# IMMORAL INVENTIONS

## Interaction between Ethics and Biotechnology Patent Law

At the heart of the intersection between biotechnology and patent law lies the highly contentious and ill-defined role of ethics and morality. The recent controversies in the US, Europe and Australia relating to the patenting of human genes and stem cells, should serve as a "wake-up call" to re-evaluate the current role of morality in biotechnology patenting which seems, at times, to have relegated ethics and morality to outside of the patent realm save for a few exceptions. This article seeks to highlight that ethics and morality should play a more meaningful role in biotechnology patenting. A possible option may be for Parliament as "custodian of public values" to delineate the OB markers, as well as provide specific guidance on the types of biotechnological inventions that will be denied patentability for being contrary to morality/*ordre public* so that the evolution of the patent system in this biotechnology revolution will hold to its core principles that have the "public interest at their center".

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## I. Introduction

1 In June 2010, the scientific and patent communities commemorated the anniversaries of two notable events that impact on biotechnology and patent law. It marked the 10th anniversary of the

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completion of the rough draft of the human genome sequence, as well as, the 30th anniversary of the US Supreme Court decision of *Diamond v Chakrabarty*. The former sought to determine the sequences of the three billion nucleotide base pairs in the human DNA and identify the 20,000–25,000 genes comprised therein.[1] Whilst the latter's oft-cited mantra that "anything under the sun that is made by man" is patentable subject matter has been credited with influencing the expansive approach of what constitutes patentable subject matter in the US and being "instrumental in spurring the creation of a dynamic and flourishing biotech industry".[2]

2 Until recently, this expansion of patent law to encompass biotechnological inventions has prompted many countries to adopt fairly liberal approaches to the patenting of such inventions in the hope of encouraging further innovation, investment in research and development and the unimpeded progress of this new technological revolution. Even in countries where the patent laws contain a general prohibition against the patenting of immoral inventions, these prohibitions have seldom been invoked successfully to exclude the patenting of certain biotechnological subject matter, such as human genes, stem cells, animals and others.

3 Encouraged to some extent by this liberal approach to patenting, biotechnology has continued almost unimpeded into many other controversial areas, including, *inter alia*, the creation of artificial meat or "test-tube meat" made from "real muscle cells" grown in laboratories which has been postulated to replace hamburgers and steaks in the future;[3] as well as the creation of a "synthetic cell" controlled solely by synthetic DNA made from "4 bottles of chemicals on a chemical synthesizer".[4] This recent creation by Craig Venter and his team has been hailed as "the first self-replicating species we've had on the planet whose parent is a computer".[5] Most scientists have

1 See *Human Genome Project information* <http://www.ornl.gov/sci/techresources/Human_Genome/home.shtml> (accessed 13 August 2010).

2 Jim Greenwood, President and CEO of Biotechnology Industry Organization quoted in Gene Quinn, "June 16, 2010: 30th Anniversary of *Diamond v Chakrabarty*" (16 June 2010) at <http://www.ipwatchdog.com/2010/06/16/june-16-2010-30th-anniversary-of-diamond-v-chakrabarty/id=11268/> (accessed 26 July 2010).

3 See Theresa Phillips, "Test-tube tissue: The reality of artificial meat" (7 June 2010) at <http://biotech.about.com/b/2010/06/07/the-reality-of-artificial-meat.htm?nl=1> (accessed 27 July 2010), where it has also been alleged that the replacement of livestock with such laboratory-generated meat "could reduce greenhouse gas emissions by up to 95%".

4 Dr Venter, quoted in Ben Coxworth, "First truly synthetic organism created using four bottles of chemicals and a computer" (20 May 2010) at <http://www.gizmag.com/first-synthetic-organism-created/15165/> (accessed 26 July 2010).

5 See James DeGiulio, "Dr Craig Venter Creates First Cell Controlled Entirely by Synthetic DNA" (1 June 2010) at <http://www.patentdocs.org/2010/06/dr-craig-

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downplayed[6] the severity of this venture since it falls short of man "playing God".

4 Nonetheless, these new biotechnological creations, coupled with the recent controversies in the US and Europe relating to the patenting of human genes and stem cells, should serve as a timely reminder of the vulnerability of the patent system in the biotechnology revolution. It should serve as a "wake-up call" to re-evaluate the current role of morality in biotechnology patenting which seems, at times, to have relegated ethics and morality to outside of the patent realm save for a few exceptions, such as, human cloning, "Frankenstein-hybrid", *etc*.

5 This article will attempt to build on the works of eminent scholars in relation to the role of morality in biotechnology patent law. It will seek to highlight that ethics and morality should play a more meaningful role in the evolution of biotechnology patenting. The author submits that a possible option may be for Parliament as "custodian of public values" to delineate the OB markers, as well as, provide specific guidance on the types of biotechnological inventions that will be denied patentability for being contrary to morality/*ordre public*. This article will: (a) analyse the function of patent law in biotechnology; (b) explore the role that morality plays in biotechnology patent law; (c) examine the morality approaches adopted in the patent laws of different jurisdictions, such as Europe, Singapore and the US; (d) compare the impact of the European and US models on the patentability of selected biotechnological subject matter, namely, human genes and embryonic stem cells; and (e) offer some closing thoughts.

## II. Role of patent law in biotechnology

6 A patent is a grant by the State of "exclusive rights" to control the exploitation of a new and useful invention for a limited time in exchange for sufficient disclosure of the invention.[7] It does not confer a possessory right over the patented invention. Neither does it accord the

venter-creates-first-cell-controlled-entirely-by-synthetic-dna.html> (accessed 27 July 2010).

6 See James DeGiulio, "Not Quite Artificial Life, But We're Getting Closer: Reactions to Venter's Synthetic Cell" (13 June 2010) at <http://www.patentdocs.org/2010/06/not-quite-artificial-life-but-were-getting-closer-reactions-to-venters-synthetic-cell.html?utm_source=feedburner&utm_medium=email&utm_campaign=Feed%3A+PatentDocs+%28Patent+Docs%29> (accessed 26 July 2010).

7 See Philip Grubb & Peter Thomsen, *Patents for Chemicals, Pharmaceuticals and Biotechnology* (New York: Oxford University Press, 5th Ed, 2010) at p 3; Lionel Bently & Brad Sherman, *Intellectual Property Law* (New York: Oxford University Press, 3rd Ed, 2009) at p 335; Maureen Cavanaugh & Natalie Walsh "Who owns your genes?" (29 July 2009), KPBS interview at <http://www.kpbs.org/news/2009/jul/29/who-owns-your-genes/> (accessed 21 June 2010).

right to practise the invention.[8] Instead, it gives the patent owner the right to stop others from commercially exploiting the invention (*eg*, by making, selling, using, *etc*). For example, the grant of a patent on human genes does not give the patent owner possession over the genes as it exists in a human body. Rather, it gives the patent owner the right to exclude others from exploiting the isolated and purified DNA sequence and information derived from it.[9]

7 The patent system, therefore, seeks, *inter alia*, to incentivise innovation, create new and useful inventions and promote scientific progress with the hope that it will benefit society for the betterment of mankind. However, attitudes toward the role of patents in biotechnology vary greatly. There are those who fear that granting patents too far upstream may actually stifle or diminish downstream innovation, slowing scientific progress and thereby undermining the basic goals and objectives of patent law. Yet, for private industry and those involved in translational science to produce useful innovations, it has been said that patents are "the only things that matter"[10] to compensate the private enterprises for their research and justify the huge investment and risk-burden.

8 As we move towards a patent paradigm where the patent "monopoly" appears to have assumed the "role of a legitimate reward for innovation, granted increasingly to multinational corporations",[11] it is, perhaps, timely to evaluate what role (if any) morality should play in biotechnology patent law.

## III. Whither the role of morality in biotechnology patent law

9 At the heart of the intersection between biotechnology and patent law lies the highly contentious and ill-defined role of ethics and

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8 The freedom to practise an invention may be "limited by legislation or regulations having nothing to do with patents, or by the existence of other patents". See Philip Grubb & Peter Thomsen, *Patents for Chemicals, Pharmaceuticals and Biotechnology* (New York: Oxford University Press, 5th Ed, 2010) at p 4.

9 See, *eg*, Gene Quinn, "Emotion and Anecdotes should not drive patent policy" (16 June 2010) at <http://www.ipwatchdog.com/2010/06/16/emotion-and-anecdotes-should-not-drive-patent-policy-debate/id=11260/?utm_source=feedburner&utm_medium=email&utm_campaign=Feed%3A+Ipwatchdog+%28IPWatchdog.com%29> (accessed 26 July 2010).

10 See Gene Quinn, "Emotion and Anecdotes should not drive patent policy debate" (16 June 2010) at <http://www.ipwatchdog.com/2010/06/16/emotion-and-anecdotes-should-not-drive-patent-policy-debate/id=11260/?utm_source=feedburner&utm_medium=email&utm_campaign=Feed%3A+Ipwatchdog+%28IPWatchdog.com%29> (accessed 26 July 2010).

11 Luigi Palombi, *Gene Cartels, Biotech Patents in the Age of Free Trade* (Cheltenham: Edward Elgar Publishing, 2009) at p xi.

morality. There are few universal principles of ethics and morality in the patenting of biotechnological creations, save for a few generally accepted exceptions, such as human cloning and Frankenstein-hybrids. In many other instances, it remains controversial. Indeed, the concept of what is moral and ethical remains amorphous and may evolve and change over time. It may subsist within a spectrum shaped by man's understanding of what is right and wrong at a particular time within a given society swayed by global norms.

10 Furthermore, some creations may pose ethical and moral concerns, yet possess facets that bring important benefits to mankind. For example, the creation of an artificial/synthetic cell may raise ethical and moral challenges, yet its use, for example, in accelerating vaccine production may bring benefits and improve healthcare.

11 The multi-faceted nature of some biotechnological subject matter, coupled with the lack of a benchmark on what constitutes unethical or immoral creations, have, *inter alia*, spawned controversy on what role (if any) ethics and morality should play in biotechnology patent law. These may broadly be summarised, *inter alia*, as follows.[12]

12 Opponents to moral scrutiny of patentable subject matter contend, *inter alia*, that:

(a) The patent system is not the proper forum to deliberate issues of ethics and morality.

(b) Patent adjudicators are ill-equipped, and are inappropriate persons, to decide issues that call for complex interplay of ethical, moral, social, religious and policy judgments.

(c) There is no universal benchmark for determining what constitutes unethical or immoral invention.

(d) Legislative intervention will unnecessarily derail private enterprise support and cause stagnation in scientific innovation.

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12 See, *eg*, Bently & Sherman, *Intellectual Property Law* (New York: Oxford University Press, 3rd Ed, 2009); Stankovic, "Patenting the Minotaur" (2005) 12 Rich JL & Tech 5; Whitehill, "Patenting Human Embryonic Stem Cells: What is So Immoral?" (2008-2009) 34 Brook J Int'l L 1045; Holman, "The impact of human gene patents on innovation and access: a survey of human gene patent litigation" (2007) 76 UMKC L Rev 295; Holbrook, "The expressive impact of patents" (2006) 84 Wash UL Rev 573; Philip Grubb & Peter Thomsen, *Patents for Chemicals, Pharmaceuticals and Biotechnology* (New York: Oxford University Press, 5th Ed, 2010) at pp 315–320; M Rimmer, *Intellectual Property and Biotechnology* (Cheltenham: Edward Elgar Publishing, 2008); D Koepsell, *Who owns you? The Corporate Gold Rush to patent your genes* (Wiley-Blackwell Publishing, 2009); R Cooke-Deegan, *The Gene Wars* (WW Norton & Co Publishing, 1995).

13 Proponents maintain, *inter alia*, that:

(a) The patent system should subject inventions to ethical-cum-moral scrutiny, so as to sift out inventions that are improper subject matter for legal protection in order to maintain the moral standards of society.[13]

(b) States, in granting patents, cannot disclaim responsibility for inventions that they grant and should not hide behind the negative character of the patent right to avoid deciding whether an invention is inherently against the public interest.[14]

(c) The grant of broad biotechnology patents, such as those on human genes, may block research, hamper innovation, create obstacles to life-saving treatments and run counter to the goal of the patent system.

14 These cogent and diverse arguments have influenced the legislators of various countries to adopt different approaches to morality in their national patent regimes. These appear to fall broadly into the following:

(a) general immorality/public interest exclusion;

(b) specific-context exclusion premised, *inter alia*, on immorality/public interest;

(c) no immorality/public interest exclusion.

15 A brief analysis of the role that morality plays in the patent laws of some jurisdictions may shed some light on its current significance on the global stage.

## IV. Current role of morality across some jurisdictions

16 The Agreement on Trade Related Aspects of Intellectual Property Rights ("TRIPS Agreement" or "TRIPS") permits World Trade Organization ("WTO") member countries to exclude, *inter alia*, "immoral" inventions from patentability. This TRIPS flexibility is reflected in Art 27.2 as follows:

> Members may exclude from patentability inventions … the commercial exploitation of which is necessary to protect *ordre public*

13 See D R J Macer, "Patent or perish? An ethical approach to patenting human genes and proteins" The Pharmacogenomics Journal 2002; 2(6): 361–366.

14 See Carolyn Abbot & David Booton, "Using patent law's teaching function to introduce an environmental ethic into the process of technical innovation" 21 Geo Int'l Envtl L Rev 219 at 225–228.

> or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment.

17 Apart from this general immorality/public interest exclusion, Art 27.3(b) of TRIPS also allows WTO countries to implement specific-context exclusion, such as those relating to animals and plants (other than micro-organisms) and essentially biological processes for the production of animals and plants.[15] It is worth noting that this TRIPS flexibility is currently under review at the TRIPS Council where some countries have proposed to amend the provision to incorporate, *inter alia*, a disclosure of origin of genetic resources and/or traditional knowledge requirement in the patent application and consequences resulting from non-compliance thereof. Others, such as Bolivia, have suggested a blanket ban on patenting of life forms altogether.[16] While most developing countries supported Bolivia, most developed countries counter-argued that patent protection is needed for biotechnological inventions, pointing to the necessity especially where financial benefits or royalties from inventions are to be shared. The results remain to be seen as the minutes of the meeting are currently restricted.[17]

18 Notwithstanding these TRIPS flexibilities permitting immoral/public interest exclusion, many commentators agree that morality has waned in importance as a basis for excluding patents for certain biotechnological subject matter. A review of the approaches adopted in Europe, Singapore and the US may be instructive.

### *A. Europe*

19 The European model relating to the patenting of immoral/*ordre public* inventions has been hailed as the main model where morality plays a significant role in patent law.[18] It contains a general immorality/*ordre public* exclusion, coupled with specific examples/guidance on the types of inventions that are prohibited and will be denied patentability under that exclusion. This specific guidance is based, *inter alia*, on the Biotechnology Directive on the legal protection

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15 See Agreement on Trade Related Aspects of Intellectual Property Rights ("TRIPS") Art 27.3(b).

16 Bently & Sherman, *Intellectual Property Law* (New York: Oxford University Press, 3rd Ed, 2009) at p 354.

17 See World Trade Organization ("WTO"), "Council debates anti-counterfeiting talks, patents on life" (8 and 9 June 2010) at <http://www.wto.org/english/news_e/news10_e/trip_08jun10_e.htm> (accessed 27 July 2010). See also Elizabeth Siew-Kuan Ng, "The impact of the bilateral US-Singapore Free Trade Agreement on Singapore's post-TRIPS patent regime in the pharmaceutical context" [2010] Int TLR 121.

18 Cynthia M Ho, "Splicing Morality and Patent Law: Issues Arising from Mixing Mice and Men" (2000) 2 Wash U JL & Pol'y 247 at 256.

of biotechnological inventions ("Directive").[19] This Directive which has the protection of "human dignity"[20] as one of its objectives became the "focal point for public concerns about the ethical and social dimensions of biotechnology generally, as well as specific concerns about the patenting of products of such activities".[21] It was adopted by the European Union in 1998 and implemented in the European Patent Convention 2000 ("EPC") and the implementing regulations ("EPC Regulation").

20 Article 53(a) of the EPC sets out a general immorality/*ordre public* exclusion which provides that European patents shall not be granted in respect of:[22]

> Inventions the commercial exploitation of which would be contrary to '*ordre public*' or morality; such 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.

21 Apart from this general prohibition, the EPC Regulation also provides specific examples/guidance on the types of inventions that are deemed to be unpatentable under the "morality/*ordre public*" exclusion of Art 53(a) of the EPC. These are specified in r 28 of the EPC Regulation[23] as follows:

> (a) processes for cloning human beings;
>
> (b) processes for modifying the germ line genetic identity of human beings;
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> (c) uses of human embryos for industrial or commercial purposes;
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> (d) 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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19 Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions.

20 See WARF/Stem Cells (G 2/06) Enlarged Board of Appeal (25 November 2008), Official Journal EPO (5/2009) 306 at 324.

21 Lionel Bently & Brad Sherman, *Intellectual Property Law* (New York: Oxford University Press, 3rd Ed, 2009) at p 453.

22 European Patent Convention 2000 ("EPC") Art 53(a). See also s 1(3) of the UK Patents Act 1977 (c 37) (as amended) which contains a general immorality/public policy exclusion that: a "patent shall not be granted for an invention the commercial exploitation of which would be contrary to public policy or morality". See Lionel Bently & Brad Sherman, *Intellectual Property Law* (New York: Oxford University Press, 3rd Ed, 2009) at p 454.

23 Similar provisions are also set out in UK Patents Act 1977 (c 37) Schedule A2.

22 Moreover, the EPC also prohibits the patenting of the human body, as well as animal or plant varieties, namely, that:

> (a) 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.[24]
>
> (b) Plant or animal varieties or essentially biological processes for the production of plants or animals; this provision shall not apply to microbiological processes or the products thereof.[25]

23 Apart from these exclusions, it should be noted that the EPC also contains specific guidance permitting the patenting of isolated biological materials, including isolated human genes and DNA sequences. These are provided in r 27 of the EPC Regulation which states that "biological material which is isolated from its natural environment or produced by means of a technical process even if it previously occurred in nature" may be patentable. This is further reinforced by r 29 of the EPC Regulation which permits the patenting of isolated genes and DNA sequences as follows:

> 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.

### *B. Singapore*

24 The Singapore Patents Act also contains a general immorality/*ordre public* exclusion, similar to that of the EPC (albeit in a different form). Section 13(2) of the Patents Act[26] provides that:[27]

> An invention the publication or exploitation of which would be generally expected to encourage offensive, immoral or anti-social behaviour is not a patentable invention.

25 Unlike the European model, it does not provide any specific examples or guidance as to when an invention will be excluded under s 13(2). There are also no specific exclusions relating to animals and plants, or essentially biological processes for their production. Be that as

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24 See EPC Regulation r 29.

25 EPC 2000 Art 53(b).

26 See Singapore Patents Act (Cap 221, 2005 Rev Ed) (as amended).

27 This provision is modelled on the old s 1(3)(a) of the Patents Act 1977 (c 37) (UK). In addition, s 13(3) of the Singapore Patents Act (Cap 221, 2005 Rev Ed) states that for the purposes of s 13(2) "behaviour shall not be regarded as offensive, immoral or anti-social only because it is prohibited by any law in force in Singapore".

it may, the recent United States-Singapore Free Trade Agreement ("USSFTA")[28] may have effectively limited Singapore's flexibilities to introduce new grounds of exclusion of patentable subject matter. The elimination of this TRIPS option may have extended patent eligibility to plants and animals, thereby enhancing the "scope of biotechnology products/inventions".[29] The precise scope and effect of this limitation on Singapore patent law remains ambiguous, particularly in view of the current review in the TRIPS Council as discussed above.

### *C. The US*

26 The US has generally adopted an expansive approach to the patenting of biotechnological subject matter. There is no statutory prohibition against the patenting of immoral inventions *per se*.[30] Generally-speaking "anything under the sun that is made by man" is patentable in the US.[31]

27 Indeed, §101, Title 35 of the US Code of Federal Regulations stipulates that:

> Whoever invents or discovers any new and useful process, machine, manufacture or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

28 Based on this liberal approach, the US Patent and Trademark Office ("USPTO") extended patentability to genetic materials, as well as plants and animals, but not human beings.[32] Some commentators have

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28 United States-Singapore Free Trade Agreement ("USSFTA"), available at <http://www.ustr.gov/trade-agreements/free-trade-agreements/singapore-fta/final-text> (accessed 23 June 2010).

29 Prior to the USSFTA amendment, Singapore's Patents Act (Cap 221, 2005 Rev Ed) did not contain any specific exclusions pertaining to plants and animals, or essentially biological processes for their production anyway. Whether they would have constituted patentable subject matter would depend, *inter alia*, on the scope of what constitutes an "invention" under the Singapore Patents Act, as well as the scope of the public morality exclusion. It would seem that Singapore may already have been prepared to adopt a liberal approach on the patentability of these subject matters even prior to the USSFTA. See Siew-Kuan Ng, "The TRIPS Agreement and its implementation in relation to Singapore Intellectual Property Law" (1997) 9 SAcLJ 334 at 356. See also Elizabeth Siew-Kuan Ng, "The impact of the bilateral US-Singapore Free Trade Agreement on Singapore's post-TRIPS patent regime in the pharmaceutical context" [2010] Int TLR 121.

30 Note, however, that there are non-patent statutes that limit patentability based on national security.

31 *Diamond v Chakrabarty* 447 US 303 (1980).

32 *Diamond v Chakrabarty* 447 US 303 (1980), cited in Adam Crane, "Of Mice and 'Man': Patentability of Genetic Material and the Protection of Intellectual Property Rights" (2009) 18 Dalhousie J Legal Stud 93 at 100.

reasoned that patents on genes are "required to assure that incentives continue to fuel the genomic revolution".[33] Others portend that the human genome should remain in the public domain and "be freely available to scientists everywhere".[34] Be that as it may, until recently,[35] genes and other genomic inventions have been regarded as patentable in the US "so long as they meet the statutory criteria of utility, novelty and non-obviousness".[36]

29 A comparative analysis of some recent developments in the US and Europe may shed further light on the impact of these different morality approaches on the patenting of selected biotechnological subject matter, such as human genes and embryonic stem cells.

## V. Impact of different morality approaches on the patenting of selected biotechnological subject matter

30 The differing role played by morality in the various jurisdictions, in particular Europe and the US, has posed challenges to the patenting of biotechnological creations, such as human genes and embryonic stem cells. Limited credence (if any) seems to be given to considerations of morality in the US. In contrast, the articulation of the policy goals in the EPC (and its implementing regulations) seems to have averted the controversies which have recently arisen in the US (and Australia) relating to the patenting of human genes. While it is outside the scope of this article to delve into a detailed discussion on these important issues that clearly merit further consideration in a separate forum, some observations will be offered on the recent controversies relating to the patenting of human genes and embryonic stem cells ("hESC") in the US and Europe.

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33 See Venter JC (2000), "Prepared statement, Subcommittee on Energy and Environment, US House of Representatives Committee on Science" <http://www.ostp.gov/html/00626_4.html> cited in Matthew Rimmer, *Intellectual Property and Biotechnology* (Cheltenham: Edward Elgar Publishing, 2008) at p 140.

34 See Clinton & Blair (2000), "Joint statement by President William Clinton and Prime Minister Tony Blair of the United Kingdom" at <http://clinton4.nara.gov/WH/EOP/OSTP/html/00314.html> (accessed 12 August 2010). See also Matthew Rimmer, *Intellectual Property and Biotechnology* (Cheltenham: Edward Elgar Publishing, 2008) at p 140

35 See *Association for Molecular Pathology et al v USPTO et al* 9 Civ 4515 US District Court for the Southern District of New York (29 March 2010) at <http://graphics8.nytimes.com/packages/pdf/national/20100329_patent_opinion.pdf> (accessed 12 August 2010) and 2010 US Dist Lexis 35418 (amended opinion of Robert Sweet USDJ).

36 Todd Dickinson (former Director of the US Patent and Trademark Office), cited in Matthew Rimmer, *Intellectual Property and Biotechnology* (Cheltenham: Edward Elgar Publishing, 2008) at p 141.

### *A. Human gene: Myriad's BRCA1 and BRCA2 patents*

31 Myriad Genetics' patents on, *inter alia*, the gene sequences (BRCA 1 and BRCA 2) and their application in diagnostic testing for predisposition to breast and ovarian cancer, coupled with its aggressive use of these patents, have generated much controversy worldwide, including Europe and the US.[37]

32 Doubts have been raised as to whether the act of isolating a naturally-occurring substance from the human body is sufficiently different from the mere finding of the substance so as to constitute patentable subject matter.[38] Whilst the European Patent Office ("EPO") recognises that "the patenting of genes is … a controversial issue in society",[39] yet it acknowledges that it is for the Legislature to balance conflicting interests and lay down legal rules".[40] In Europe, this issue has been outweighed by the "policy goal outlined in the Biotechnology Directive"[41] which seeks to encourage research aimed at isolating natural elements "valuable to medicinal production".[42] This has resulted in the promulgation of specific rules in the EPC Regulation permitting the patenting of isolated genes and DNA sequences.[43] In applying these rules, the EPO permitted the patenting of some of Myriad's claims, but narrowed a number of its patents and revoked some others based on the usual patentability criteria.[44]

33 Unlike Europe, there is no specific statutory guidance on the patentability of biotechnological creations in the US. Nonetheless, until recently, the US has adopted a liberal approach in permitting the patenting of genes and other genomic materials. However, in a recent surprising departure from this generally accepted approach, Judge

37 See Philip Grubb & Peter Thomsen, *Patents for Chemicals, Pharmaceuticals and Biotechnology* (New York: Oxford University Press, 5th Ed, 2010) at p 313; Matthew Rimmer, *Intellectual Property and Biotechnology* (Cheltenham: Edward Elgar Publishing, 2008) at p 187. See also Cook-Deegan, "Gene patents and licensing: Case studies prepared for the Secretary's Advisory Committee on Genetics, Health and Society" Genetics in Medicine 2010; 12(4): S1–S2.

38 See Lionel Bently & Brad Sherman, *Intellectual Property Law* (New York: Oxford University Press, 3rd Ed, 2009) at p 423.

39 S Moore, "Challenge to the Biotechnology Directive" (2002) 24 EIPR 149 at 154.

40 S Moore, "Challenge to the Biotechnology Directive" (2002) 24 EIPR 149 at 154.

41 See the Biotechnology Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions. See Lionel Bently & Brad Sherman, *Intellectual Property Law* (New York: Oxford University Press, 3rd Ed, 2009) at p 424.

42 Lionel Bently & Brad Sherman, *Intellectual Property Law* (New York: Oxford University Press, 3rd Ed, 2009) at pp 423, 424.

43 See EPC Regulation r 29 (discussed above).

44 These are, namely, novelty, inventive step and industrial applicability. See Philip Grubb & Peter Thomsen, *Patents for Chemicals, Pharmaceuticals and Biotechnology* (New York: Oxford University Press, 5th Ed, 2010) at p 313.

Robert Sweet of the US District Court invalidated the BRCA gene patents. The learned judge opined, *inter alia*, that DNA was unique and could not be treated like other chemical compounds[45] and that the mere isolation of DNA did not transform its unique characteristics into something patentable as they were no more than products of nature.[46] This case is on appeal to the US Court of Appeals for the Federal Circuit and, regardless of the outcome of that decision, is widely expected to be followed by an appeal to the US Supreme Court.

34 Perhaps encouraged by the "recent victory" in the US, an action has also recently been commenced in Australia challenging the validity of the BRCA gene patents. Depending on the outcome of these challenges, it may prompt a review of the current policy adopted in the European Biotechnology Directive in relation to gene patenting. In this regard, it is worth noting that the US Secretary's Advisory Committee on Genetics, Health and Society ("SACGHS") recently released a draft report[47] which found, *inter alia*, that:

> (a) Patents on genetic discoveries do not appear to be necessary for either basic genetic research or the development of available genetic tests.
>
> (b) Patents have been used to narrow or clear the market of existing tests, thereby limiting, rather than promoting, availability of testing.
>
> (c) The substantial number of existing patents on genes and methods of diagnosis also pose a threat to the development of multiplex testing, parallel sequencing, and whole-genome sequencing, the areas of genetic testing with the greatest potential future benefits.

### *B. Human embryonic stem cell ("hESC"): Wisconsin Alumni Research Foundation ("WARF") patent relating to stem cell lines*

35 The patent in this case relates, *inter alia*, to WARF's patent on human embryonic stem cell lines. In 1998, Dr James Thomson of the University of Wisconsin was the first to successfully isolate and culture hESCs that could grow *in vitro*. This was regarded as a major scientific breakthrough having great potential for medical therapies and other

45 *Association for Molecular Pathology et al v USPTO et al* (09 Civ 4515) at 134.

46 *Association for Molecular Pathology et al v USPTO et al* (09 Civ 4515) at 135–136.

47 See the Secretary's Advisory Committee on Genetics, Health and Society report, *Gene patents and licensing practices and their impact on patient access to genetic tests* (April 2010) at <http://oba.od.nih.gov/oba/sacghs/reports/SACGHS_patents_report_2010.pdf> (accessed 19 August 2010).

applications, and worthy of patent protection.[48] However, the validity of these patents has been challenged, *inter alia*, in Europe and the US.

36 At the EPO, the Enlarged Board of Appeal relied on the specific morality guidance provided in r 28(c) of the EPC Regulation (formerly r 23d(c) of the EPC Regulation) and found that it forbade the patenting of claims directed to products which at the filing date could be prepared exclusively by a method which necessarily involved the destruction of the human embryos from which those products were derived, even if that method was not part of the claims. It was irrelevant that after the filing date the same products could be obtained without having to resort to a method necessarily involving the destruction of human embryos.[49] It concluded that the use involving the destruction of human embryos rendered the application in violation of the EPC morality prohibitions[50] and upheld the EPO Examining Division's rejection of WARF's European application.

37 In contrast, the USPTO had adopted the "position that purified and isolated stem cells are patentable subject matter".[51] It "relatively quickly" granted WARF the patents relating to hESC based on almost similar claims to the ones rejected by the EPO.[52] However, these patents have since been challenged in the US. Recently, the USPTO Board of Patent Appeals and Interferences ("BPAI") invalidated one of WARF's patents on stem cell cultures based on the usual patentability criteria, such as anticipation and obviousness.[53] It appears that examination of the patents may continue at the USPTO and this issue still awaits resolution in the US.[54]

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48 See WARF/Stem Cells (G 2/06) Enlarged Board of Appeal (25 November 2008), Official Journal EPO (5/2009) 306 at 310.

49 WARF/Stem Cells (G 2/06) Enlarged Board of Appeal (25 November 2008), Official Journal EPO (5/2009) 306.

50 See Bagley, "The new invention creation activity boundary in patent law" (2009) 51 Wm & Mary L Rev 577 at 596.

51 See Todd Dickinson (1999), "Statement of the Commissioner of Patents and Trademarks before the Subcommittee on Labour, Health and Human Services, Education and Related Agencies of the Senate Appropriations Committee" (12 January 1999) <http://www.uspto.gov/web/offices/ac/ahrpa/opa/bulletin/stemcell.pdf> (accessed 1 October 2010).

52 Joshua Whitehill, "Patenting Human Embryonic Stem Cells: What is So Immoral?" (2008–2009) 34 Brook J Int'l L 1045 at 1048.

53 See *The Foundation for Taxpayer & Consumer rights v Patent of Wisconsin Alumni Research Foundation* (28 April 2010) at <http://www.consumerwatchdog.org/resources/WARFDecision042910.pdf> (accessed 21 August 2010). See also Conley, Dobson & Vorhaus, "WARF Re-examination takes another bite out of biotech patents" (19 May 2010) at <http://www.genomicslawreport.com/index.php/2010/05/19/warf-biotech-patents/> (accessed 17 August 2010).

54 Geron has stated that the immediate effect of the US Patent and Trademark Office Board of Patent Appeals and Interferences decisions is that WARF will have the opportunity to continue examination of the claims of the '913 patent at the

(*cont'd on the next page*)

## VI. Conclusion: Some closing thoughts

38 It would come as no surprise that there is a lack of global consensus on the patentability of biotechnology-related creations that are immoral or contrary to *ordre public*. Although the TRIPS Agreement permits such exclusion, not all WTO member countries have utilised this flexibility. In the US, it has been noted that the policy shift in the development of law "has taken the morality 'ax' out of the hands of the USPTO and the courts".[55] Others have observed that "[i]n modern times … issues of morality and of public policy are irrelevant in the determination of whether or not an invention has patentable utility".[56] Similarly, in the UK, eminent scholars have found patent law over the 20th century in "startling and marked isolation from matters cultural, political and ethical".[57] They reasoned that part of this resulted from "patent law [being] continually presented as a neutral, inert system, which is above or beyond ethics"[58] and contend that "the image of patent law [has been] understood and explained in positivist terms and thus is logically premised on the absence of morality".[59] Other reasons proffered for the decline in reliance on moral utility as a basis for rejecting patents include the subjective nature of determining what is an immoral invention and differences in that determination across generations.[60]

39 While some may find these arguments persuasive, it should be borne in mind that one of the goals of the patent system is to incentivise research and development and to "encourage public disclosure of new knowledge".[61] It would, therefore, seem anomalous for the State to encourage research and development and the public disclosure of knowledge in areas that are immoral or contrary to *ordre public*. In

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examination level of the Patent Office, see Geron Comments on Decision by USPTO on WARF Patent (30 April 2010) at <http://www.geron.com/media/pressview.aspx?id=1219> (accessed 17 August 2010).

55 Joshua Whitehill, "Patenting Human Embryonic Stem Cells: What is So Immoral?" (2008–2009) 34 Brook J Int'l L 1045 at 1075.

56 James P Daniel, "Of Mice and 'Manimal': The Patent & Trademark Office's Latest Stance against Patent Protection for Human-Based Inventions" (1999–2000) 7 J Intell Prop L 99 at 121–122.

57 Lionel Bently & Brad Sherman, "The Ethics of Patenting: Towards a Transgenic Patent System" Med Law Rev 1995; 3(3): 275–291, at 275.

58 Lionel Bently & Brad Sherman, "The Ethics of Patenting: Towards a Transgenic Patent System" Med Law Rev 1995; 3(3): 275–291, at 275.

59 Lionel Bently & Brad Sherman, "The Ethics of Patenting: Towards a Transgenic Patent System" Med Law Rev 1995; 3(3): 275–291, at 275.

60 James P Daniel, "Of Mice and 'Manimal': The Patent & Trademark Office's Latest Stance against Patent Protection for Human-Based Inventions" (1999–2000) 7 J Intell Prop L 99 at 122.

61 See Australian Government Advisory Council on Intellectual Property, *Patentable subject matter – Option paper* (September 2009) at p 16.

addition, the grant of patents for inventions that are immoral, abhorrent or repugnant will dilute the integrity of the patent system and eventually bring it into disrepute.[62]

40 The author is mindful that "morality" is an exceedingly complex and difficult standard to implement as one of the criteria of patentability and that patent law should not frustrate or impair scientific endeavours and should tread cautiously when seeking to foreclose incentives for "what might be done in the future". The patent regime is ill-equipped and was never designed to deal with issues relating to the "patenting of life" that involves the complex interplay between morality, science and law. Yet, it may be time to call for collective wisdom to calibrate an appropriate response to this – one that is guided by core principles of sound moral values of humanity. It is submitted that a possible option may be for Parliament as "custodian of public values" to delineate the OB markers for the exclusion of immoral inventions that are contrary to *ordre public*. Coupled with the provision of appropriate and specific guidance from the law makers, ethics and morality may then play a more meaningful role in the evolution of a patent system that holds to its core principles that have the public interest at their centre.[63] Arguably, an adapted version of the European model based on general immorality exclusion-cum-specific examples/ guidance customised to accommodate the public interest of each nation has much to be commended in this respect. Hopefully, common principles of moral values would serve to chart the course where difficulties prove intractable.[64]

41 As President George W Bush once remarked:[65]

> I believe [the US] must vigorously pursue the tremendous possibilities that science offers to cure disease and improve the lives of millions. Yet, as science brings us ever closer to unlocking the secrets of human biology, it also offers temptations to manipulate human life and

62 See Australian Government Advisory Council on Intellectual Property, *Patentable subject matter – Option paper* (September 2009) at p 16.

63 See World Intellectual Property Organization ("WIPO") Patent Agenda: Options for development of the international patent system (A/37/6) at Annex I p 2.

64 See Elizabeth Siew-Kuan Ng, *The Impact of the International Patent System on Developing Countries* (WIPO Doc A/39/13 Add.3, 2003) a report (presented to WIPO under terms of a Special Service Agreement) commissioned by the Director-General of the WIPO and submitted by the WIPO Secretariat to the WIPO 39th General Assembly of Member States of WIPO at <http://www.wipo.int/meetings/en/doc_details.jsp?doc_id=17557> (accessed 18 August 2010) (translation of this report into French, Spanish, Chinese, Russian and Arabic are also available at the WIPO website).

65 President George W Bush Stem Cell Bill Veto Message (2006) at <http://usgovinfo.about.com/od/thepresidentandcabinet/a/bushstemveto.htm> (accessed 18 August 2010), also cited in Matthew Rimmer, *Intellectual Property and Biotechnology* (Cheltenham: Edward Elgar Publishing, 2008) at p 258.

> violate human dignity. Our conscience and history as a Nation demand that we resist this temptation. With the right scientific techniques and the right policies, we can achieve scientific progress while living up to our ethical responsibilities.

42 As the US continues to pursue its policy of accelerating some aspects of patent reform, *inter alia*, through bilateral Free Trade Agreements ("FTAs"), it is perhaps time to re-evaluate the *Chakrabarty* mantra and the author submits that: Perhaps *not* everything "under the sun that is made by man" should be patentable subject matter.