work and expense in tracing patentees and negotiating licenses.

The programme for Approved Technology in Health ("PATH")[554], part of the Malaria Vaccine Initiatives ("MVI")[555] set up to develop vaccines for malaria, supported the development of a vaccine for malaria. Its path was hindered by the proliferation of patents that had been granted in respect of or relating to MSP-1, a protein produced by the malaria parasite and which was likely to form the basis of any vaccine. At least 22 related patents were discovered each of which had to be checked for relevance and ownership had to be sourced so as to obtain relevant permissions. This involved significant loss of time, futile effort and needless cost, but in the end proved to be successful.

Different combinations of stacking can also lead to problems. Sometimes drugs have to be administered via a combination of dosages for different treatments. A single party could hold several patents which form one treatment, but if several patentees

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[553] Overwalle G, '*Gene Patents and Public Health*', Bruylant, 2007, at page 23

[554] PATH is an international non-profit organisation set up to improve global health and well-being

[555] MVI aims to increase development of malaria vaccines throughout the world

own different drugs which form part of a combination, and they refuse to co-operate towards efficient production of one particular treatment, patient care and further research will suffer as a consequence[556]. Two companies might refuse to combine patents to form one treatment with the result that two fees need to be paid, or several companies with different aims and patents may cause difficulties for one company wishing to combine all patents to form one medicinal product, as in the malaria example above.

This type of situation should not be enabled by a system that is intended to encourage overall access and innovation. In particular in cases where there may be several uses for an invention and patentees have not either exploited that use or have not realised its potential there should a procedure available to free up access or at least to encourage cooperation.

CS (3) Human Genome Sciences Inc. and CCR5 Receptor

Human Genome Sciences Inc. (HGS) was granted a patent over a protein with claimed functions including acting as a receptor for screening and as a diagnostic tool. HGS did not appreciate at the time that the same protein was also a foundation through which the human immunodeficiency virus (HIV) enters white blood cells. The protein was thus an essential step in the pursuit of treatments for AIDS and HIV infection. Once the connection between the CCR5 protein and HIV had been had been discovered researchers found that they were prevented from using CCR5 for further research because of the HGS patent. After public outcry, in particular against the speculative

[556] See Médecins Sans Frontières, 'Drug Patents Under the Spotlight' for further examples.

nature of the stated utility in the HGS patent, HGS granted a licence so research could continue.

The case illustrates the dangers of granting broad product patents. One method of preventing similar problems arising in future is to limit the patent on products to a specific function. Alternatively a mechanism could be created to be instigated after the grant of a patent to enable such obstructions to be eased, and the final chapter suggests a method of achieving this.

Had HGS been awarded a patent only for the particular uses stated in its patent, and some would argue that the patent system should only award patents with stated and specific function as opposed to broad product patents, then there would not have been a blockage. In that case would there be a detrimental effect on initial research? Reports suggest that research companies rely upon licences of such patents in order to pay for their own research and continue to develop other research tools. In most cases licences are agreed without huge controversy but in the event that patentees become over restrictive, as with HGS, initially, and with the Myriad Genetics example, should a remedy not be available to force a release of the blockage, or would that also have a detrimental effect on the incentive to research? The latter is a less restrictive method of allowing research to flow and it is suggested that post-grant sanction would be a preferable way ahead in similar circumstances.

CS (3) Severe Acute Respiratory Syndrome

Severe Acute Respiratory Syndrome (SARS) virus, a form of atypical pneumonia[557] is a viral respiratory illness caused by a coronavirus[558], which became a world health concern in 2003 as it spread across the globe from Asia, infecting 8098 and killing 774 people[559]. Urgent action to find a cure began and included the isolation of the virus by a network of collaborating scientific institutions. This was also a cause of rivalry between competitors to obtain commercial protection for their endeavours, so there was a race to the patent offices to patent part or all of the SARS genome. In this case the competitors in the race were research institutions (the US Center for Disease Control and Prevention, the Canadian British Columbia Cancer Agency, and the University of Hong Kong and Versitech Limited), opting to patent 'defensively' so as to ensure that the information would remain within the public domain and so prevent commercial interests from monopolising treatment of SARS in the future. Clearly they envisaged major difficulties with the current patent system, otherwise they would not have undertaken such expensive and pro-active measures:

> They did so in order to prevent private companies from monopolising the future diagnosis and treatment of SARS and in the realisation that patents on early research results can prevent others from exploiting this knowledge in their quest for treatment. The idea, then, was to ensure that no one had a

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[557] See M Rimmer, 'The Race to Patent the SARS Virus: The TRIPS Agreement and Access to Essential Medicines' [2004] Melbourne Journal of International Law, 335. Available at < http://works.bepress.com/matthew_rimmer/17>.

[558] A coronavirus is a cone-shaped enveloped virus that infects the upper respiratory and gastrointestinal tract of birds and mammals and includes most common colds (Center for Disease Control and Prevention <http://www.cdc.gov/NCIDOD/SARS/factsheet.htm>). Last accessed 3rd January 2008

[559] Ibid.

monopoly on knowledge about the disease, thus delaying the development of a treatment for it[560].

Altruism may appear to be the winner but there is a dark side too. The intervention was one-off and did not solve the original problem, namely that in the normal course of events it was believed by the relevant institutions that private enterprise would have stifled the search for a vaccine. This therefore implies that in further similar cases when an open approach like this is not followed, altruism of this sort could be unsustainable[561], and if that proved to be the case then future research will be impeded because of the very system set up to encourage it.

> ...as genomic patents increase in number, it will become prohibitively expensive for public organisations to afford not only the expense of patenting genomes and DNA sequences, but also the significant costs of entering into licences and administering those licences. Expecting non-profit organisations to obtain patents on all their genomic inventions is not a sustainable solution to maintaining an open free public domain.[562]

A complete solution has not therefore been found to the openness issue especially as these were not the only parties to apply for patents over the SARS virus. A number of pharmaceutical companies and other scientists in Hong Kong and Canada[563] were involved. Moreover a proactive open patent policy would not prevent applications and

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[560] Danish Council of Ethics, 'Patenting Human Genes and Stem Cells', 55–6.

[561] See Rimmer, 'The Race to Patent the SARS Virus'.

[562] R Gold, 'SARS Genome Patent: Symptom or Disease?' (2003) 361 The Lancet.

[563] Danish Council of Ethics, 'Patenting Human Genes and Stem Cells'.

product patents that involve the SARS virus from being patented and kept out of the public domain.

Endeavours to keep research open as illustrated by the above scenario are to be applauded but clearly they do not present long term answers if similar situations arise[564] where commercial interests react more defensively and perhaps succeed in impeding further research. It can also be asserted that moving all patents away from such early stage research is also not really an appropriate response because of the necessity for patents in the promotion of general research, as outlined earlier. The patent system therefore appears to be 'caught between two stools' in these cases – remove patents and research is not promoted or encouraged, but keep patents and research is inhibited.

> There are no clear-cut answers. But when pre-emptive patenting is necessary to ensure that rapid solutions are found to an important health problem, something seems to be out of balance. Policy-makers should investigate what checks and balances are necessary to ensure that the patent system continues to do its job of stimulating innovation for the public good.[565]

The key would seem to be to find appropriate 'checks and balances' in a system that appears to consist of irreconcilable and opposing tensions; open or closed, patent or no

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[564] Other examples of similar situations have arisen, such as patents held by Genentech Inc, over human epidermal growth factor receptor 2 (HER2) and Trastuzumab, and patents held over two mutations in the haemochromatosis gene (HFE) which resulted in a reduction in research into genetic testing for HFE mutations, see B Goldman, 'HER2 testing: The patent 'genee' is out of the bottle', 8 May 2007 CMAJ.

[565], 'Gene Patents and the Public Good' (15 May 2003) 423 Nature, 207.

patent. A solution must presuppose a compromise in certain cases but the difficulty is defining how concessions can be expressed in a system that relies upon the lottery effect where one winner takes all; therein lies its strength and its weakness: '...the patent system needs to be adjusted – not discarded – by governments to better reach the goal of that system: the attainment of the public good'[566].

[566] Ibid.

(5) (B) (III) OPTIONS FOR ACCESS

It is likely that biotech patenting will continue despite the objections that have arisen and regardless of the degree of animosity towards some aspects of biotechnology by particular interest groups and by governments. The limits of patenting are however likely to continue to be keenly contested, both in relation to the extent that objections to science are expressed within the patent system and to whether the granting of patent rights hinders development rather than promotes it.

Overall patent law is neither an appropriate nor a useful forum within which to govern the course of research and development nor to direct responses to complex ethical debate surrounding particular technologies. Patent law nevertheless has a part to play as a pertinent platform upon which ethical objections to the exercise of patent monopolies can be coordinated and countered. A number of alternative methods of addressing access issues have been mooted, and are discussed below, but it is submitted that none have the advantages of patent law which is, after all, the harbinger of objections yet also the foundation of incentive. The justification for patent law is the balance that it keeps between incentive and reward, so it is appropriate for patent law to be accountable towards the maintenance of that balance. 'The key therefore is to offer patent protection while protecting society's right to benefit from new discoveries'[567].

[567] Goldman, 'HER2 testing'.

Two main alternatives[568] lie within different stages of the patent process. The first is an extension of the compulsory licence system and research exemptions. The second is exclusion of more inventions from patent protection by tightening of patent qualifications or through the morality clause. This work suggests that a solution could also be found in applying morality more precisely and within the relevant stage of innovation and this will be examined in chapter six. There are limitations with other options available at present as the following suggests

(5) (b) (iii) (a) Tightening of patent qualifications

One way of attempting to tackle the access issue is to raise patent hurdles and thereby grant fewer patents. This suggestion has been advocated by the Organization for Economic Cooperation and Development and was mentioned in its report on genetic inventions: '...patent offices may choose or be asked to apply stricter guidelines when interpreting whether an invention is novel, useful or represents an inventive step'.

Furthermore the Nuffield Council on Bioethics proposed:

> ...that in general, the granting of patents which assert rights over DNA sequences as research tools should be discouraged. We take the view that the best way to discourage the award of such patents is by a stringent application of the criteria for patenting, particularly that of utility.[569]

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[568] As Van Overwalle noted 'Only two measures exist to temper cases of *extreme* monopolistic licensing behaviour of patent holders: the compulsory licensing scheme in patent law and the abuse of dominant position provision in competition law.' Overwalle G, *Gene patents and Public Health*, Bruylant, 2007, page 21

[569] Nuffield Council on Bioethics, 'The ethics of patenting DNA', page 71 paragraph 6.11.

Patent guidelines should be followed when assessing patentability but there is no justification to increase these hurdles for particular inventions merely as a response to overzealous exploitation by a minority of patent holders.

Another alternative is to limit 'product patent' and to allow only the specific purpose[570] contained in the patent application. Similarly patent law could enable protection only for end products[571] such as drugs targeted at specific diseases. Such 'purpose bound protection' has been adopted in Germany and France so 'DNA patent can be claimed but only in respect of a specific use'[572]. There are difficulties with these approaches in that issues could remain whereby patents are dependent upon others and so the same sorts of problems as already alluded to may arise. The risk is that a single purpose turns out to be so uneconomic or trivial that the project fails without any further prospect when continued research might have brought success and encouraged innovators to proceed. Proliferation of patents results in patent stacks and specific use patents would inevitably result in more patents, which encourages the growth of patent stacks. It is the ways in which patents can be exploited to advance patentees' commercial positions that cause the difficulties mentioned above, rather than the grant of patents per se.

(5) (b) (iii) (b) Compulsory licences

Provisions exist for the award of compulsory licences in strictly defined circumstances. These may apply, in the United Kingdom, in circumstances where, after a period of

[570] Danish Council of Ethics, 'The Ethics of Patenting Human Genes and Stem Cells', 36.

[571] Overwalle, 'Reshaping bio-patents: measures to restore trust in the patent system', 245.

[572] Dutfield, 'DNA Patenting: Implications for public health research'.

three years from the grant of a patent, demand is not being met, the invention can be worked in the UK, that a license has been unreasonably refused, and is at the discretion of the comptroller[573]. The issuing of compulsory licences is limited and is aimed at encouraging the use of inventions that have not been worked, rather than tackling the sort of situations discussed above.

There have been calls for the compulsory licensing system to be extended[574]. On the one hand an extension to the use of compulsory licences may harm incentives[575] but on the other hand compulsory licences may not be sufficient and a broader approach to post-grant control is suggested[576]. It will also be suggested that one option open to patent authorities should be compulsory licensing but justified on a moral basis of the manner of exploitation rather than under the current situation and that such compulsory license can relate to specific uses of invention. Thus compulsory licenses per se are not objected to herein but they are seen a part of a broader picture of post-grant control.

(5) (b) (iii) (c) Competition Law

The objections arise in the above instances because the patents have been one of a number of factors that have contributed to the 'interplanetary alignment' theory, described above, and because of the method adopted by patentees to exploit their inventions. One could suggest that competition law would be an appropriate mechanism to decide the fairness or otherwise of such situations because one can

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[573] See section one above and s. 48 Patents Act 1977 (UK).

[574] See IPI, 'Patents for Genetic Sequences: The Competitiveness of Current UK Law and Practice'.

[575] See Danish Council of Ethics, The Ethics of Patenting Human Genes and Stem Cells, in particular SJR Bostyn, 'DNA Patents in Europe: Controversy Remains'.

[576] See section five.

clearly see tension between awards of monopolies and provisions that relate to increasing competition[577]. As we have seen, though, the existence of monopolies is not necessarily detrimental as their effect is determined by other factors, including the behaviour of the monopolist. 'Indeed, both bodies of law share the same basic objective of promoting consumer welfare and an efficient allocation of resources'[578].

Articles 81 and 82 of the EC Treaty deal with European competition law and although this work is not concerned with competition law, it is worth mentioning these provisions as they can, in particular circumstances, apply to intellectual property agreements:

> Any abuse by one or more undertakings of a dominant position within the common market or in a substantial part of it shall be prohibited as incompatible with the common market... Such abuse may, in particular, consist in:
>
> 1) directly or indirectly imposing unfair purchase or selling prices or other unfair trading conditions;
> 2) limiting production, markets or technical development to the prejudice of consumers;
> 3) applying dissimilar conditions to equivalent transactions with other trading parties, thereby placing them at a competitive disadvantage;

[577] The European Commission has declared: 'The fact that intellectual property laws grant exclusive rights of exploitation does not imply that intellectual property rights are immune from competition.' Commission Notice, 'Guidelines on the Application of Article 81 of the EC Treaty to technology transfer agreements' OJ 2004/C 101/02.

[578] Ibid.

4) making the conclusion of contracts subject to acceptance by the other parties of supplementary obligations which, by their nature or according to commercial usage, have no connection with the subject of such contracts.[579]

There is some tension between competition law and the granting of patent rights but the holding of a patent does not mean that the patentee has a dominant position that amounts to abuse. What amounts to abuse in these circumstances is still being tested and will perhaps be tested even more in the future as the growth in unique medical-related patents continues. Refusal of a licence by itself, unless there are 'exceptional circumstances'[580], would not amount to an abuse[581].

It is tempting to argue that Myriad being compelled to license the use of the *BRCA* tests on condition that the samples must be tested in their own laboratories was going beyond the specific subject matter of the patent[582], but if the tie-in licence is indispensable for successful exploitation of the patent (which Myriad argue is the case anyway) then this would not succeed[583]. It is therefore submitted that Article 81 would not be of assistance in the above circumstances. Furthermore Article 81 does not apply if trade between member states is unaffected.[584] In any event, despite the

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[579] Article 82 Treaty of Rome

[580] Joined cases C-241/91 and C-242/91P, *RTE and ITP v Commission (Magill)* [1995] ECR I-743.

[581] See also Case C-238/87, *Volvo v Veng* [1988] ECR 6211, [1989] CMLR 122.

[582] See Case C-193/83 *Windsurfing International v Commission* [1986] ECR 611, [1986] 3 CLMR 489.

[583] Articles 2 (1) (1) of the Intellectual Property Block Exemptions were replaced by Technology Transfer Block Exemption in 1996 and again by revised exemptions and guidelines.

[584] Article 81 applies where '...practices...may affect trade between member states...' and see also Re A. Raymond & Co. and Nagoya Rubber Ltd Agreement, EC Commission 72/238, (1972) OJ L143/39.

unprecedented objections to the Myriad *BRCA* patents and their chosen commercial practices, there were no cases brought under competition law and changes to competition law are not seen as a way forward.

> ...an antitrust remedy cannot be a panacea to resolve the blocking or restricted access issue for all time to come. Rather, if the blocking issue becomes pervasive, it may be more prudent to devise a more focused remedy[585].

> It should be noted that the role of the competition authorities in regulating IP markets should not extend to price regulation: patents are exclusive rights which enable owners to charge monopoly prices. However, there should be increased collaboration between the Patent Office, the Competition Commission and the Office of Fair Trading to establish an understanding of how healthy competition can flourish in the information market and how IP can both stimulate and occasionally stunt dynamic competition[586].

The problems discussed above have been created because of the grant of patents and can be addressed through a softening of patents in similar circumstances. Patents, as noted, are 'blunt instruments' and it is suggested that a sharpening or focusing of approach to their use in exploitation is the way forward.

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[585] Basheer, 'Block Me Not', 2.

[586] Gowers Review.

(5) (c) Where Now for Patent Law

This section has examined some of the objections and controversies that have arisen during recent years with the expansion of biotechnology research and the patenting of its derivatives. The objections against biotechnology have been varied but the response to them has not reflected this variety in that the main instrument of addressing concerns in European Patent Law has been the morality clause, which is not designed for such issues nor able to act effectively to answer them.

The three case studies illustrate different scenarios to enable study of the various regulatory nuances within patent law. The debate in relation to the patenting of human embryonic stem cells illustrated a number of difficulties in using patent law to address issues of science. If such a regulatory role is accepted as legitimate for patent law, and this work has argued against that, then there are criticisms to be made of how the objections are to be approached by patent law because, for example, there are no clear guidelines as to what the morality clause is aimed at or how matters of moral balance should be decided. Furthermore such a role is fundamentally flawed in that regardless of the merit of the deliberations there is no direct connection between the decision to refuse a patent over such inventions and the invention per se.

> But the relevant debates should begin at the right point, with the research and its potential uses and not with the wholly subordinate question of patents. The patent issue is no short-cut to the resolution of the more

difficult questions, and until these have been properly addressed, patenting should not be singled out for attack.[587]

The grant or potential grant of a patent does not cause unethical behaviour, nor does the withdrawal of incentive prevent it.

The discussion regarding the issue of obtaining consent for the removal of human tissue illustrates similar flaws to the HESC cases in that the method adopted by patent law fails to address the issue with any consequence. Yet the discussion shows a closer relationship (objection to commercialisation) between the issue (i.e. consent) and the method (i.e. patent law)[588], and it also juxtaposes to this a number of weaknesses in treating consent with patent law, not least the provision of a link between donor and patented material[589] (yet which, by definition, has no link[590]) and provision of a connection between donor and material within patent law when no such link is permitted in regulation. This rather complicated summary is in part due to the manner in which the law treats ownership of body material but more usefully however, leaving the issue of consent to national rules, as stated by Recital 26 of the Biotechnology Directive, as opposed to tying with patent rules provides a sensible way of going forward.

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[587] S Crespi, 'Biotechnology Patenting: The wicked animal must defend itself' [1995] 9 EIPR 431 at 441.

[588] See Consent case study two above

[589] See Consent case study two above

[590] See Consent case study two above

The third case study examined the approach taken by patent law towards commercial exploitation insofar as the issue of immoral exploitation rather than immoral invention is concerned. But there would appear to be a willingness to interpret patent qualifications based on inventions per se in order to exclude inventions rather than seek to question patent monopoly after grant. Patent law is aimed at promoting research and development so decisions taken regarding the exclusion of inventions should be focused upon advancing that goal:

> Everybody seems to acknowledge the assumption that the legitimacy of the patent system lies in its ability to promote research and development of new diagnostic methods and therapies to the benefit of public health. If patenting human genes and stem cells fails to further these goals – or even works against them – it does not fulfil its 'contract' with society and thereby loses its raison d'être. [591]

It is of value to appreciate the contribution that can be made to the debate surrounding ethical research through the mechanisms of patent law yet this is not matched by an equal ability to address conclusions that may be reached. In fact in some cases patent law has been the only forum in which such debates have been aired. Patent law may have the heart to debate but does not (nor indeed cannot) have the legs to fulfil conclusions for the reasons discussed.

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[591] Danish Council of Ethics, 'The Ethics of Patenting Human Genes and Stem Cells', 8.

Part of the difficulty with interpretation of objections is that in many cases the objections that have been levied against patents are for reasons that are not related to patenting and the questions that have been related to patenting have not been effectively addressed. In view of this another way of approaching the position of patent law in the regulatory process is to decide what the cause of a particular objection is and what will be the result of using the exclusion of a particular invention to address that specific problem. Thus the way forward should be first to differentiate between objections which arise because of the grant of patents from those which arise because of objections to the technology under protection and second to appreciate the consequences of using the exclusion of the grant of patents so that particular objections are appropriately addressed. The final chapter examines this more closely.

(6) Chapter Six Moral Relevance

(6) (a) Patent Grant and Morality

Patent law and biotechnology have a complex relationship. Clearly there are characteristics[592] of biotechnology that are apposite for the application of patent law as a motivator and protector. Equally apparent are the tensions[593] within this relationship; tensions that patent law endeavours to address through validity requirements[594] and exclusions to patentability at the time of grant. The discussion has indicated the failings of this approach and also that current forms of redress through patent or competition law after grant are sometimes inadequate[595] or are not aimed at relevant problems.

The role of morality within patent law is undergoing a metamorphosis[596]. One of the many difficulties encountered by patent law include moral questions that arise

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592 In particular the high cost of innovation and often low cost of reproduction, see discussion in section one as discussed in section three

593 Such as between defining the line between discovery and invention, keeping a balance between encouraging innovation through creation of incentives but watchful that incentives do not repress other innovators. Patent law has acquired a twin but opposing role in that it promotes innovation on the one hand yet is seen as part of regulatory regimes that restrict innovations for perceived moral wrongs and it must carry these tasks out whilst keeping aware of differences between incentive regimes and those that regulate science. See Sections three and four. As discussed in sections three and five.

594 The validity requirements, novelty, inventive step, industrial application and morality must be interpreted so as to ensure the standard of patentability is kept high. The temptation is to increase the standard in an attempt to address other issues such as to question the morality of research or to anticipate manner of exploitation. The thesis has concluded above that radical changes into the rules that define the grant of a patent are unnecessary

595 See discussion regarding compulsory licences

596 The limit of these changes, discussed with section three and four, has not yet been fully appreciated nor settled. The pending appeal by WARF may assist in understanding the sentiment of the EPO but it may not provide a satisfactory answer to national states whose practice and law do not reflect the perceptions of morality as interpreted centrally.

throughout the innovation time line and the fact that assessments have not taken place as to what is relevant for patent law nor indeed about what patent law can or should do. There is not sufficient appreciation of the different moral issues at each stage of the innovation process. This work has examined the different stages and through case studies has illustrated how morality can be reflected in different ways at each stage in the process. The purpose of this chapter is to discuss how patent law can address morality within each stage. It has been thus necessary to untangle objections and to find a viable function for morality within patent law. This chapter isolates pertinent questions for morality and suggests a way forward. The different moral concerns that arise at each stage of innovation should take into account factors that are pertinent to each stage. Accordingly, this requires appreciation, not just of the different moral questions that can arise at each stage of the innovation process, but also of the relationship of a grant of patent to those moral issues. Rather than envisaging morality attaching to, for example, research or exploitation of inventions, it is more appropriate to enquire whether exclusion of inventions from patent protection has direct or indirect effects upon objections. In other words exclusions of inventions from patentability should take into account the consequences of excluding specific inventions from patentability as well as the objections per se. The completed innovation time line summarises the points made in this chapter which proposes that morality should be addressed more specifically at each stage of innovation.

The regulatory position at each stage of innovation is different so patent morality has to reflect those differences. The United Kingdom's Human Fertilisation and Embryology Act, for example, requires that strict procedures must be followed in

relation to research upon human embryos. Any resulting invention, however, is clearly a separate entity from both research and from the material that was used to invent it. Indeed the biotechnology Directive requires that inventions must be 'new'[597]. Any cells that arise from human embryonic research are separate from the original embryo (which will have been destroyed) and so are no longer reliant upon the embryo and are subject to different regulations and should such cells be commercially exploited that exploitation will also be subject to separate regulation. Patent law should reflect such differences so as to illustrate which moral questions are relevant for patent law and that answers to applicable moral issues can be addressed appropriately.

Table Ten - Innovation Time Line

	Innovation or Incentive Stage	**Grant Stage**	**Exploitation Stage**	**Generic Stage**
Patent Theory	Utility Theory/incentive Fund raising	Disclosure	Reward or Natural Right theory – Democratic tax theory	Distribution to all funded by prior higher prices
The Patent Effect	The prospect of a patent provides an incentive to commence research and development. Patents may also encourage commercialisation so distinguish between incentive to research and incentive to commercialise the results of research	Assess inventive quality – novelty/inventive step and Utility – Morality Priority date (application) Publication within 18 months – nb section 21 applications representations by 3rd parties Max, time to grant 4.5 years NB – EPO 9 months for 3rd party to oppose patent grant	Monopoly Publication – encourages (a) further research (b) inventing around patent (c) compulsory licenses (d) research exemption	Open competition

[597] See chapter three above and Article three Biotechnology Directive

Regulation	Ethical and legal rules that govern the envelope of research e.g. HFEA. Any other legal requirements – e.g. Health and safety/environmental regulations etc – consent from participants. Human Tissue Act 2004 **Regulation relating to research**	Different regulation may be relevant i.e. from that which governs particular research to that which is pertinent for resulting inventions. **Regulation relating to invention resulting from research**	(a) Strength of market demand (b)licensing practices (c) Competition Law **Regulation relating to method of exploitation**	Generics still under regulations – i.e. will still have to comply with any regulatory requirements re safety etc
Benefit to Public	Incentive created with long term aim of increasing public welfare	Information in public domain and invention becomes available	Invention available albeit at higher than normal market price Publication -	Generic competition means prices likely to reduce
Moral Concerns	Unnecessary blocking effect of patents already granted – a direct cause of patent grant Research – danger to environment/animal cruelty/unknown potentially hazardous outcomes – not caused by grant of patents	Encouraging or rewarding particular immoral innovation. Symbolism of acceptance in event of absence of regulation	Stacks/reach-through licences – potential blocking – research – restrictive licenses caused by patent grants	Other IP – Trade secrets/
Patent and Regulation Interaction	Incentive effect of patent in direction of research? Conflict between what is patentable and what is legally permissible?	Morality clause – invention/commercialisation – have consent procedures been followed? – Recital 26	Competition law – monopolies	

The increase in the breadth of the application of morality exclusions from patentability, resulting from objections raised against biotechnology, is fairly apparent but the effects of this are probably not fully appreciated. The historical moral elucidation is much narrower than assessing the morality of an invention the purpose of which is to endow life by beneficially promoting improvements to health[598] and wellbeing, or to increase

598 As in any of the following: Case T 1374/04, November 2005; Edinburgh Patent (EP 0695351); HARVARD/ ONCO-mouse [1991] EPOR 525.

crop yields[599] or to ease the pain of childbirth[600] and so on. Even to use the morality clause to debate such technology is of itself an extension of the ambit of the morality provisions. This step of considering inventions, which have praiseworthy goals, as being immoral because of some other factor is also an amplification of earlier views of morality and patent law because there are no precedent morality cases that display clearly that the invention was immoral. Furthermore factors that may have led to inventions being queried could be numerous; objection to the invention per se, to the research that led to it, to ownership of the rights to exploit the invention etc. Even the particular grounds of hostility may arise for diverse and emotive reasons such as animal cruelty, perception of human dignity, religion, potential harm to the environment etc.

In view of this complex and expanding panoply it is no wonder that there have been mixed interpretations by national patent offices[601], the European Patent Office and the groups of advisors[602] set up to assist with interpretation. This is despite intentions of harmony behind the Biotechnology Directive and those expressed in case law[603]. The elucidation of the morality clause has been aggravated by further extensions through

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599 *PLANT GENETIC SYSTEMS/Glutamine Synthetase Inhibitors* [1995] EPOR 4.

600 *HOWARD FLOREY/Relaxin* [1995] EPOR 541

601 See UK Patent Office Guidelines compared to interpretations within European Patent Office. The UKPO will grant patents, providing they surmount the usual hurdles, for pluripotent stem cells because they do not have the ability to develop into a human body whilst totipotent stems cells, which can develop into a human body, are not patentable. The EPO, as discussed in sections three and four, will not grant patents for inventions relating to HESCs if their creation involves "uses of human embryos for industrial or commercial purposes" even if such uses are not claimed.

602 European Group on Ethics in Science and New Technologies, 'Study on the Patenting of inventions related to human stem cell research' Report to the European Commission, Office for Official Publications of the European Communities, 2002.

603 For example *Kirin-Amgen Inc and others v Hoechst Marion Roussel Ltd and others* [2004] UKHL 46 (House of Lords) "It would be most unfortunate if we were to uphold the validity of a patent which would on the facts have been revoked in opposition proceedings in the EPO."

the four specific moral exclusions[604] within the Articles and two in the Recitals[605] of the Biotechnology Directive. These have been interpreted by the European Court of Justice[606] as being separate and additional to the morality clause rather than as pure examples of what may fall foul of the clause, clearly extending the reach of the morality clause[607].

There are appreciable reasons behind objections to biotechnology and an understandable rationale for the expansive interpretation of morality by the European Patent Office. Moreover the debate over the moral position is as welcome as it is important but the unchecked expansion of exclusions to patentability without proper direction and under questionable authority[608] is not. Re-evaluation of exclusions to patentability is essential. As stated moral questions arise throughout the innovation time line and any re-evaluation should take account of the whole process, so as to include the consequences of patenting before and after grant and all of the ethical

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604 Article 6 2 (a)–(d) Biotechnology Directive.

605 Recital 40 Biotechnology Directive.

606 Kingdom of the Netherlands case. and see *MICHIGAN STATE UNIVERSITY/Euthanasia Compositions* [2005] T 0866/01

607 "So it would appear that the specific exclusions refer to those for which a certain degree of "European consensus" can be gathered, while the general is open to interpretation by member states according to their own "ethics or morality". A general provision is essential in so far as it is advisable to "freeze" morality as per any particular time in history." Thambisetty S, Understanding Morality as a Ground for Exclusion From Patentability Under European Patent Law, Eubios Journal of Asian and International Bioethics 12 (2002), 48 - 53

608 The EPO position is in contradiction to practices of national states and it is questionable whether it is an appropriate role for patent authorities to reach into areas of law that are more appropriately dealt with by specific regulation. See, inter alia Laurie G Laurie G, Patenting Stem Cells of Human Origin, [2004] EIPR 59, "...but it is not for patent law to address that concern if the objection is to the science rather than to the grant of a monopoly right. Not only is it a matter more appropriately tackled by regulatory authorities using their entire gamut of legal tools, but the deep irony is that patent law cannot address such a concern."

issues that arise because of the negative effects of patents upon access. Changes must consider the aims behind patent law and what effect such exclusions will have.

A number of points can be concluded from this evaluation of moral exclusions from European patent law. A consistent theme of the concluding points is that there are different moral issues which cannot be answered in the same way at the same point in the innovation process. Moral diversity can be arranged into three categories:

(6) (A) (I) MORALITY ONE – UNIVERSAL MORAL AGREEMENT

Some inventions are clearly immoral and are considered so by all European States so can be excluded from patentability without deliberation. The morality clause as it has been interpreted historically is a workable solution for patent authorities to express antipathy towards particular invention of clear and obvious immorality. This interpretation has been reflected to a greater extent in the original biotech morality case discussed in section three. This raises the question as to what amounts to immorality sufficient to determine an invention as unpatentable and how such a European standard of morality should be determined. If an investigation is needed into whether or not an invention is immoral then there is clearly not a common European standard. In fact if there is evidence that one country views an invention as acceptable then there cannot be an agreed European Standard[609].

[609] See PATGEN PROJECT, The Patenting of Human DNA: Global Trends in Public and Privet Sector Activity, November 2006, Final Project Report at page 112 "...the acceptability of an invention in even one Contracting country would constitute evidence of absence of a European wide morality and ordre public." At page 112

(6) (A) (II) MORALITY TWO – CONTROVERSIAL BUT NO CONSENSUS

The situation when no consensus exits causes a different scenario to emerge through the patenting of biotechnology and the dangers of a change in moral interpretation have come to light in the interpretation of the Article 6 (2) exclusions. The motives and results of excluding inventions from patentability in respect of HESCs place patent law in the position of a regulator of science rather than of incentive.

> "The law must adequately reflect two competing (and often conflicting) public policy considerations: on the one hand it must facilitate research in view of the gains in knowledge....whilst on the other it must repress such research as is regarded as unacceptable, primarily due to doubts about its ethical justifiability."[610]

Similar arguments have been made[611] that patent law can express the regulatory tilt of an amber light, neither encouraging nor prohibiting but clearly exerting an influence against what are otherwise legal activities. This quasi-regulation should be resisted, at the very least at European level, and care must be taken at national level to define the boundaries between regulation and patent law. The interface between patent law and regulation, on the one hand, and between European Law and patent law, on the other, require different considerations and breaches between them have different

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[610] Halliday S & Steinberg D L, "The Regulated Gene: New Legal Dilemmas", Medical Law Review 12, Spring, pp 2 – 13, Oxford University Press 2004, at page 4

[611] Brownsword R, "Red lights and rogues: regulating human genetics, chapter three in Somsen H, *The Regulatory Challenge of Biotechnology: Human Genetics, Food and Patents*, Edward Elgar Publishing, 2007

repercussions. To put this a different way, the question whether morality should be interpreted broadly at European Level involves issues of disharmony among signatory states. The same question at national level suggests friction between regulation and patent law.

The second point therefore is that in the event that a European consensus cannot be found then morality should be an issue for each state to interpret in accordance with its internal rules and regulations. Different moral perspectives should not prevent the award of a European Patent as these can easily be reflected at the time of enforcement within each individual country. Enforcement of patents occurs at national level and thus provides a method for moral concerns to be raised.

(6) (A) (III) MORALITY THREE – MORAL COMMERCIAL EXPLOITATION

The third category highlighted by this study is the failure to appropriately address moral issues during commercial exploitation and the final section examines this more closely.

(6) (b) All Heart and no Legs

'You can have all the heart in the world, but it doesn't mean anything unless you've got the legs.'[612]

The discussion of moral issues provides patent law with an effective platform for the discussion of complex ethical difficulties. Unfortunately the efficacy is not matched with the ability to address the issues raised within. The vision of '...higher ranking legal and moral principles...' [613] is directed towards pre-grant activities which have already taken place and which patent law can do little to influence, rather than post-grant activities, thus avoiding the area where patent law has the greatest influence and where there is arguably the greatest need for reform[614]. It is understandable that some parties express fear or concern in reaction to any suggested changes that interfere with the power of patent monopoly after grant regardless of the harm or potential harm of failure to address issues relating to access. This can be seen in the restricted way in which the compulsory licensing system is structured, as an example of post-grant control of patents, and in comments in reaction to suggestions to expand the use of them, such as:

> Lowering the threshold... [i.e. to compulsory licenses]...to e.g. health care related issues in general can have serious effects, since it would open the door to a broader application of the system, thereby depriving the patent

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[612] Lance Armstrong, Lance Armstrong: Tour de Force (Collins Willow 2005) 45.

613 Open Letter from Professor Alain Pompidou former President of EPO dated 28th September 2006 at page 34 available from < www.cipa.org.uk/download_files/epo_warf.pdf >

614 See case study three

holder of the exclusionary rights he is entitled to under the patent. This could have negative effects on technological development.[615]

Refusal of patents for dubious moral reasons may also have a negative effect but that has not stopped the European Patent Office[616] from doing just that. Furthermore aggressive use of broad patents can also have negative effects on development[617]. The question is whether a balance has been achieved. This work asserts that failure to include post-grant effects of patents in a broader morality is mistaken and indicates a need for a more holistic approach.

There is little doubt that the morality clause has been the catalyst through which the array of contentious issues arising out of the development of biotechnology have been able to be debated in such great detail. It has been said that patent law may have provided the only forum for concerns into biotechnology to be aired[618] and so whilst those who have concerns about biotechnology have found an effective means through which to advance arguments against progress that offends them, the remedy wished for has not been available.

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615 Bostyn, 'DNA Patents in Europe: Controversy Remains', 41.

616 As is alleged above regarding the *Edinburgh Patent* (EP 0695351) and *WARF Wisconsin Alumni Research Foundation*, November 2005, Case T 1374/04, G 2/06, stem cell patents See also Harmon S, the rules of Re-engagement: The use of Patent Proceedings to Influence the Regulation of Science (What The Salmon Does When it Comes back downstream") (2006) 4 Intellectual Property Quarterly 378 – 403

617 See Chapter five and cases of *Biogen v Medeva* [1997] RPC 1, HL, and Kirin - Amgen v Transkaryotic Therapies [2004] UKHL 46

618 "It is ironic that these ethical questions have not been faced head on, but rather, and then only in an indirect way, by proxy through the patent system, which has the misfortune to provide the only forum in which such objections can be advanced." Cook T, '*A Users Guide to Patents*' Butterworths, 2002, page 341 See also Harmon S, the rules of Re-engagement: The use of Patent Proceedings to Influence the Regulation of Science (What The Salmon Does When it Comes back downstream") (2006) 4 Intellectual Property Quarterly 378 – 403

Despite what has been said above it is not intended to advocate the dismissal of morality from patent law. Arguments regarding the suitability of morality clauses in general tend to either extol their virtues or deride them altogether[619]. This work suggests that morality should be refocused towards the negative effects of patents. Rather than seeking to interpret the morality of an invention, the question of morality should be focused upon the 'added value' that patent law donates to the exploitation of inventions. Grants of patents carry moral consequences in that they enable holders to restrict others. The extent of that restriction and the effects that it can have are reviewed herein. Although case law[620] indicates that restriction of access is about economics rather than morals, it is difficult to avoid the conclusion that humanitarian issues are important so that if people are in need of new treatments or if beneficial research is prevented or hindered through the use of patents then moral questions arise. Indeed it would be nonsense to suggest otherwise. This focus is based upon the effect of patent grants, or more accurately the effect of exclusion of particular inventions from patentability, rather than the effect of inventions.

Taking the above into consideration it is apparent that there is a role for moral issues within patent law. However that role must be reviewed in order to provide an

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619 See for example Thambisetty S, Understanding Morality as a Ground for Exclusion From Patentability Under European Patent Law, Eubios Journal of Asian and International Bioethics 12 (2002), 48 – 53, Beyleveld D, Brownsword R & Llewelyn M, The Morality Clauses of the Directive on the Legal Protection of Biotechnological Inventions: conflict, compromise and the patent community, Pharmaceutical Medicine and European Law, Cambridge University Press 2000, page 157 and Mills O, *'Biotechnological Inventions: Moral Restraints and Patent Law'*, Ashgate Publishing, 2005, and discussion in chapter four above

620 See *Leyland Stanford* [2002] EPOR 2, page 44, *NOVARTIS/Transgenic Plant* G1/98 [2000] E.P.O.R. 303; [2000] 3 OJEPO 111 and *Human stem Cell/BIOCYTE* [1999] Opposition Division EP 0343217 and EPO Guidelines

understanding about what ought to be open to objection and what point defines whether an issue is or is not moral. The complete period of influence of patent grants throughout the innovation time line should be considered relevant including the period of exploitation subsequent to grant. This clearly involves a redefined role for morality because the question of what is moral is different within each stage of innovation and the following section outlines some of the features of this more holistic approach. It may be helpful to refer to the innovation time line again overleaf:

	Innovation or Incentive Stage	Grant Stage	Exploitation Stage	Generic Stage
Patent Theory	Utility Theory/incentive Fund raising	Disclosure	Reward or Natural Right theory – Democratic tax theory	Distribution to all funded by prior higher prices
The Patent Effect	The prospect of a patent provides an incentive to commence research and development. Patents may also encourage commercialisation so distinguish between incentive to research and incentive to commercialise the results of research	Assess inventive quality – novelty/inventive step and Utility – Morality Priority date (application) Publication within 18 months – nb section 21 applications representations by 3rd parties Max, time to grant 4.5 years NB – EPO 9 months for 3rd party to oppose patent grant	Monopoly Publication – encourages (a) further research (b) inventing around patent (c) compulsory licenses (d) research exemption	Open competition
Regulation	Ethical and legal rules that govern the envelope of research e.g. HFEA. Any other legal requirements – e.g. Health and safety/environmental regulations etc – consent from participants. Human Tissue Act 2004 **Regulation relating to research**	Different regulation may be relevant i.e. from that which governs particular research to that which is pertinent for resulting inventions. **Regulation relating to invention resulting from research**	(a) Strength of market demand (b)licensing practices (c) Competition Law **Regulation relating to method of exploitation**	Generics still under regulations – i.e. will still have to comply with any regulatory requirements re safety etc
Benefit to Public	Incentive created with long term aim of increasing public welfare	Information in public domain and invention becomes available	Invention available albeit at higher than normal market price Publication -	Generic competition means prices likely to reduce
Moral Concerns	Unnecessary blocking effect of patents already granted – a direct cause of patent grant Research – danger to environment/animal cruelty/unknown potentially hazardous outcomes – not caused by grant of patents	Encouraging or rewarding particular immoral innovation. Symbolism of acceptance in event of absence of regulation	Stacks/reach-through licences – potential blocking – research – restrictive licenses caused by patent grants	Other IP – Trade secrets/
Patent and Regulation Interaction	Incentive effect of patent in direction of research? Conflict between what is patentable and what is legally permissible?	Morality clause – invention/commercialisation – have consent procedures been followed? – Recital 26	Competition law – monopolies	

Table Eleven – Innovation Time Line

(6) (c) Horses for Courses – Direct and Indirect Effects of Exclusions from Patentability

Two apparently incongruous objections to biotechnological patents[621] were mooted above. The first objection was that such patents reduce innovation[622], referring to potential difficulties caused by blockage by patents on early stage inventions. The second objection was that biotechnology patents encourage unethical innovation. These contradictory objections arise, in part, because at the time of grant the consequences of granting patents are unknown and partly because encouraging research and blocking research occur at opposite ends of the innovation time line. Thus they expose the various objections against patents for biotechnology arising during the different stages. If both objections are to co-exist there must be two contrasting incentive mechanisms within patent law, one which encourages innovation and another which discourages it. These objections can be seen in the balance within patent law between reward and incentive; factors which arise at different stages of the innovation time line. The reward restricts others within the parameters of the defined invention of a patent and the incentive of a reward encourages others. It is of value to examine the relationship between these objections now so as to illustrate morality three.

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621 That patent law can on the one hand be blamed for encouraging unethical research but can also be seen as liable for discouraging ethical research see chapter one

622 Due to creation of a disincentive effect which for patent law to succeed must be less than the incentive produced by patent grant

(6) (d) Direct and Indirect Effects of Patent Grants

A patent once granted enables the patentee to restrict[623] others from defined uses[624] of particular inventions. In the event that alternatives to a particular patented invention are unavailable then everyone without the permission of the patentee is excluded. This results in reduced access, and is a direct result of the power of patents, but this power of prevention expressed through patent monopolies is also the reason why inventors want to be in the position of patentee, which in turn produces the incentive effect. Clearly the two are distinct for a number of reasons but they are also interdependent and it is their relationship that determines the effectiveness of the patent system.

One of the undertakings of this thesis is to examine the reasons for either refusing patent grants or revoking or diluting them after grant for reasons that are unrelated to their inventive qualities[625]. This final section proposes methodology within which objections can be aired and if necessary answered through patent rules and this particular chapter isolates common factors in objections so that patent law can address them. The proposal depends upon whether a particular objection is a direct or indirect result of the grant of patents and in turn this depends upon whether objections are part of the incentive or disincentive effect. The question is therefore: what is the effect of excluding an invention from patent protection or weakening/reducing[626] the protection

623 For example, s. 60 (1) Patents Act 1977 defined infringement as including any person who –'... makes disposes of, offers to dispose of, uses or imports the product or keeps it whether for disposal or otherwise...'.

624 As defined by, for example, s. 60 Patents Act 1977

625 In other words that the invention would ordinarily qualify for patent protection because it satisfies the tests of inventive step, novelty and industrial application.

626 For example through compulsory licenses

that a patent provides? There should be a nexus between objections raised and the effect of remedy requested.

(6) (D) (I) INCENTIVES EFFECT

The prospect of a patent encourages inventors to invent and so the incentive effect upon others occurs pre-grant. Patents will help commercially but are only part of a bigger picture[627] in that there are many other factors that will determine the success or otherwise of inventions. Furthermore there are other methods of protection such as trade marks or trade secrets that could also be used. Objections to inventions (whether to research or the invention) are related to the use of the invention, how it was made or what it is. In other words objections are made against an existing physical entity; an invention. Therefore there is no direct effect of a refusal of patent grant upon the invention in question in these circumstances. It is accepted that the inventor in such a scenario cannot obtain a patent and market under a monopoly, but that was the case before application and so the situation stays the same vis-à-vis the hypothetical patentee. The patentee in these circumstances may have already 'used' or been influenced by the incentive effect, but only to see the anticipated reward disappear. Thus the only direct effect of refusal of a patent is that the prospective patentee does not obtain the monopoly he envisaged.

627 See above 'Interplanetary Alignment'

Other inventors hoping to emulate similar research may feel inclined to seek their fortunes elsewhere because of the removal of incentive[628]. Thus the exclusion of inventions from patentability for moral reasons at the time of grant may have a discouraging and indirect effect on others[629]. Removal of the patent incentive, with the aim of re-directing research of stem cells away from human embryonic stem cells, was the aim of Professor Virt in his dissenting opinion of the European Group on Science and Ethics[630], a view that appears to have been adopted by the European Patent Office[631]. A narrow view of morality would not encompass this indirect and constraining effect of patent grants but the emerging European Patent Office morality would do so.

The following table summarises the position:

628 On the other hand by not granting a patent there is no protected monopoly and so anyone can reproduce the particular invention and so it could be argued that the effect of using patent law to reduce innovation in a certain area could have the opposite effect.

629 Research into how policy decisions impact upon industry strategies is part of the many functions of the Innogen project. For example, one of the particular research questions is 'To classify policy and regulatory instruments according to their impact on industry strategies, based on whether they are enabling or constraining, discriminating or indiscriminate'. Further details can be obtained from <www.innogen.ac.uk>.

630 European Group on Ethics in Science and New Technologies, 'Study on the Patenting of inventions related to human stem cell research'.

631 As with the stem cell cases discussed above

Table Twelve - Direct and indirect effects of (a) refusal of patent grant and (b) alteration of patent monopoly

Incentive Effect upon other inventors	**Disincentive Effect of monopoly upon competitors/those in similar area or work**
Occurs pre-grant	Is felt post-grant
Transpires because of inventors' motivation to invent because of potential for patent reward and desire to commercialise an invention – but not necessarily dependent upon the grant of patent incentive because invention and/or commercialisation are not prevented if a patent is refused. Moreover there are other methods of commercial protection available, for example, trade marks, trade secrets and copyright.	Arises because of the effect of monopoly resulting from granted patents which creates a complete bar to all within the description of patent claims. This results from the patent reward and is the trade off for granting patent rights.
The moral issue is whether patent grant would encourage unethical research or be seen as rewarding unethical research or ability to derive greater benefit from unethical work.	The moral issues is whether the grant of a patent will prevent others and reduce access but this restriction is seen as acceptable because the resulting incentive effect upon others, also hoping for similar reward, should more than offset short term reduction in access.
A broad interpretation of patent morality relates to objections against physical inventions, what they do or how they were created.	Research exemption/compulsory licences/competition law – aimed at how inventions are exploited – i.e. immoral exploitation
Reason for refusal of patent grant is discouraging others from doing similar, following similar research, for example. But dependent upon a commonly accepted understanding of morality.	Reason to interfere in patent monopoly, whether through compulsory licences, withdrawal of patent or otherwise is to encourage others to research and innovate in area subject to patent monopoly.
Importantly the refusal of patent grant has only an indirect effect because immoral inventions or their commercialisation are not the direct result of patent grants	Whereas restrictions on others occur as a **direct effect** of patent grants.
In the event that a patent grant is refused for moral reasons because of objection to research, for example, the removal of incentive does not effect the cause of concern – the research or the invention, although the refusal of a patent **MAY indirectly effect** other innovation.	The elimination of a patent or alteration in the scope of patent monopoly has a **direct effect** upon the cause of concern – for example blocking of further research.

(6) (D) (II) DISINCENTIVE EFFECT

A disincentive effect on innovation can arise because of granted patents. This is part of the trade-off for patents but, as discussed earlier, gives grounds for concern in the event that the trade-off is weighed excessively against the patent paradox[632], thus creating the situation where the disincentive created by patent grants is more powerful than the incentive as outlined by the examples in the third case study above. Patent law is equipped with limited means with which to react against such situations; i.e. where the grant of a patent works against the principles and justifications of the patent system. Compulsory licensing may seem an appropriate utility with which to address such a situation but the compulsory licences are aimed at encouraging the use of inventions that have not been utilised to exploit the invention under protection and competition law is aimed at different scenarios[633]. Ensuring the continuity of the patent paradox lies at the heart of the justification of patent law but there is a gap between the narrow remedies available within patent law and those that may be available through competition law. Furthermore in the examples in case study three there are moral reasons for access issues to be addressed and those moral reasons are associated with the commercial exploitation of inventions through the monopoly of patents. The failure to examine the need for post-grant morality omits to tackle an important fault and ignores an important and powerful regulatory device. The solution below suggests refocusing morality within patent law so that both indirect and direct moral concerns

632 See introduction. The patent paradox refers to the paradoxical methodology with which the patent system functions; the reduction of access by the grant of a monopoly with a corresponding increase in access brought about by the provision of incentives in the form of patent monopoly. If the patent paradox fails then so, too, does the patent system.

633 See above chapter five

can be addressed. This in turn requires the introduction of a procedure into patent law which enables objections to patents to be addressed during the exploitation stage and away from grant stage, thus focusing upon the effects that patent grants have, not what they may do or what perceived harm the inventions they relate to may cause.

(6) (e) Morality Three and Commercial Exploitation

The essence of objection to the grant of a patent must be understood. Motives for opposing inventions are dealt with above but it is asserted here that commercial exploitation requires a different approach than objecting to inventions; such as: what does commercial exploitation add to an invention that makes it immoral or is the particular form of commercial exploitation enabled by patent grant immoral? If objections to patent grant arise because patents are equated with the perceived immorality of inventions per se then the essence of such objection is that the grant of a patent will encourage or increase the availability of immoral inventions. In these cases then the issue should be addressed through morality 1 or 2 above. Here the thesis is concerned with objections to patent grants because they have the opposite effect; they reduce access and restrict availability. Here immorality arises because the grant of a patent has enabled commercial exploitation to occur in a particular way with the result that the patent paradox fails.

The aim is to establish a new protocol within patent law that examines the effect that patents have upon exploitation. In cases where it appears that a grant of patent has enabled exploitation to occur in a way that is contrary to morality, then the particular patent is open to reconsideration by the patent office. The object is to examine morality from the point of the specific exploitation of inventions enabled by the grant of patents rather than from focusing upon inventions. The crux of examination will be the patent paradox, so if the grant of a patent results in failure of the patent paradox it will be possible to rebalance the system subject to certain conditions.

Objections to patents can occur for various reasons, which need not be repeated[634] here, but understanding the root cause of objections is important for appreciating the role, if any, that patent law can play. For example objections may be consequent upon the actual grant of patents or they can occur in any event. Objections could also be classified in relation to the affect that ring fencing particular inventions from patent protection has; whether exclusion directly addresses particular concerns or whether concerns are only indirectly influenced. For example the exclusion of patents as a result of objections to specific inventions does not effect inventions per se. Such exclusions, however, prevent the specific inventions from being exploited through monopoly benefit, therefore if objections are directed at that form of commercial exploitation then refusal of a patent directly effects the relevant objection.

Grants of patent rights result in a number of consequences relating to access to resources. The initial incentive created by potential of patents occurs within incentive stage of the innovation time line. There is also a restrictive effect of patent grant enabled by patentee's monopoly as judged by definition within patent claims. This may be combined with other factors and aggressive exploitation by patentee creating restrictions upon (a) potential users of patented inventions and (b) further research which arises in the exploitation stage of the innovation time line. The negative effect of patent grant should always be less than the positive.

[634] See chapters three, four and five

The act of excluding particular inventions also has indirect and direct effects as discussed in the previous section. The following indicates a means of using the effects to create a method of assessing post-grant objections.

The features of such a system ought to include the following:

(1) That the role of patent law in relation to specific objections should be focused upon excluding patents on inventions for objections arising by virtue of patent grant and which relate only to cases where exclusion of inventions from patent protection directly affects the causes of the objections.

(2) Greater flexibility should be introduced into the patent system so enabling restrictions on monopoly provided rather than removing the protection altogether.

(3) Expansion of the morality provisions should be focused upon whether or not it is immoral to enable the applicant or patentee to prevent others from competing through enforcement of patent monopoly. A range of alternative remedies should be open to the patent authorities to enable them to exert greater flexibility into what is at present an inflexible and 'blunt instrument'[635]. It is important that is considered as an ongoing role which would explore the 'commercial exploitation' throughout the period of monopolistic exploitation. This proposal therefore envisages a new element of post-grant control of the manner in which patent grants are used to exploit inventions.

635 Laddie, Prescott and Vitoria, '*The Modern Law of Copyright and Designs*', Vol. 1.

(4) That morality within patent law should also[636] address questions that are directly related to the grant of a patent. Such issues would equate with the repercussions resulting from provision of a monopoly as opposed to indirect effects upon inventions or research.

[636] The aim is to address morality across the innovation time line. The role of morality is different at each stage.

(6) (f) Direct Morality – Post-Grant Intervention

The morality clause in European Patent law links with commercial exploitation.[637] Commercial exploitation has not been defined but has been interpreted as referring to inventions (with a European moral consensus or with room for national interpretation) and in Article 6 (2) (a) as reflecting European Consensus but has been interpreted in ways that fail to reflect such a consensus. The re-evaluation of morality by this study suggests that moral focus should address the additional value that is added to commercialisation by the grant of a patent. Commercialisation occurs after patent applications and thus the ramifications stemming from it cannot be envisaged at the time of grant and so can only be properly assessed throughout the period of exploitation. The question should be; are there additional moral concerns raised by the granting of a patent throughout the invention's commercial exploitation and can the patent system intervene at this stage to address these concerns effectively?

The aim is to arrive at a solution or formula that enables patent decisions to be re-evaluated in the event of negative consequences either due to the blocking of further innovation or the results of patent grants turning out to be immoral. Decisions made in relation to negative effects of patent grants are to involve a balance between the incentives created by patent grants and any reduction in incentive brought about as a result of the manner in which patented inventions are exploited.

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[637] "Biotech Directive Art 6 (1) Inventions shall be considered unpatentable where their commercial exploitation would be contrary to ordre public or morality..."

The effect of granting patents is that patentees will be able to exclude others from, inter alia, using[638] inventions described in the patent claims. The subsequent results of awards of patent protection are unknown at the time of grant yet decisions regarding patent morality are centred at that point in time. Thus decisions regarding the morality of commercial exploitation at the time of grant necessarily involve an element of supposition in the face of unknown circumstances. In the event that the effect of that monopoly is negative, judged through an imbalance in the patent paradox, there are no effective mechanisms in place through which that can be addressed; in other words cases where the grant of a patent has resulted in overall restrictions of access and even if a patentee abuses that position the options for redress are limited – and it is submitted that a form of control is essential in certain circumstances. Inventions should not be excluded from patentability unless and until there is clear proof of harm directly linked to patent grant whether because a particular grant, judged throughout the patent term, has restricted access or whether a particular grant has been contrary to morality. Patent law would thereby be able to answer and manage moral questions rather than merely debate them.

The patent paradox should be redressed in cases where the exploitation of inventions is being abused by virtue of the fact the patentees are beneficiaries of patents. Further research could be being thwarted or additional investigations and research into beneficial products for the common good unnecessarily hindered or impeded. A balance must be struck between the incentive created by patent grant and what is taken away as a result.

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638 See s. 60 (1) Patent Act

(6) (F) (I) JUSTIFICATION

Patent law can address situations where grants of patents have resulted in unforeseen effects such as a reduction in overall benefit resulting from grant of patent. Therefore this proposal espouses a mechanism which can be applied during the validity period of patents that would enable the validity to be questioned when immorality arises during exploitation. The basis for this suggestion is that it is not the grant of patents that cause concerns but rather exploitation or more accurately the way in which patented inventions are exploited.

> The preceding discussion does not touch on the way the holder of any gene patent might choose to exploit it. Any attempt to suppress research on the basis of a claim to the gene itself is bound to attract opposition from a number of research groups...Ultimately this may be the real problem rather than the grant of the patent itself.[639]

The importance of morality over the exercise of rights once granted is not a new phenomenon and such a mechanism can be seen in the Community Plant Variety Right Scheme:

> ...a Community plant variety right, once granted, does not permit the rights holder to use the right for any purpose whatsoever, but that Member States may restrict the exercise of the right by national legislation. Instead of determining morality by reference to grant, determination over the exercise

639 Crespi, 'Patents on Genes: Can the issues be clarified?'.

> of the right once granted suggests moving the question of morality away from the intellectual property right per se. This is in stark contrast to the operation of the patent system where a determination of morality lies in respect of the *grant* of the right itself...[640]

Limitations of the exercise of protection have intended to strike a balance between the rights of plant breeders on the one hand and agriculture on the other.[641] Similarly patent law is intended to strike a balance between diverse and competing interests[642] but as discussed this balance is not achieved in some cases because of an absence of power to prevent abuse of disproportionate patent monopolies. I suggest that efforts should be made to explore post-grant remedies further as Overwalle advocated:

> ...efforts should be made to design adequate institutional and legal responses to this finding and develop ways to further monitor the exercise of patent rights in an attempt to reach an adequate balance between private and public interests in the post-grant stage.[643]

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640 Mills, '*Biotechnological Inventions*', 159.

641 'In this manner, the CPVR scheme is safeguarding the interests of agriculture while at the same time protecting those of breeders', ibid., 158.

642 See introduction 'A Good Armchair'

643 Overwalle G, '*Gene Patents and Public Health*', Bruylant, 2007

(6) (F) (II) TEST FOR IMMORAL EXPLOITATION

The basic tenet required, before objections to the exploitation of patented inventions will be considered, is that there should be proof of harm arising because of the grant of a patent. The object is to gain a degree of control, or at least reduce the negative effects, of strong and broad monopoly rights, especially in the biotech field where there are early stage patents covering broad uses and where patentees' actions result in a lessening of overall incentives. It is easy to envisage circumstances where a patentee is following one line of approach to a particular problem whilst other researchers are following different courses with alternative aims. It would be wrong if they were being thwarted because of an overzealous approach by a patent holder. A test along the following lines is suggested:

> The exercise of the grant of patent rights must not be used in a manner which offends against morality or where it is likely to result in harmful consequences upon health, welfare, medical treatment, research and development.

The factors that should be considered in such a test should include the following:

- Commercial exploitation of the patented invention must tie in with the immorality under question. Although Article 6 Biotech Directive also links morality with commercial exploitation it is suggested here that this should tie in with the way in which exploitation occurs but specifically relating to the exercise of a patent.

- Therefore it is not sufficient to illustrate that commercial exploitation by itself is contrary to the proposed test; the objection must be related to the additional value that has been provided by the grant of a patent. In other words there must be a connection between the 'harm' complained of and the award of the patent in question – i.e. situations where it is the grant of patent that has enabled the particular situation to arise

- An important balance exists within patent law between incentive for others and reward for patentees. A potential objection[644] against post-grant controls in patent exploitation is that such interference may influence other inventors with similar innovation to either not produce the invention in question or to use other methods to protect such as trade secrets. This could possibly have a negative effect upon future innovation and so decisions should take into account whether the disincentive created by interference in the patent monopoly is likely to be less than the incentives generated to those who stand to benefit from the opposition.

- Determination of issues likely to arise as a result of this suggested procedure is going to be a value judgement, perhaps through a reasonableness test.

- One difficultly, as argued in chapter four, with use of patent exclusion as a method of addressing a concern such as, for example, research is that research

[644] See below, page 276, for some of the objections that may be raised against this type of proposal

will have already occurred and so any effect upon innovation will be against other patentees rather than the particular applicant. It has been argued that using patent law in such an indirect way to attack the wider industry is mistaken. Thus I suggest that if intervention by the patent office is to be justified it should have a direct effect upon the objection in question. By 'direct effect' it is intended that reaction is linked to immediate consequences of patent grant and that the action corresponds with the patent at issue rather than affecting indirectly other patents or potential patents.

- The size of the market and market share of the patentee is clearly of importance as that will determine the availability to the public of treatment in question or alternatives. The way in which a patentee uses that position is also important as the market position may enable him to charge abnormally high prices or restrict availability against the public interest. Such factors are directly related to the use of and grant of a patent and if a patent grant leads to unreasonable restrictions in access then that should central in the decision making process. The French ex-officio licensing regime justifies the instigation of the ex-officio licensing procedure in a variety of circumstances taking into account a number of factors[645]: (1) insufficiency of quantity or quality of medicines (2) abnormally high prices (3) exploitation contrary to public health interests and (4) patent worked in anti-competitive way[646].

[645] Article L613-16 French Intellectual Property Code

[646] See Overwalle G, '*Gene Patents and Public Health*', Bruylant, 2007, page 135

- The grant of a patent enables holders to exploit their inventions in a particular way. If that form of exploitation is against the public interest then it is suggested that it is a matter for patent law to address.

Taking the case of *Myriad Genetics*:

> Much of the debate surrounding the *Myriad* case, however, concerned not the validity of the patents as such – similar patents held by other entities have not attracted the same criticism – but rather the ethics of how the patent rights were exercised commercially.[647]

(6) (F) (III) DIFFICULTY OF DEFINITION

Parties seeking to use this proposed mechanism against a granted patent would have to surmount some difficult hurdles:

(1) Abuse may be alleged, but where is the dividing line between exploitation and abuse? This is likely to be set by precedent, but a number of factors would guide such decisions, including the behaviour of patentees (marketing or licensing practices, for example), their market share, alternatives available, whether their rewards are greater than the contributions made etc.

(2) Ascertain whether the advantage provided by patent grant is the reason for the objection raised.

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647 Von der Ropp and Taubman, 'World Intellectual Property', Global IP Issues Division, WIPO magazine 2006, Issue 4.

(3) A weighing exercise of the disincentive effect of withdrawing a patent against the incentives created. This criterion is justified on the basis that the patent system is designed to maximise incentives and change should facilitate that.

(6) (F) (IV) POSSIBLE COMPLAINANTS

The starting point is to consider whether the proposed new procedure is to be open to all third party opponents as with opposition procedures under the European Patent Office or whether applications should be limited to, say, direct competitors. The advantage of an open procedure is that it avoids the difficulties of defining who is qualified to make objections. This procedure differs from infringement proceedings in that a person affected by any alleged 'harm[648]' will be unlikely to have a relevant patent because the 'harm' alleged will not be determined by reference to another patent. Furthermore as the questions outlined above involve a moral element there is likely to be a broader range of affected parties than merely direct competitors and so a wider range of applicants is envisaged. As a preliminary step applicants ought to be required to demonstrate a direct and justified connection to the complaint. It is intended to include a provision, outlined below, that discourages groundless or vexatious claims or claims that appear to intend to gain commercial advantage to the

[648] 'The essence of science is cumulative investigation combined with hypothesis testing. The notion of cumulative innovation, each discovery building on many previous findings, is central to the scientific method. Indeed, no respectable scientist would fail to recognize and acknowledge the crucial role played by his or her predecessors in establishing a foundation from which progress could be made. As Sir Isaac Newton put it, each scientist 'stands on the shoulders of giants' to reach new heights.' Shapiro C, 'Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard Setting, Chapter Four, Jaffe A, Lerner J and Scott S, *Innovation Policy and the Economy'* National Bureau of Economic Research, London pages 119-120. Thus 'harm' may likely be cumulative which may hinder this cumulative growth. 'In short, our patent system, while surely a spur to innovation overall, is in danger of imposing an unnecessary drag on innovation by enabling multiple rights owners to 'tax' new products, processes, and even business methods.' Shapiro page 121

disadvantage of promoting innovation. Mechanisms could be available to other regulatory bodies to apply in specific cases.

(6) (F) (V) LIMITATION

The basis of the proposal, in relation to post grant morality[649], is that morality is connected to exploitation and as this arises throughout the period of patent, from date of application until expiry it should then be possible to make an application under the proposed rules at any time during this period but it is suggested that there should be a time limit upon objections from the date of knowledge of circumstances that gave rise to the 'harm' concerned. Therefore, objections can be made at any stage after grant but will be time barred in the event that there is delay in making an application. This is important not only for the same reasons that apply to the rules of limitation but also to ensure commercial certainty. Moreover the provisions are intended to be of relevance where the consequences are serious, so that should be reflected in the urgency of application. Of course it may take time before consequences become apparent and for evidence to be gathered for evaluation, thus a balance should be struck between enabling investigation and achieving certainty for patentees. Thus an application against a patent in relation to post-grant morality can be brought at any stage throughout the life of a patent. However it is suggested that a limitation be placed upon applications starting from the date of knowledge of reason for objection.

[649] Pre – grant morality is discussed above

(6) (F) (VI) FORUM FOR OBJECTION

Various possibilities can be envisaged to facilitate the raising of objections. A form of amended opposition proceedings to the European Patent Office is one possible approach. This would have the advantage that a single European body would interpret the proposed provisions. Yet this strategy may raise similar criticisms to those expressed above vis-à-vis the lack of an accepted European standard for morality. It would be better to enable proceedings to be brought within national jurisdictions thereby providing opportunity for morality to be interpreted in accordance with national principles and those that are pertinent within the specific market place where the invention may be exploited.

In this way morality may be determined according to national norms as opposed to the central position of the European Patent Office. This would also be in line with principles of national determination of morality as discussed in chapter three.

(6) (F) (VII) OPTIONS OPEN TO PATENT AUTHORITIES

The idea injects increased flexibility into a fairly rigid or limited system, so there should be options in the decision-making process to provide options for patent authorities apart from revocation, that reflect the circumstances within each case. Such options may include compulsory licensing, revocation or licensing of a particular use, monitoring coverage and, as the ultimate deterrent, the revocation of complete patent. The existence of such a mechanism should encourage reticent patentees from refusing to cooperate or licence.

Enabling broad product patents can result in patents covering many potential uses but patentees may be unaware of all uses or may not intend to develop them all; the Human Genome Sciences patent on CCR5 Receptor[650] is a case in point. In the event that research is likely to stagnate due to similar conditions then the availability of an application procedure may encourage cooperation. But if that does not arise then there may be justification for proceedings under this proposal as one aim is to encourage the proliferation of all uses of inventions covered by such patents. The suggestion of limiting patents to specific use may provide a similar result but one which is less advantageous to patentees. The option proposed encourages specific uses from subsequent inventors to be enabled without limiting any other potential uses that the particular patent may have.

(6) (F) (VIII) UNJUSTIFIED INTERVENTION

The proposal aims to liberate inventive activity and attempts to place balance into the scheme in the event that there is clear and obvious inequity. The mechanism which could be termed 'abuse of monopoly' is not to be used as a business tool to coerce patent licences or threaten competition unnecessarily. Certainly the consequences of unjustified threats of litigation or unreasonable claims made to force negotiations could be significant and so such a mechanism would seem to be warranted in the circumstances. Thus unjustified advances should be discouraged through the availability of a counter claim. The test should be one based upon reasonableness weighing up all the factors of a given case. Were there reasonable grounds for the

650 See chapter five

application given the facts that were available to the applicant? If it is shown that threats were justified, that is not of itself sufficient to succeed with a suit of 'abuse of patent' as more is required. If justification for an application cannot be sustained or if groundless threats to sue can be established then a counter claim for damages may arise.

(6) (F) (IX) CONSEQUENCES OF APPROACH PROPOSED

The intended consequence of enabling intervention in the patent monopoly is that in the case of inventions that have been exploited in a manner[651] whereby the grant of a patent hinders development and/or access, there is an option open through patent law with which complaints can be raised and action, if appropriate can be taken. It is anticipated that action will only be required relatively rarely because in the vast majority of cases where issues that could fall under this provision, as discussed[652], the patent system and flexibility of patentees has resulted in agreement or licences. In spite of this, the proposal is justified because in the minority of instances, such as those outlined in case study three above, the implications of not taking action are of such gravity that it is important to have systems in place that can address the situation.

[651] Indeed it may not have been exploited at all

652 See chapter five

(6) (g) Objections to Post-grant Control

(6) (G) (I) ECONOMIC EFFECTS ARE IRRELEVANT FOR PATENT LAW

Post-grant objections to the manner of exploitation have been considered as irrelevant for patent authorities: 'The EPO has not been vested with the task of taking into account the economic effects of the grant of patents in specific areas of technology and of restricting the field of patentable subject-matter accordingly'[653].

In the case of *LELAND STANFORD/Modified animal* [2002] EPOR 2 similar sentiments prevailed. Thus the consequences of providing a monopoly and the exclusivity it provides to patent holders has been considered to be (a) irrelevant and (b) an economic matter rather than a moral one.

Yet there are clear moral issues relating to the use of patents over biotech inventions[654]. The influential Nuffield Council report, entitled 'The ethics of patenting DNA', concentrated in particular upon the restrictions that can arise as a result of biotechnology patents, thus they clearly must have viewed the difficulties that may arise from such restrictions as a moral or ethical issue.

Furthermore the most recent manifestation of the morality clause within the European Patent Convention links morality with 'commercial exploitation' yet exploitation is ignored in favour of investigations into the morality of inventions. Directing morality at how inventions are exploited relates morality to the consequence of patent grants

653 European Patent Office Guidelines, paragraph 4.4 quoting from *NOVARTIS/Transgenic plant* [2000] EPOR 303, paragraph 3.9.

654 As discussed in chapter five

and enables patent law to provide an effective remedy. The European Patent Office is casting a bigger moral net. Thus although case law has previously held that inventions per se and the research that led to them are not relevant to the question of patentability, the line of human embryonic stem cells cases and the comments of Alain Pompidou indicate that a change of attitude is afoot. This work suggests that to address morality of patenting they are looking in the wrong direction.

(6) (G) (II) INTERVENTION IS UNNECESSARY

It will be seen from chapters three and four above that although there is evidence of cooperation between patentees it is the forefront of innovation that is likely to be hampered and that this has the potential for general benefit but at the same time produces blocking effects. It has also emerged that the morality clause as it stands at present is in need of some refocusing.

(6) (G) (III) WEAKENING OF PATENT RIGHTS AND CREATION OF UNCERTAINTY

It is likely that any change to the patent system at the point of exploitation will be criticised by industry on the grounds that attacks against granted patents deprive whether through revocation of patent or reduction in scope of potency or breadth of protection, the holders of the monopoly rights for their commercial purposes, and thus the prospect of invalidation of valid patents creates a climate of uncertainty. Companies relying upon such rights and finding that they may be open to attack in this way will be cautious, thereby creating a negative effect upon development because of

the obvious uncertainty. However the proposed model may result in an incentive to competitors to cooperate and to licence without the need for further action. This may be crucial to the obtaining of venture capital from those who are interested in the prospect of high returns secured upon a successful and enduring patent.

If a weakening of patent rights is perceived then the rational of the whole patent system may be in question and is likely be deprived of its basis. The patent system relies upon strong rights and certainties and if these are weakened it is possible that some inventors may be disinclined to apply for patents because of the quid pro quo that has hitherto been built into the system, i.e. the disclosure requirement and relinquishing of rights after expiry. To put that another way potential patentees may feel that the patent bargain has changed. This is hypothetical but it nevertheless creates a potential criticism.

The answer to these criticisms is that there is no intention to create a climate of uncertainty and it is expected that the invalidation of patents would be a remedy of last resort and that there may be other options open to address concerns more specifically than at present; whether through compulsory licences or licences for specific uses. It is not intended that it should be used as a business tool to enable competitors to challenge others purely for financial advantage. A system to discourage ungrounded applications will be built in to deter these sorts of applications. In any event it is in the interests of every commercial venture that progress opportunities are maximised and if the grant of a patent causes inequitable reduction of opportunity then it is in the interests of commerce that the position is redressed.

Although the numbers of cases that have actually caused concern regarding access are relatively small, such cases tend to involve particularly important areas of research, such as cancer and SARS, and because of that there are likely to be many interested parties, including scientists and the public. The full effects of blocking may not be known for some time[655], so decisions made at the grant stage about future problems also cause uncertainty because what might happen in the future cannot be anticipated. This proposal enables decisions to be made at times when the consequences are relatively clear. It is important that early stage innovation is encouraged and that it is not wrongfully challenged nor held back because of moral objections to science when the ethics of science should be directed elsewhere.

(6) (G) (IV) DIFFICULTY OF PROOF

The proof necessary to show 'abuse' may have to be assessed by experience but my proposal is that change is necessary if patent law is to address morality effectively, that a more holistic approach is important. This would include a review of granted patents in particular cases. The factors in relation to that relate to the potential for obstructing further progress and a clear elimination of the patent paradox, combined with positive steps towards obstruction by patentees. It is beyond the terms of this work to describe how the hurdle should be negotiated and this may be something that cannot fully be appreciated in the absence of precedent but it is suggested that it is likely that only a minority of cases will be relevant.

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655 See discussion chapter five and also Gowers Review; OECD, 'Patents and Innovation: Trends and Policy Challenges'.

(6) (H) (V) ALTERNATIVE METHODS AVAILABLE

The argument may be raised that there is no requirement for any further restrictions upon the use of patents because there are sufficient controls already in existence. There are provisions for compulsory licences in the event that particular conditions are met, but as discussed above the conditions that have to be met in order to qualify for a compulsory licence are purposely tough, '...the compulsory licensing scheme has been designed to be applied in exceptional circumstances only. It is therefore a burdensome procedure.'[656] It is also aimed at situations where inventions are not being commercialised as distinct to those in which inventions are aggressively commercialised. There may be remedies outside patent law, such as within the realms of competition law that may come to bear upon a patentee in aggressive pursuit of monopoly abuse but it is submitted herein that this is inappropriate.

Competition law provides a high hurdle which would not address the issues that apply to this proposal. Despite the examples provided in case study three not one was referred under competition rules yet clearly concerns existed as discussed. Changes to competition law to adapt so as to cater for such circumstances would be unwelcome as they would also have a knock on effect upon other non-patent cases. The proposal relates to concerns that are caused by the grant of patents and, more particularly, to concerns that can be answered by patent law. The provision of compulsory licences could form part of the proposal as one option open to patent authorities but they are not able to do so under their limited role at present. In particular licenses for specific uses

656 Bostyn, 'DNA Patents in Europe: Controversy Remains', 27.

would enable greater use of resources and more research without necessarily encroaching upon patentees rights.

It can be possible to argue that patent hurdles at the time of the grant are sufficient to address accessibility issues, as shown in the *Myriad* case. But this is unlikely to occur in every such case and weakening of strong patents should not occur as a matter of course. Ensuring quality within granted patents is to be welcomed but purposeful extension of patent hurdles to address problems that occur before and after grant is not. The reasons for such intervention may be understandable but a solution that involves wholesale exclusion from patentability, merely because inventions are at the cutting edge of technology, is not the most appropriate or effective way forward. The proposal therefore suggests that a number of options should be available to address moral concerns. Yet this is what appears to be occurring[657], and is certainly suggested by some[658] as a means of progress. Likewise restricting patents to allow grants for specific purposes only is also likely to deter innovation. Grant-stage interventions, such as those which increase hurdles for biotechnology patents, result in withdrawal of incentive for research at the start of the process and the reason is likely to become invalid if the next stage receives a full product patent. The problem of access is caused by the method of exploitation and should be addressed in the exploitation stage.

The purpose of this proposal is to offer a different solution to the objections but one which does not have the same harmful consequences and which is morally consistent

657 See chapters four and five

658 Nuffield Council Nuffield Council on Bioethics, 'The ethics of patenting DNA, a discussion paper', July 2002 and OECD, 'Patents and Innovation: Trends and Policy Challenges', Report, 2002

with the aims of patent law and ethical rules that govern science. The difficulty is that changes to patent rules will always have repercussions somewhere along the chain of innovation, however patent law is about balance and the aim is to have a more balanced system than at present.

(6) (H) (VI) EXPENSE RETICENCE AND COMPLEXITY

Perhaps the strongest argument against any system that aims to regulate the power or scope of patent monopoly after grant is the potential cost, for gamekeepers and poachers and bureaucrats who would fret over the complexity of such a system. Finance to set-up and administer a post grant process would be required and that would likely fall to be paid eventually by patentees, within the costs of patenting. In the event of involvement within such a system the costs of opposing legal action would inevitably be high. Clearly there would be opposition from potential patentees, innovators and industry who may feel the costs involved in patenting are no longer warranted if the scope of monopoly, presuming they surmount the existing hurdles, is at risk of curtailment. There may be a point at which innovators either do not innovate or may switch to alternative methods of innovation because patenting no longer fulfils their need due to additional risk and possible expense.

(6) (G) (VII) RESPONSE TO OBJECTIONS

Arguments against post-grant intervention in patent monopoly are undeniably potent. In particular the fear that such a scheme may renter the patent monopoly impotent is of concern. Nevertheless given the potential for harm to access through overzealous

exploitation because of strong patents the benefits of such a scheme should not be ignored[659]. As Drahos has pointed out[660], there is a social contract inherent within patent grants which should be honoured and not abused. It is worth noting that the French legislator has already adopted a post-grant system, albeit different in operation from the one proposed herein, in relation to patents relating to public health, through an ex-officio licensing system through amendment to the French Intellectual Property Code ('FIPC').

> The amendment concerns a rather unique system in the field of public health. It is regularly highlighted as an interesting option that deserves more attention on the international level for follow-up.[661]

In France the Myriad situation is unlikely to arise again because if it does mechanisms exist to address the situation in the event that opposition to patents fails:

> If, in the future, another company – that unlike Myriad may not be <<defeated>> by opposing its patents at the EPO – would decide to impose comparably harsh licensing conditions, the French government may have a well-tailored instrument to confront the antagonist[662]

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[659] '...efforts should be made to design adequate institutional and legal responses to this finding and develop ways to further monitor the exercise of patent rights in an attempt to reach an adequate balance between private rights and public interests in the post-grant phase' Overwalle G, '*Gene Patents and Public Health*', Bruylant, 2007 page 23

[660] See Drahos P, *'A Philosophy of Intellectual Property'*, Dartmouth Publishing Group, 1996, page 220 'Holders of Intellectual Property privileges are subject to those duties that maximise the probability that the purpose for which the privilege was first created is achieved' and page 221 'If the purpose in creating the privilege is to fulfil some approved goal then it should also follow that the privilege [patent] holder is subject to duties not to exercise the privilege in a way that defeats the purpose for which the privilege [paten] was granted'

[661] Ibid Overwalle G, page 125

[662] Ibid Overwalle, page 134

Despite the differences between the system proposed by this work and the French system the same criticisms as against post-grant regimes arise. Yet they do not appear to have been realised in practice. Interestingly the French example has not brought the patent system into question nor spawned an unmanageable quantum of applications. In fact "In France, for now the ex-officio licensing regime has never been put to practice."[663] Indeed compulsory licensing systems are rarely put into practice[664]. This may suggest that both the compulsory licensing systems and the French ex-officio systems are restrictive and/or cumbersome and so applications are thereby discouraged or that such systems encourage cooperation between potential licensing partners[665]. Observers will have to wait to see whether cases similar to Myriad are brought through the French system and whether the complexities of interpretation will prove to be too difficult but it is likely that possible applications under the system will encourage co-operation with licensing practice.

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[663] Ibid page 139

[664] See above page 236 "compulsory Licenses" and Bostyn S J R, '*Enabling biotechnological inventions in Europe and the United States. A study of the patentability of Proteins and DNA sequences with special emphasis on the Disclosure Requirement*' (European Patent Office, Maastricht, December 2001). See also Danish Council of Ethics, The Ethics of Patenting Human Genes and Stem Cells, Conference Report and Summaries (University of Copenhagen, 2004) available from http://www.etiskraad.dk/sw475.asp last accessed 27th December 2007

[665] This has been seen to occur in some countries through their compulsory licensing systems: 'Lawyers and patent attorneys argue, however, that the presence of these mechanisms brings pressure to bear upon non-cooperative patent holders and serves as a convincing argument to settle and drag them into licensing agreements." Ibid Overwalle page 137

(7) Conclusion

This work has examined many of the complex interactions that occur through the promotion of biotechnology by patent law and between various parties and interests. The most obvious relationship is that between private rights of inventors and public rights of access which can be seen, at times, to contradict each other; and yet, the inherent paradox of the patent system is that the former is justified because it is supposed to benefit the latter. Moreover there are additional and compound pressures which act upon the complex web of relationships that typify the patent system and its stakeholders, and which will on occasion favour one or more set of interests over others. While this is to be expected in an imprecise and imperfect system (as the patent system surely is) there are good reasons to consider imbalance in these relationships as a significant moral question requiring an urgent solution in the context of biotechnology and the patenting of biotechnological inventions.

It is trite to confirm that the patent system is an instrument of public policy which is intended to encourage and reward innovation. Furthermore it is no surprise that questions have been raised about the role of patent law in promoting controversial technologies such as research into human embryonic stem cells, which many regard as 'morality one'[666]. Yet not to encourage such research – or indeed, to actively discourage it - are also moral issues. In fact, a range of moral questions surround the patent system, and these are made more complex by the interactions that occur between the patent world and other spheres of human activity, such as commerce,

[666] See above 6 (a) (i)

trade, regulation, governance, promotion of public good and the protection of public health (to name but a few). Fundamentally however, the limits of what is permissible within science are arguably best set outside of commercial regimes – such as the patent system - which are dominated by private interests. That is not to suggest that moral issues cannot be addressed within the patent system, but it is to suggest that we should not expect the patent system to address all moral issues that arise with respect to new technologies or their exploitation.

This thesis has examined two particular relationships that are associated with the patent system - access and ethics. It has utilised a particular version of the innovation time line and regulation theory to visualize where, and when, various objections arise, their specific nature, and when and how they can be addressed effectively. Much attention has been paid in the literature to the role of the so-called 'morality clause' especially in European patent law, and many of the perceived 'moral' issues in this field have been addressed within its shadow. Notwithstanding, the argument developed in chapter four and beyond suggests that, despite the apparent intent of the European Patent Office, the scope for patent law to address specific moral issues relating to inventions per se and research is curtailed by practical limitations, and that the morality clause is of limited utility. Moreover moral questions that relate specifically to the monopoly that patents provide are ignored or at least considered irrelevant for patent law. There is, therefore, a dichotomy between morality issues pre-grant and post-grant, suggesting that there can be no one-size-fits-all approach. Addressing the failure to appreciate the diversity of moral considerations – and therefore the need for a plurality of moral solutions – is one of key area of original contribution of this thesis.

There are understandable reasons for this dichotomy, not least because of the additional bureaucracy, expense, uncertainty and likely opposition from interested parties that would arise if we were to turn as much attention to post-grant morality issues as that which has been invested in pre-grant concerns. None the less, and despite the objections, it has been argued that the value of post-grant control of the exploitation of patented inventions should not be shunned altogether and that at the very least the ramifications of such an approach should be studied. There is an important social contract between patentees and the public which begins with the grant of a patent, yet too often the attainment of the patent is characterised as the morally significant (or problematic) act. I strongly believe that it should not be stretched to the point where the provision of a patent is abused. French patent law has adopted a post-grant system, albeit different to the one suggested herein, and it is not without its merits nor does it appear to have brought the French patent system into disrepute. Rather, while the mechanism has rarely been put into practice, it has nonetheless encouraged negotiation between parties.

This is clearly not the end of the story but merely one proposal out of various alternatives with which to tackle the ongoing questions over the imbalances that so often arise within the public/private rights relationship in patent law. Further study is clearly necessary, in particular in relation to the cost of such a system and potential negative influence on innovators who must not loose the incentive both to innovate and to share through publication of their invention, as is required by the patent system. Yet to over-protect can be just as unwarranted and damaging as threats to the exclusivity of

particularly powerful patents – a better balance must be struck and the above is one way that it can be achieved.

Bibliography

Books

Armitage E and Davies I, *Patents and Morality in Perspective*, Common Law: Institute of Intellectual Property, London, 1994

Baldwin R, *Rules and Government* (Clarendon Press, Oxford 1995)

Baldwin R and Cave M, *Understanding Regulation: Theory, Strategy and Practice* (OUP 1999).

Bannock G, Baxter R E and Rees R, *The Penguin Dictionary of Economics* (2nd edition, 1978).

Bostyn S J R, *Enabling biotechnological inventions in Europe and the United States. A study of the patentability of Proteins and DNA sequences with special emphasis on the Disclosure Requirement* (European Patent Office, Maastricht, December 2001).

Beyleveld and Brownsword, Mice Morality and Patents, London: Common Law institute of Intellectual Property, 1993

Brownsword R, Cornish W R and Llewelyn M, *Law and Human Genetics: Regulating a Revolution* (Hart, 1998)

Conrad Joseph, *The Secret Agent*: A simple Tale (Twentieth Century Classics), 31st May 1990

Cook T, *A User's Guide to Patents* (Butterworths, London 2007).

Cornish W R & Llewelyn D, *Intellectual Property: Patents, Copyrights, Trademarks and Allied Rights* (6th edition, Sweet & Maxwell, 2007).

Cornish W, *Intellectual Property, Omnipresent, Distracting, Irrelevant* (OUP 2004).

Craig P and De Burca G, *EU Law Text and Materials* (3rd edition, OUP 2003)

Davies M, *Textbook on Medical Law* (2nd edition Blackstone, London 1998)

Drahos P and Mayne R, *'Global Intellectual Property Rights: Knowledge Access and Development'*, Oxfam, 2002

Drahos P, *'A Philosophy of Intellectual Property'*, Dartmouth Publishing Group, 1996

Dutfield G, *Intellectual Property Rights and the Life Science Industries: A Twentieth-century History* (Globalisation and the Law series, Ashgate, Aldershot Hants. 2003

Fowler C, *Unnatural Science: Technology, Politics and Plant Evolution* (Yverdon: Gordon and Breach, 1994).

Goldberg R and Lonbay J, *Pharmaceutical Medicine, Biotechnology and European Law* (CUP, 2000).

Goozner M, *The $800 Million Pill: The True Cost of New Drugs* (University of California Press 2004).

Grubb P W, *Patents For Chemicals, Pharmaceuticals and Biotechnology: Fundamentals of Global Law, Practice and Strategy* (4th edition, OUP 2004).

Jaffe AB and Lerner J *Innovation and its discontents: How our broken patent system is endangering innovation and progress and what to do about it* (Princeton University Press 2004).

Jaffe A, Lerner J and Scott S, *Innovation Policy and the Economy'* National Bureau of Economic Research, London

Kamstra G, Doring M, Scot-Ram N, Sheard A and Wixon H, *Patents on Biotechnological Inventions: The E.C. Directive* (Sweet & Maxwell, London 2002).

H Laddie, P Prescott and M Vitoria, *The Modern Law of Copyright and Designs*, Volume 1, (2nd edition, Butterworths, London 2000).

Ladas S P, *Patents Trademarks and Related Rights, National and International protection,* Harvard University press, Harvard 1990

Laurie G, *Genetic Privacy. A Challenge to Legal Norms* (CUP 2002).

Lloyd I J, *Information Technology Law* (3rd edition, Butterworths, London 2000).

Maienschein J, *Whose View of Life: Embryos, cloning and stem cells* (President and Fellows of Harvard 2003).

MacQueen H, Waelde C & Laurie G, *Contemporary Intellectual Property*, Oxford University Press, 2007

Mason JK and Laurie GT, *Mason and McCall Smith's Law and Medical Ethics* (7th edition, OUP 2005).

Mills O, *Biotechnological Inventions: Moral Restraints and Patent Law* (Ashgate, Aldershot 2005)

Monbiot G, *The age of consent: A manifesto for a new world order* (Flamingo, 2003).

Ogus A I, *Regulation. Legal Form and Economic Theory* (Hart 2004), Oxford Portland Oregon.

Overwalle G, *Gene Patents and Public Health*, Bruylant, 2007

Robinson J, *The Accumulation of Capital* (London - Macmillan 1956)

Schumpeter JA, *Capitalism, Socialism and Democracy, London*, George Allen & Unwin Ltd, 1976

Somsen H, *The Regulatory Challenge of Biotechnology: Human Genetics, Food and Patents* (Edward Elgar, Cheltenham 2007).

Sterckx S, *European Patent Law and Biotechnological Inventions*, Sigrid Sterckx (ed), Ashgate Publishing, UK, (1997)

GA Stobbs, (2000); Gaithersburg, '*Software patents*' [1996] Aspen Law & Business

Sulston J & Ferry G, *The Common Thread: A Story of Science, Politics, Ethics and the Human Genome* (Bantam Press 2002).

Torremans P, *Holyoak & Torremans Intellectual Property Law* (3rd edition Butterworths, London 2001).

Articles

Barzel Y, 'Optimal Timing of Innovations' (1968) 50 Review of Economics and Statistics 248.

Basheer S, 'Block Me Not: Are Patented Genes "Essential Facilities"?' (University of Oxford, Berkeley Electronic Press, 2005), available from < http://law.bepress.com/expresso/eps/577 >

Beyleveld D, 'Why Recital 26 of the E.C. Directive on the Legal Protection of Biotechnological Inventions should be implemented in National Law' [2001] IPQ No1, pp1-26

Beyleveld D, Brownsword R & Llewelyn M, 'The Morality Clauses of the Directive on the Legal Protection of Biotechnological Inventions: Conflict, compromise and the patent community' [2000] Pharmaceutical Medicine and European Law 157.

Black J, 'Regulation as facilitation: Negotiating the genetic revolution' in R Brownsword, WR Cornish and M Llewelyn (eds), Law and Human Genetics: Regulating a Revolution Hart Publishing, Oxford Portland, (1998).

Bostyn SJR, 'DNA Patents in Europe: Controversy Remains', in The Ethics of patenting human genes and stem cells. Conference Report and Summaries (Danish Council of Ethics, University of Copenhagen, 28 September 2004) available from < http://www.etiskraad.dk/sw475.asp last accessed 27th December 2007

Brownsword R, 'Red lights and rogues: Regulating human genetics', in H Somsen (Ed), The Regulatory Challenge of Biotechnology: Human Genetics, Food and Patents (Edward Elgar, Cheltenham 2007) chapter 3

R Brownsword, 'The Ethics of Patenting: A Legal Perspective', Sheffield University, Bioethics Today, 7 October 2003

Cameron E, Patents and Public Health: Principle, Politics and Paradox, Inaugural British Academy Law Lecture, Edinburgh University, 19th October 2004

Campbell P Patentable Subject Matter in Biotechnology, CASRIP, UW School of Law available from: http://www.law.washington.edu/Casrip/Newsletter/Vol14/newsv14i1Campbell.html#IV last accessed 8th July 2008

Caulfield T and Brownsword R, 'Human dignity: A guide to policy making in the biotechnology era' (2006) 7 Nature, 72.

Crespi S, 'Biotechnology Patenting: The wicked animal must defend itself' [1995] 9 EIPR 431.

Crespi SR, 'Patents on Genes: Can the Issues be Clarified?' (1999/2000) 5(3) Bio-Science Law Review 199. Available from: <http://pharmalicensing.com/features/disp/982797689_3a944d79e9fc8>

Dresser R, 'Ethical and legal issues in patenting new animal life', [1998] Jurimetrics Journal, 399–435.

Dutfield G. 'DNA Patenting: Implications for public health research' (2006) 84(5) Bulletin of the World Health Organization 5

Eisenberg R, Genes, Patents, and Product Development, 257 Science 903
Eisenberg R, Patents and the Progress of Science: Exclusive Rights and Experimental Use, 56 U. Chi. L. Rev. 1017, 1076-77

Gold R, 'SARS Genome Patent: Symptom or Disease?' [2003] The Lancet, 361

Goldman B, 'HER2 testing: The patent "genee" is out of the bottle' 8 May 2007, CMAJ.176 (10). Doi:10.1503

Grubb P, 'Stem Cell Patents', 7 March 2004, Novartis

Heller M and Eisenberg R, 'Can patents deter innovation? The Anticommons in Biomedical Research' (1998) Science 698

Herder M, Proliferating Problems with Human Embryonic Stem Cell Research, Journal of Bioethical Inquiry, Springer (Netherlands), Volume 3, Numbers 1-2/August 2006 pages 69-79

Joly, Yann, "Open Source Approaches in Biotechnology: Utopia Revisited" . Maine Law Review, Vol. 59, No. 2, p. 386, 2007 Available at SSRN: http://ssrn.com/abstract=943011

Patients and consent: Exploring the interface between regulation and innovation regimes', in H Somsen (ed.), The Regulatory Challenge of Biotechnology: Human Genetics, Food and Patents (Edward Elgar, Cheltenham 2007) chapter 11

Laurie G, Example of the Moment: Embryonic Stem Cell Patents – The European Experience, 2004"Bioethical Issues of Intellectual Property in Biotechnology"
International Conference Hall, Tokyo International Exchange Center
September 6 – 7, 2004

Laurie G, 'Patenting Stem Cells of Human Origin' [2002] EIPR 59

Leveque F and Menière Y, The Economics of Patents and Copyright, July 2004, page 83

E Mansfield, 'Patents and Innovation: An Empirical Study', (1986) 32 Management Science, Vol. 32. No.2 (Feb. 1986) pp 173–181.

Mansfield E, 'Imitation costs and patents: An empirical study', E Mansfield, M Schwartz & S Wagner, (1981) 91 Economics Journal 907–918 .

Matthijs G & Halley D, "European-wide opposition against the breast cancer gene patents", European Journal of Human Genetics 10, 783-784 (2002)

R MERGES and R. Nelson 'On the Complex Economics of Patent Scope', (1990) 90 Columbia Law Review, 839.

HL MacQueen, "Towards Utopia or Irreconcilable Tensions? Thoughts on Intellectual Property, Human Rights and Competition Law", (2005) 2:4 SCRIPT-ed 466 @: http://www.law.ed.ac.uk/ahrc/script-ed/vol2-4/hlm.asp last accessed 27th December 2007

Overwalle GV, 'Reshaping bio-patents: measures to restore trust in the patent system' in H Somsen (ed.), The Regulatory Challenge of Biotechnology: Human Genetics, Food and Patents (Edward Elgar, Cheltenham 2007) chapter 12.

Paradise J, 'European opposition to exclusive control over predictive Breast Cancer Testing and the inherent implications for U.S. Patent Law and Public Policy: A Case Study of the Myriad Genetics BRCA Patent Controversy' (2004) 59 Food and Drug Law Journal 59.

Rimmer M, 'Myriad Genetics: Patent law and Genetic Testing' [2003] EIPR 20

Rimmer M, 'The Race to Patent the SARS Virus: The TRIPS Agreement and Access to Essential Medicines' [2004] Melbourne Journal of International Law, 335. Available at: <http://works.bepress.com/matthew_rimmer/17>.

Rivette, KG and Kline D, 'Discovering New Value in Intellectual Property' [2000] Harvard Business Review 54

Scherer F M, 'The Economics of Human Gene Patents', 17 Academic Medicine Volume 77 No.12 December 2002, Part 2, 1348

Scott C, 'Rethinking regulatory governance for the age of biotechnology', in H Somsen (ed.), The Regulatory Challenge of Biotechnology: Human Genetics, Food and Patents (Edward Elgar, Cheltenham 2007).

Selznick P. Focusing organisational research on regulation. In: Noll R, ed. Regulatory policy and the social sciences. Berkeley: University of California Press, 1985:363-368.

Sherman B, 'Patent Law in a Time of Change: Non-Obviousness and Biotechnology' (1990) 10 Oxford Journal of Legal Studies, 278.

Stobbs N, 'Lockhart Review into human cloning and research involving human embryos – closing the gap?' (2006) 26 Queensland Lawyer 247.

Sulston, Staking claims in the biotechnology Klondike, Bull World Health Organ, Vol.84 no 5 Genebra May 2006

Thambisetty S, 'Understanding Morality as a ground for exclusion from patentability under European Patent Law' (2002) 12 Eubios Journal of Asian and International Bioethics 48.

Von der Ropp A and Taubman T, 'World Intellectual Property', Global IP Issues Division, WIPO Magazine 2006, Issue 4.

Warren-Jones, A, 'Patenting DNA: A lot of controversy over a little intangibility' (2004) 12 Medical Law Review 97

Webber P, Patentability of human embryonic cells under the EPC, Pharmalicensing, Bioscience Law Review, 2008, page 5, available from http://pharmalicensing.com/public/articles/view/1119630334_42bc33fe14906 last accessed 8th July 2008

Wells A, 'Patenting New Life Forms: An Ecological Perspective' [1994] 3 EIPR 111

Williams-Jones B, 'History of a gene patent: Tracing the development and application of commercial BRCA Testing' (2002) 10 Health Law Journal, 124

Professor Peter J Whittaker, 'Stem Cells, Patents and Ethics', Centre for Economic and Social Aspects of Genomics (2002), Institute for Environment, Philosophy and Public Policy, Lancaster University

Case Law

United Kingdom

Aerotel Ltd v Telco Holdings Ltd, Telco Global Distribution Ltd and Telco Global Ltd [2006] EWCA Civ 1371

Beecham Group Limited v *Bristol Laboratories International SA* [1978] RPC 521

Biogen v *Medeva* [1997] RPC 1, HL

Boulton v Bull 126 Eng. Rep., 656 – "...the specification is the price which the patentee is to pay for the monopoly"

Genentech Inc.'s Patent (Human Growth Hormone) [1989] RPC 147, CA

Gillick v *West Norfolk and Wisbech Area Health Authority* [1986] AC 112, [1985] 3 All ER 402 HL

In the matter of an Application for a Patent by A. and H. (1927) 44 RPC 298

In the matter of an application for a patent by Rufus Riddlesbarger (1935) 53 RPC 57

Kirin-Amgen v *Hoechst Marion Roussel Limited and others* [2004] UKHL 46

Liardet v Johnson (K.B. 1778), 1 WPC 53

Marshall v *Curry* [1933] 3 DLR 260

Pfizer v Ministry of Health [1965] AC 512

RE T (adult) (refusal of medical treatment) [1992] 4 All ER 649, (1992) 9 BMLR 46, CA

Re C (adult refusal of medical treatment) [1994] 1 All ER 819, (1993) 15 BMLR 77

Re Wyatt (a Child) (medical treatment: parents' consent) [2004] Fam 866

Société Technique de Pulvérisation Step v *Emson Europe Ltd* [1993] RPC 513

Technograph Printed Circuits Limited v *Mills and Rockley (Electronics) Limited* [1972] RPC 346

Williamson v *East London and City Health Authority* (1998) 41 BMLR 85

Windsurfing International Inc. v *Tabur Marine (Great Britain) Limited* [1985] RPC 59

Europe

Aerotel Ltd v *Telco Holdings Ltd, Telco Global Distribution Ltd and Telco Global Ltd* [2006] EWCA Civ 1371

European Patent Office

Case T-1374/04 *18th Wisconsin Alumni Research Foundation*, November 2005

California Institute of Technology Case T 522/04 CIT [2003] ED EP 93921175.1

CIBA GEIGT/Propagating Material [1984] OJEPO 112

Edinburgh Patent (EP 0695351)

HARVARD/ ONCO-mouse [1991] EPOR 525

HOWARD FLOREY/Relaxin, V 0008/94 OD, [1995] EPOR 541

Human Stem Cell/BIOCYTE unreported regarding patent number EP 03432317

LELAND STANFORD/Modified animal [2002] EPOR 2

Lubrizol Genetics Inc [1992] EP – B1-122 791 (opposition Division) unreported

Upjohn's Application Case number 89913146.0

EPO Board of Appeal Decisions

CIBA GEIGT/Propagating Material [1984] OJEPO 112

PLANT GENETIC SYSTEMS/Glutamine Synthesase Inhibitors [1995] EPOR 4

LUBRIZOL/Hybrid plants T 320/87 [1990] O.J. EPO 59

NOVARTIS/Transgenic Plant [2000] EPOR 303

MICHIGAN STATE UNIVERSITY/Euthanasia Compositions [2005] T 0866/01

Welcome – Pigs I (T116/85) [1989] OJ EPO 13; [1988] EPOR 1;.EPO Tech. Bd. App

European Court of Justice

Kingdom of the Netherlands v *European Parliament and the Council of the European Union*, Case C-377/98, [2001] ECR I-7079

RTE and ITP v *Commission (Magill)* Joined cases C-241/91 and C-242/91P, [1995] ECR I–743

Volvo v Veng, Case C-238/87 [1988] ECR 6211, [1989] CMLR 122

United States

Amgen Inc. v *Hoechst Marion Roussel Inc. and Transkaryotic Therapies Inc.* Civil action No 97-10814-WGY United States District Court District of Massachusetts, 19th January 2001

Diamond v *Chakrabarty*, 447 US 303 (1980)

Lowell v Lewis, 15 (a. 1018 No. 8568) (C.D. mass.1817)

Moore J v *Regents of the University of California* 793 P. 2d 479, CAL. 1990

Legislation & Regulation

European

Directive 98/44 of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions ('Biotechnology Directive')

United Kingdom

Data Protection Acts 1984 and 1998

Human Fertilisation and Embryology Act

Patents Act 1977

Parliamentary Papers

The United Kingdom Parliament, Select Committee on Science and Technology, Fourth Report, 20 March 2001, Chapter 7

UK Government's consultative report, 'Human Bodies, Human Choices' (2002)

Reports, Guidelines and Opinions

Bostyn SJR, 'Patenting DNA sequences (polynucleotides) and the scope of protection in the European Union, an evaluation'. Background Study for the European Commission within the Framework of the Expert Group on Biotechnological Inventions, European Commission 2004, EUR 21122.

Commission on Intellectual Property Rights, 'Integrating Intellectual Property Rights and Development Policy', Report (London, September 2002).

Corrigan O, Liddell K, McMillan J, Stewart A and Wallace S, 'Ethical legal and social issues in stem cell research and therapy', Briefing Paper from Cambridge Genetics Knowledge Park (2nd Edition, March 2006).

Danish Council of Ethics, 'Cloning, Statements from the Danish Council of Ethics', 2002, available from http://www.etiskraad.dk/sw475.asp last accessed 27th December 2007

Danish Council of Ethics, The Ethics of Patenting Human Genes and Stem Cells, Conference Report and Summaries (University of Copenhagen, 2004) available from http://www.etiskraad.dk/sw475.asp last accessed 27th December 2007

Danish Council of Ethics, 'Patenting Human Genes and Stem Cells: A report to the Danish Council of Ethics' 2004, available from http://www.etiskraad.dk/sw475.asp last accessed 27th December 2007

Dent C, Jensen P, Walker S and Webster B, 'Research Use of Patented Knowledge: A Review', STI Working Paper 2006/2 (OECD 2006),

Ernst & Young 'Total Value of Information' (2004)

Ernst & Young, 'Beyond Borders: Global Biotechnology Report (2007)'

The European Commission's Directorate-General for Research – 'Eurobarometer 64.3

Europeans and Biotechnology in 2006: Patterns and Trends', May 2006

European Commission, Opinion of the group of advisors on the ethical implications of Biotechnology to the European Commission, Number 8, 25 September 1996

European Commission, 'Development and implications of patent law in the field of biotechnology and genetic engineering', Report to the Council and the European Parliament, Brussels 7 October 2002, COM (2002) 545 final

Ditto,14 July 2005, COM (2005) 312 final.

European Commission, 'Guidelines on the Application of Article 81 of the EC Treaty to technology transfer agreements', Notice OJ 2004/C 101/02.

European Group on Ethics in Science and New Technologies, 'Study on the patenting of inventions related to human stem cell research', Report to the European Commission, Office for Official Publications of the European Communities, 2002

European Group on Ethics in Science and New Technologies, 'Ethical aspects of human stem cell research and use', Report to the European Commission, number 15, 14 November 2000

European Group on Ethics in Science and New Technologies, 'Ethical aspects of patenting inventions involving human stem cells', Report to the European Commission, number 16, 7 May 2002

Gowers Review of Intellectual Property, London, HMSO, December 2006

House of Lords Science and Technology Committee, 'Human Genetic Databases: Challenges and Opportunities', Fourth Report, London, 20 March 2001, available from <http://www.publications.parliament.uk/pa/ld200001/ldselect/ldsctech/57/5701.htm >

United States House of Representatives Standing Committee on Industry, Science and Technology Report, 'Genetic Manipulation: The Threat or the Glory', February 1992, paragraph 7.99.

05-09-2007 HFEA statement on its decision regarding hybrid embryos available from http://www.hfea.gov.uk/en/1476.html - last accessed 28th December 2007

Intellectual Property Institute, 'Patents for Genetic Sequences: The Competitiveness of Current UK Law and Practice. A study by the Intellectual Property Institute (IPI) on behalf of the DTI' (May 2004), available from <www.dti.gov.uk>

Lockhart Review, Legislation Review Committee, 'Prohibition of Human Cloning Act 2002 and the Research of Human Embryos Act 2002, Final Report' (December 2005) < www.lockhartreview.com.au>.

Medical Research Council, 'Public Perceptions of the Collection of Human Biological Samples' (London, 2000)

Médecins Sans Frontières, 'Drug Patents under the Spotlight: Sharing practical knowledge about pharmaceutical patents', June 2004

Nuffield Council on Bioethics, 'Human Tissue: Ethical and Legal Issues', 1 April 1995

Nuffield Council on Bioethics, 'The ethics of patenting DNA, a discussion paper', July 2002

OECD, 'Patents and Innovation: Trends and Policy Challenges', Report, 2002

The Patent Office, 'Guidelines for Patent applications relating to Biotechnological Inventions in the UK Patent Office' (November 2003) - The UK Patent Office now has the operating name of UK Intellectual Property Office

The Patent Office, 'Inventions involving human embryonic stem cells' (2003), available at <www.patent.gov.uk>

PATGEN Project, 'The Patenting of Human DNA: Global Trends in Public and Private Sector Activity' Final Project Report, November 2006, Priority: FP6-2003-Lifescihealth-II.

Professor Alain Pompidou, President EPO, to Mr Steven Perryman, Rapporteur, Enlarged Board of Appeal, European Patent Office dated 28th September 2006

Plomer A, 'Stem Cell Patents: European Patent Law and Ethics' Report, FP6 'Life Sciences, genomics and biotechnology for health', SSA LSSB-CT-2004-005251

'Reaping the Benefits of Genomic and Proteomic Research: Intellectual Property Rights, Innovation, and Public Health' committee on Intellectual Property Rights in Genomic and Protein Research and Innovation, National Research Council 2006

Report of the Committee of Inquiry into Human Fertilisation and Embryology 1984, 'Warnock Report' Cm 9314

The Royal Society, 'Keeping Science open: the effects of intellectual property policy on the conduct of science', London, April 2003

Trilateral Project WM4, Comparative Studies in new technologies, "Report on comparative study on Examination Practice Relating to Single Nucleotide Polymorphisms

(SNPs) and Haplotypes, June 10-12, 2003, available from http://www.trilateral.net/projects/biotechnology/examination_snp/examination_on_snps_haplotypes.pdf

WR 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', Public Health Genetics Unit, Cambridge Genetics Knowledge Park, funded by the Department of Health (UK), July 2003.

Yale Levin Survey 1987, Carnegie-Mellon University survey 2000

Letters

European Patent Office, Christof Friedrich, in response to my email dated 11th June 2007

United Kingdom Patent Office, Dr Rowena Dinham, Senior Patent Examiner, Dated 18th June 2007

Open Letter from Coalition of Patent Examiners, dated April 13th 2007

Professor Alain Pompidou, President EPO, to Mr Steven Perryman, Rapporteur, Enlarged Board of Appeal, European Patent Office dated 28th September 2006

Press Articles

Callahan D, 'When Science is just another good cause' *New Scientist* (28 February 2004)

Coghlan A, 'Baby Cells patch up Mother's Brain' *New Scientist* (20 August 2005), 8

Coghlan A, 'How to Turn Your Skin into Bone' *New Scientist* (2 July 2005), 16

Cohen P, 'Rabbit-Human Stem Cell claims provoke Controversy and Doubt' *New Scientist* (23 August 2003), 14

'Development Biology: Field Leaps Forward with New Stem Cell Advances', *Science Now* (23 November 2007), 1224–1225

'Enlarged BoA to review WARF stem cell case' available from www.epo.org/topics/news/2008/20080617.html last accessed 8th July 2008

'Gene Patents and the Public Good', *Nature*, 423 (15 May 2003)

'Great Expectations – Embryonic Stem Cells could work wonders – if we knew how to get them', *New Scientist* (28 May 2005), 5

Harris J, 'The Moral Choice', *New Scientist* (17 June 2006), 24

Hoge W, US Stem Cell policy Delays UN Action on Human Cloning, New York Times 24th October 2004 available from < http://www.nytimes.com/2004/10/24/international/24nations.html > last accessed 16th January 2008

'Human Embryonic stem cell lines derived from single blastomeres', *Nature*, doi: 10.1038/nature 05142

Institut Curie, 'Breast and ovarian cancer susceptibility gene *BRCA* 1', press release (Paris, 31 January 2005) available from <www.curie.fr>

Nowak R, 'Do nose cells know how to bridge the spinal gap?', *New Scientist* (13 July 2002), 18

'Organs on demand, no embryo needed', *New Scientist* (7 October 2006), 9

Pinock S, 'The Philosopher's Tone: Bioethicists can be our moral pathfinders when research poses new dilemmas, or mere cheerleaders for a particular view', *FT Magazine*, 22 January 2005, 13

'Primitive Streak', *New Scientist* (6 May 2006) 54

Professor Joseph Stiglitz of Columbia University 'A Better Way to Crack it' (*New Scientist*, 16 September 2006, page 20

Watson R, 'France Challenges patent for genetic screening of breast cancer', (2001) 323 *BMJ*, 888

Westphal S P, 'Transformers', *New Scientist* (12 October 2002), 39.