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THE PATENTABILITY OF HUMAN EMBRYONIC STEM CELLS: IS THE INCONSISTENT APPLICATION OF THE EUROPEAN UNION BIOTECHNOLOGY DIRECTIVE'S MORAL EXCLUSION CLAUSE UNDERMINING INVESTOR CONFIDENCE IN EUROPE, PROVIDING A COMPETITIVE ADVANTAGE TO THE UNITED STATES?

Stephen R. Donnelly*

INTRODUCTION

The original justification for Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions (the Directive)¹ was to promote the growth of the European life science sector by harmonizing and clarifying European biotechnology patent laws.² As early as 1985, the European Commission had identified the fragmentation of European patent laws as a potential problem.³ The Directive thus aimed to address obstacles to the unity of the internal market, which would arise if national Member States adopted divergent and uncoordinated policies and legislation in a field of economic activity that had been earmarked as poised for spectacular growth.⁴ The Commission further identified the lack of guidance within the European Patent Convention 1973 (EPC)⁵ on how its provisions were to be applied to biotechnological inventions meant that researchers were unsure if their work could be legally protected within Europe.⁶

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¹ EC, *Commission Directive 98/44/EC of 6 July 1998*, [1998] OJ, L 213/13.

² A Plomer & P Torremans, *Embryonic Stem Cell Patents: European Law and Ethics* (New York: Oxford University Press, 2009) at xxxvii.

³ *Completing the Internal Market: White Paper from the Commission to the European Council*, COM (85) 310 final, 14 June 1985.

⁴ R Gold & A Gallochat, *The European Directive on the Legal Protection of Biotechnological Inventions: History, Implementation and Lessons for Canada* (2001).

⁵ *Convention on the Grant of European Patents*, Oct. 5, 1973, as amended by Decision of the Administration Council of the EPO Dec 21, 1978, 13 ILM. 268 (1974).

⁶ G Laurie, *Biotechnology and Intellectual Property: A Marriage of Inconvenience?* in S McLean, ed, *Contemporary Issues in Law, Medicine and Ethics* (London: Dartmouth Publishing Group, 1996) at 237-67.

The Commission's concerns were lent greater political urgency by three significant events⁷ that combined to establish the dominance of the United States (U.S.) biotechnology industry.⁸ First, biology researchers in the U.S. were increasingly developing new techniques that had substantial commercial application. Second, the U.S. Congress created the Court of Appeals for the Federal Circuit to promote greater uniformity in the application of patent law and to reduce the possibility of forum shopping by parties seeking favorable courts.⁹ Thirdly, the landmark Supreme Court ruling in *Diamond, Commissioner of Patents and Trademarks v Chakrabarty*,¹⁰ took an important step towards patent liberalization by stating that living matter was not excluded as a 'product of nature' and that patents shall be available for 'anything under the sun made by man'.¹¹ It was not long after the *Chakrabarty* decision that the U.S. Patent and Trademark Office (USPTO) began issuing patents on gene fragments, transgenic bacteria, and cell lines expressing DNA sequences producing therapeutically useful proteins.¹² A trend had been for European companies to move their biotechnology research from the European Union (EU) to the U.S. because they regarded the commercial and legal climate there as more encouraging.¹³ The Commission concluded that European biotechnology patent laws should be clarified and harmonized in order to provide the incentives and legal certainty required for the biotechnology industry to flourish.¹⁴

Given the nature of the objectives pursued, one might have expected that the drafting of the Directive would be a relatively straightforward administrative exercise in harmonizing the legal criteria of novelty, inventive step, and industrial application in the context of biotechnological inventions. Indeed, the first draft of the Directive¹⁵ framed the problem solely in these terms with the legal standards proposed largely reflecting the more permissive approach of the USPTO.¹⁶ The project soon ran into difficulties.¹⁷

The Directive differs in a key way from the approach of the U.S., as it establishes a prominent role for 'morality' as an evaluative criterion within European patent law.¹⁸

⁷ K Sibley, *The Law and Strategy of Biotechnology Patents*, (New York: Butterworth-Heinemann, 1994) at 1.

⁸ G Porter, *The Drafting History of the European Biotechnology Directive*, in A Plomer & P Torremans, *Embryonic Stem Cell Patents: European Law and Ethics* (New York: Oxford University Press, 2009) at 8.

⁹ O Mills, *Biotechnological Inventions: Moral Restraints & Patent Law* (Wiltshire: Ashgate, 2010) at 45.

¹⁰ *Trademarks v Chakrabarty*, 447 US 303 (1980).

¹¹ G Porter, *supra* note 8 at 8-9.

¹² L Demaine & A Fellmeth, "Reinventing the Double Helix: A Novel and Nonobvious Reconceptualization of the Biotechnology Patent" (2002) 55:2 Stan L Rev 303 at 319.

¹³ S Thaker, *The Criticality of Non-Market Strategies: The European Biotechnology Patents Directive*, online: Northwestern Kellogg School <<http://www.kellogg.northwestern.edu/biotech/faculty/articles/shail.pdf>>.

¹⁴ G Porter, *supra* note 8 at 9.

¹⁵ COM (88) 496, 1988 OJ C10/3.

¹⁶ G Porter, *supra* note 8 at 10.

¹⁷ *Ibid.*

¹⁸ *Ibid* at 5.

This unique stance emerged during extensive discussions between the Parliament, the Commission, and the Council, and was a political concession to the view expressed by the Parliament that the patenting of biological materials, in particular those of human origin, raises important ethical and social concerns.¹⁹ Attempts to address these anxieties resulted, *inter alia*, in the inclusion of a ‘morality clause’ in Article 6 of the Directive.²⁰ Article 6(1) provides that inventions shall be considered unpatentable where their commercial exploitation would be contrary to *ordre public* or morality. Article 6(2), intended to clarify how the general morality exclusion in Article 6(1) should be applied, contains a list of specific examples of biotechnology inventions that are excluded from patentability on moral grounds.²¹ Ironically, it has been Article 6(2) that has been the source of great uncertainties in the years since the Directive was enacted.²² In particular, questions regarding how Article 6(2)(c), which excludes ‘uses of human embryos for industrial or commercial purposes’ from patentability, should be applied in relation to patent applications for inventions concerning human embryonic stem cells (hESCs) have given rise to long-running legal, ethical, and policy debates.²³ The debate revolves around the fact that Article 6(2)(c) is silent with regard to hESCs.²⁴ This is because the first ever isolation of hESCs from an embryo was reported four months after the adoption of the Directive.²⁵

Although the Directive was ‘addressed’ only to EU Member States,²⁶ the European Patent Office (EPO), which is independent of the EU, voluntarily incorporated the Directive’s rules within the EPC.²⁷ Thus moral exclusions are now a fixture of European patent law.²⁸ Most patents in Europe are granted via the EPO; however, European patents must still be enforced in individual Member States who may interpret the Directive differently.²⁹ Whereas the EPO has not granted any patents on hESC claims, an overview of EU Member States interpretation of Article 6(2)(c) reveals a patchwork of permissive and restrictive regulatory policies towards the patentability of hESCs. In contrast to Europe, U.S. patent law contains no statutory basis for the USPTO or a court to deny patent protection to morally controversial biotech subject matter. The U.S. has adopted probably the most liberal patenting policies on stem cell research, with the

¹⁹ R Gold & A Galloch, “The European Biotech Directive: Past as Prologue” (2001) 7(3) Eur LJ 331 at 332.

²⁰ L Bently & B Sherman, *Intellectual Property Law* (Oxford: Oxford University Press, 2009) at 454.

²¹ G Bahadur & M Morrison, “Patenting human pluripotent cells: balancing commercial, academic and ethical interests” (2009) Human Reproductions 1-8.

²² G Porter, *supra* note 8 at 5.

²³ G Laurie, “Patenting Stem Cells of Human Origin” (2004) EIPR 59.

²⁴ H MacQueen *et al.*, *Contemporary Intellectual Property: Law and Policy* (Oxford: Oxford University Press 2008) at 501

²⁵ G Porter *et al.*, “The Patentability of Human Embryonic Stem Cells in Europe (2006) 26:6 Nature Biotechnology 653.

²⁶ EC, *Commission Directive 98/44/EC of 6 July 1998* [1998] OJ L213/13 at art 18.

²⁷ (1999) OJ EPO 437; (1999) OJ EPO 574.

²⁸ G Porter *et al.*, *supra* note 25.

²⁹ D Rickard & C Murphy, *End muddle over stem cell patents or U.S. will race ahead*, Times Online, 9 July 2009. Online: Timesonline

<<http://business.timesonline.co.uk/tol/business/law/article6667637.ece>>.

USPTO granting in excess of forty-one patents that claim hESCs in their title and front pages.³⁰

The purpose of this paper is to consider whether the inconsistent application of the EU Biotechnology Directive's moral exclusion clause could undermine investor confidence in Europe, providing a competitive advantage to the U.S.³¹

Understanding the science is essential for engaging in knowledgeable debate about the ethical issues surrounding hESCs.³² Part II provides an analysis of the biology that underpins the human embryo setting out the crucial distinction between totipotent and pluripotent hESCs.³³ In Part III our attention turns to *pre* Directive jurisprudence under Article 53(a) EPC, where the EPO showed a willingness to interpret the moral exclusion clause in a narrow manner that afforded patent protection to controversial biotechnology inventions. It was against the EPC framework and the jurisprudence emerging from the EPO that the Commission conceived the need for European biotechnology patent laws to be clarified and harmonized. Part IV charts the troublesome enactment and transposition of the Biotechnology Directive that exposed inherent European conflicts regarding patent protection for biotechnological inventions concerning 'living matter' of human origin. In Part V our focus turns to the subsequent emergence of hESC technology, providing an analysis of the *post* Directive EPO decision in *Edinburgh Patent*³⁴ which set a precedent for the recent decision in *Wisconsin Alumni Research Foundation (WARF)*³⁵ where the EPO moved away from its *pre* Directive narrow approach embracing a broad interpretation of the moral exclusion clause setting out a restrictive policy on the patentability of hESCs. Part VI analyses the patentability of hESCs at the national level, comparing the relatively permissive United Kingdom (UK) and Swedish regulatory approaches to the more restrictive German regime, a comparison that raises interesting questions as to the legal certainty of biotechnology inventions claiming hESCs within Europe. In Part VII our attention turns to the patentability of hESCs in the U.S. This section of the paper begins with an analysis of the Constitutional basis of U.S. patent law prior to setting out the link between 'utility' and 'morality' in U.S. patent law. Part VII then considers the liberation of U.S. patent law, the application of the Thirteenth Amendment to biotechnological inventions, along with the rejection of the doctrine of moral utility before finally examining the recent full frontal attack on biotechnology patents in the U.S. and the reinstatement of federal funding for hESC research.

³⁰ G Porter et al, *supra* note 25.

³¹ D Rickard & C Murphy, *supra* note 29.

³² L Gruen et al, *Stem Cell Research: The Ethical Issues* (London: Wiley-Blackwell Publishing, 2007) at 3.

³³ G Van Overwalle, "Study on the Patenting of Inventions related to Human Stem Cell Research" (2002) European Communities at 218.

³⁴ Commonly used name for European Patent No 0695351.

³⁵ G2/06 25 November 2008.

I. HUMAN EMBRYONIC STEM CELLS – THE SCIENCE

When human life begins with the union of the sperm and egg, there is but one cell: the *zygote*. Over a matter of hours this cell divides and divides again and at this stage the cells that are created have no dedicated function they are said to be undifferentiated.³⁶ Within this initial period, lasting no more than 3-4 days, these undifferentiated hESCs are totipotent, each having the capacity to become a complete and separate embryo.³⁷ Therefore, totipotent hESCs have the potential to develop into an entire human body.³⁸ By days 5-7 the organism has become a blastocyst, a ball of around 100 cells each of which is now pluripotent, that is, each has the capacity to develop into any of the 200 cells types that make up the human body, for example heart muscle cells³⁹ and possibly even organs in due course,⁴⁰ but it is no longer possible for them to develop into separate embryos or an entire human body.⁴¹

The patenting of hESCs is highly ethically contentious, as it involves the destruction of viable human embryos in the process of the extraction of hESCs from the inner cell mass of the early stage blastocyst.⁴² Many believe that the human embryo, from the moment of fertilization, should be protected as a full grown human being or at least merits respect incompatible with its use as a mere means to obtaining stem cells.⁴³ In their opinion, killing embryos for stem cells can never be justified, even if this would save or improve the lives of millions of people.⁴⁴

The utilitarian approach argues there are no principled reasons not to produce, destroy, and use embryos for research and therapeutic purposes were such destruction benefits man kind.⁴⁵ The most high profile and widely anticipated use of hESCs is the creation of therapeutic products to treat a range of serious and debilitating medical conditions caused by cell damage; including spinal cord injury, heart disease, and neurological disorders such as Parkinson's disease and Alzheimer's disease. This would be achieved by generating replacement cells or tissues and injecting them into damaged areas within

³⁶ G Laurie, *supra* note 23 at 3.

³⁷ *Ibid.*

³⁸ R Fitt, "New guidance on the patentability of embryonic stem cell patents in Europe" (2009) 27:4 Nature Biotechnology 338.

³⁹ Marquis, *The Moral-Principle Objection to Human Embryonic Stem Cell Research*, in L Gruen et al, eds, *Stem Cell Research: The Ethical Issues* (London: Wiley-Blackwell Publishing, 2007) at 51.

⁴⁰ A Agovic, "Stem Cell Patents on a Knife Edge" (2008) 3:11 Journal of Intellectual Property Law and Practice 718.

⁴¹ G Laurie, *supra* note 23 at 3.

⁴² G Porter, *supra* note 8 at 5.

⁴³ Devolder and Ward, *Rescuing Human Embryonic Stem Cell Research: The Possibility of Embryo Reconstitution After Stem Cell Derivation*, in L Gruen et al, eds, *Stem Cell Research: The Ethical Issues* (London: Wiley-Blackwell Publishing, 2007) at 105.

⁴⁴ *Ibid.*

⁴⁵ T Tannsjö, *Why No Compromise is Possible*, in L Gruen et al, eds, *Stem Cell Research: The Ethical Issues* (London: Wiley-Blackwell Publishing, 2007) at 189.

the body. Although much work remains to be done to demonstrate both the safety⁴⁶ and effectiveness⁴⁷ of therapeutic stem cell technology, hESCs have become a source of hope for the sufferers of serious illness and injury around the world.⁴⁸

Sales of commercial stem cells products were projected to reach US\$ 87 million in 2008 soaring to US\$ 8.5 billion within a decade. Due to profound investments poured into hESC research, stem cell technology is heavily reliant on patent protection.⁴⁹ However, the first controversial biotechnological inventions concerning 'living matter' that came before the EPO, under the moral exclusion clause in Article 53(a) EPC, did not concern hESCs, they concerned the patenting of animals, plants, and human tissue.

II. PRE-DIRECTIVE MORAL EXCLUSIONS UNDER ARTICLE 53(A) EPC

The EPC 1973 is an international treaty in force since 1977. The concept of a 'European patent', really only a bundle of national patents, predominates by virtue of the EPC. The EPC established the EPO, and also sets out the substantive law on patentability and exclusions in all EPC signatory states.⁵⁰ Neither the EPO nor the provisions of the EPC require Member States to bring their national patent laws and practice into conformity with the EPC, but most of the Member States have actually amended their laws to achieve such conformity, and national patent authorities follow the case law of the EPO.⁵¹ This represents 'cold harmonization'.⁵² The EPC is not an instrument of EU law. The EPO is therefore not an organ of the EU, and the EU institutions have no jurisdiction over the EPC.

The Guidelines for Examination first published by the EPO in 1977⁵³ outline the policy underlying the interpretation of the moral exclusion clause under Article 53(a) EPC. The Guidelines state that the purpose of the exclusion is to prevent the patenting of inventions likely to induce riot or public disorder or to lead to criminal or other generally offensive behavior. It is to be invoked only in rare and extreme circumstances. The Guidelines suggest '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'.⁵⁴ The EPC, however, was not drafted with the special

⁴⁶ M Baker, 'Unregulated Stem Cell Transplant Causes Tumors' (2009), online: Nature Reports <<http://www.nature.com/stemcells/2009/0902/090226/full/stemcells.2009.32.html>>.

⁴⁷ "A Stem Cell Therapy Fails to Help After Heart Attack" *International Herald Tribune*, 2 March 2006; Zohnhofer et al, eds, "Stem Cell Mobilization by Granulocyte Colony-Stimulating Factor in Patients with acute Myocardial Infarction: A Randomized Controlled Trial" (2006) 295:9 JAMA 1003.

⁴⁸ G Porter, *supra* note 8 at 5.

⁴⁹ A Agovic, *supra* note 40 at 718.

⁵⁰ The EPC has 36 signatories compared to the EU's 27 Member States.

⁵¹ A Hellstadius, *A Comparative Analysis of the National Implementation of the Directive's Morality Clause*, in A Plomer & P Torremans, eds, *Embryonic Stem Cell Patents: European Law and Ethics* (New York: Oxford University Press, 2009) at 118.

⁵² *Ibid.*

⁵³ Guidelines for Examination 1977, updated in 2007.

⁵⁴ R Clark & S Smyth, *Intellectual Property Law in Ireland* (Dublin: Tottel, 2005) at 54.

characteristics of biotechnological research and inventions in mind.⁵⁵ Biotechnology presented the EPO with a set of problems with which they are uncomfortable.⁵⁶ The early jurisprudence, however, shows a willingness by the EPO to interpret Article 53(a) EPC in a narrow manner that afforded protection to new technology.⁵⁷

i. *Harvard/Onco-Mouse*

The role of the morality exclusion under the Article 53(a) EPC was first considered in the notorious 1989 *Harvard/Onco-Mouse*⁵⁸ decision.⁵⁹ The case concerned the patentability of mice that had been genetically modified so that they would develop cancer: a result that the applicants hoped would be useful in cancer research.⁶⁰ The Examining Division of the EPO initially rejected the applicant's patent application stating patent law, and Article 53(a) in particular, was not the correct legislative tool for regulating problems arising in connection with genetic modification of organisms.⁶¹ On appeal, the Technical Board of Appeal (TBA) disagreed with the Examining Division, stating in a case like this there were compelling reasons why the implications of Article 53(a) should be considered such as the interests in remedying human diseases, avoiding animal suffering, and environmental concerns.

The TBA, referring to its previous jurisprudence in *Lubrizol/Hybrid Plants*,⁶² held 'any exception (to patentability) under Article 53(a) EPC must be narrowly construed'. Under a utilitarian balancing of risks and benefits the TBA explained that the *Onco-Mouse's* purposes of facilitating cancer research was of great importance for human health and welfare, and the benefits outweighed the adverse consequences of the invention.⁶³ The Examining Division,⁶⁴ directed to do so by the TBA, concluded that the invention could not be considered immoral so as to preclude it from patentability by virtue of Article 53(a). However, the Examining Division stressed that the considerations outlined applied solely to the present case.⁶⁵ The balancing test in *Onco-Mouse* provides an example of 'asking questions first, patenting later'. One problem with the test is that the Examining Division never defined morality nor stated a rational basis for choosing those particular factors to balance as opposed to other possible concerns.⁶⁶ Nevertheless, the test does provide the EPO with a mechanism for evaluating the patent eligibility of morally

⁵⁵ O Mills, *supra* note 9 at 82.

⁵⁶ M Bagley, "A Global Controversy: The Role of Morality in Biotechnology Patent Law" (2007)

⁵⁷ University of Virginia L S 331.

⁵⁸ O Mills, *supra* note 9 at 82.

⁵⁹ *Harvard/Onco-Mouse*, [1990] EPOR 4.

⁶⁰ V Vossius, "Patent Protection for Animals" (1990) EIPR 250.

⁶¹ L Bently & B Sherman, *supra* note 20 at 455.

⁶² O Mills, *supra* note 9 at 57.

⁶³ *Lubrizol/Hybrid Plants*, T320/87, [1990] EPOR 173.

⁶⁴ G Porter, *supra* note 8 at 12.

⁶⁵ T19/90, [1990] EPOR 501.

⁶⁶ O Mills, *supra* note 9 at 59.

⁶⁷ H Jaenichen & A Schrell, "The 'Harvard Onco-Mouse' in the Opposition Proceedings Before the European Patent Office" (1993) 15 EIPR 345.

controversial biotech inventions under Article 53(a) before granting a patent. In two later cases, the EPO articulated two additional morality tests.⁶⁷

ii. *Plant Genetic Systems v Greenpeace*

In *Plant Genetic Systems v Greenpeace*,⁶⁸ Greenpeace objected to a patent that had been granted for a genetically engineered plant on the grounds that it was inherently immoral and created risks to the environment.⁶⁹ The Opposition Division rejected the opposition and Greenpeace then appealed to the TBA.⁷⁰ In framing the nature of the morality inquiry under Article 53(a), the TBA looked to the intent of the drafters of the EPC, as evidenced by historical documents, and explained:

The concept of morality is related to the belief that some behavior is right and acceptable whereas other behavior 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...European society and civilization. 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.⁷¹

The Board concluded that none of the claims in the patent violated the morality provision of Article 53(a) because they concerned ‘activities and products which cannot be considered to be wrong as such in the light of conventionally accepted standards of conduct of European culture.’ In other words, the Board ignored the more fundamental concerns regarding the patent’s subject matter and focused narrowly on the general types of products and activities the patent concerned. This narrow focus allowed the Board to avoid broader concerns and tied patentability to the ‘public acceptability’ of the general categories of patentable subject matter.⁷²

In reaching its decision, the Opposition Division expressly declined to employ the balancing test used in the *Harvard/Onco-Mouse* decision, noting that it ‘(was) not the only way of assessing patentability’ under Article 53(a) but was ‘just one possible way, perhaps useful in situations in which an actual damage (e.g., suffering of animals)...exists.’⁷³ This ‘unacceptability’ standard is certainly a lower hurdle for an invention to overcome than the *Harvard/Onco-Mouse* balancing test, because balancing

⁶⁷ M Bagley, *supra* note 56 at 332.

⁶⁸ *Plant Genetic Systems v Greenpeace*, T 356/93 EPO, TBA (1995), EP No87400141, [1995] EPOR 357, [1995] OJ EPO 545.

⁶⁹ L Bently & B Sherman, *supra* note 20 at 456.

⁷⁰ O Mills, *supra* note 9 at 65.

⁷¹ *Plant Genetic Systems*, *supra* note 68 at 373.

⁷² M Bagley, *supra* note 56 at 332.

⁷³ *Plant Genetic Systems*, *supra* note 68 at 373.

does not even come into play unless concrete societal disadvantages of the invention are presented.⁷⁴

A criticism of the EPO ruling in *Plant Genetic Systems* lies in the fact that there is scant evidence suggesting a culture inherent in European society. If there were such a culture, Article 53(a) second half sentence, namely, that relating to law and regulation in some or all of the Contracting States would be redundant. This part of Article 53(a) is an acknowledgement that behavior acceptable in some Member States can be unacceptable in others.⁷⁵ The European Group on Ethics in Science and New Technologies (EGE) has stated that 'Pluralism may be seen as a characteristic of the EU' and 'respect for diverse national culture is essential to the building of Europe.'⁷⁶

iii. **Howard Florey/H2 Relaxin**

The third test for patentability under Article 53(a) EPC was set out in *Howard Florey/H2 Relaxin*.⁷⁷ The application was for a patent for the DNA sequences of a naturally occurring substance that relaxes the uterus during childbirth, which is obtained from the human ovary.⁷⁸ Several groups filed an opposition to the issuance of the patent on the basis that the patent offended Article 53(a) because, among other things, it covered the patenting of human genes and involved taking tissue from a pregnant woman, thus offending human dignity. The EPO Board disagreed and articulated the 'public abhorrence' test for exclusion under Article 53(a):

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. If it is clear that this is the case, objection should be raised under Article 53(a); otherwise not.

According to the Opposition Division, it would be abhorrent to the overwhelming majority of the public if the invention involved the patenting of human life, an abuse of pregnant women, or a return to slavery. The EPO noted that the tissue used in the research was donated during the course of necessary gynecological operations and thus had not offended 'human dignity'. Moreover, the Opposition Division stated that the argument that the applicant was 'patenting life' was misconceived, as DNA, once extracted and treated, was characterized not as 'life', but as a substance carrying genetic information, which can be used to produce proteins that are medically useful.⁷⁹

Finally, the Opposition Division rejected the assertion that such patenting was equivalent

⁷⁴ M Bagley, *supra* note 56 at 333.

⁷⁵ O Mills, *supra* note 9 at 66.

⁷⁶ Opinion 12 –Ethical aspects of research involving the use of human embryo in the context of the 5th Framework Programme, online: European Union <http://ec.europa.eu/european_group_ethics/docs/avis12_en.pdf>.

⁷⁷ *Howard Florey/H2 Relaxin* App. No. 83307553.4, [1995] EPOR 541.

⁷⁸ L Bently & B Sherman, *supra* note 20 at 456.

⁷⁹ W Cornish & D Llewelyn, *Intellectual Property: Patents, Copyright, Trade Marks and Allied Rights* (London: Thomson Sweet and Maxwell, 2007) at 884.

to slavery on the ground that such an assertion misunderstood the nature of a patent. This was because a patent does not give the proprietor any rights over a human being; all a patent monopoly provides is the right to prevent someone from practicing the same invention.⁸⁰ The significance of permitting the patent meant that the Opposition Division condoned the commercialization of human genes under the EPC.⁸¹ The decision also provides guidance for future cases as to what constitutes an abhorrent invention precluded from patentability.⁸²

The ‘public abhorrence’ test thus presents an even lower hurdle for a morally controversial invention to overcome since fewer inventions are likely to be deemed ‘abhorrent’ to society than simply ‘unacceptable’ to society. Importantly, none of the three tests requires the exclusion of patentability to be tied to a ban on the commercial exploitation of the invention.⁸³ It was against the EPC framework, and the confusing jurisprudence relating to the legal protection of biological inventions emerging from the EPO, that the Commission conceived the need for further patent law harmonization.⁸⁴

III. ADOPTION AND TRANSPORTATION OF THE BIOTECHNOLOGY DIRECTIVE

The Biotechnology Directive, first proposed by the Commission in 1988,⁸⁵ turned out to be one of the most heavily lobbied and controversial pieces of legislation ever produced through the European democratic process.⁸⁶ As early as 1989, the Parliament took the view that the Directive, whose original version did not contain a specific morality clause,⁸⁷ would need to pay greater attention to the moral aspects of biotechnology patenting.⁸⁸ Thus in stark contrast to the comparatively uncontroversial extension of patent protection to biotechnological inventions in the U.S., questions of morality provided a central point of reference for debates on the acceptable limits of patent law in Europe.⁸⁹ The Directive’s adoption, in 1998, came after ten years of difficult negotiations, and followed the Parliament’s rejection of an earlier draft in March 2005.⁹⁰

In essence, the Directive establishes a harmonized framework for the patentability of biotechnological products and processes throughout Europe. It clarifies that in accordance with the general principles of patent law, intellectual property protection will be available for biotechnological inventions that satisfy the requirements of novelty,

⁸⁰ L Bently & B Sherman, *supra* note 20 at 456.

⁸¹ O Mills, *supra* note 9 at 147.

⁸² *Ibid* at 63.

⁸³ G Porter, *supra* note 8 at 349.

⁸⁴ *Ibid* at 7.

⁸⁵ EC, “Proposal for a Council directive on the legal protections of biotechnological inventions” COM (88) 496 final, (1988).

⁸⁶ D Gitter, “Led Astray by the Moral Compass: Incorporating Morality into European Biotechnology Patent Law” (2001) 19:1 Berkeley J Int’l L 1.

⁸⁷ G Porter et al, *supra* note 25.

⁸⁸ (1989) OJ C159/10

⁸⁹ S Jasanoff, *Designs on Nature: Science and Democracy in Europe and the United States* (Princeton: Princeton University Press, 2005) at 217-218.

⁹⁰ (1995) OJ C68/26.

inventive step, and industrial application. Further guidance is given on the legal distinction between a non-patentable ‘discovery’ and a patentable ‘invention’.⁹¹ The Directive was ‘addressed’ only to EU Member States,⁹² obliging them to amend their national biotechnology patent laws in order to comply with the Directive by the deadline of 30 July 2000.⁹³ The EPO voluntarily incorporated the Directive’s rules within the EPC in June 1999 via the insertion of a new Chapter VI, Article 53(a) of the EPC,⁹⁴ entitled ‘Biotechnological Inventions’, into Part II of the EPC Implementing Regulations.⁹⁵ The incorporation of the Directive rules within the EPC was to ensure consistency of approach as between EU Member States and the EPO. Article 6(2)(c) of the Directive was transposed as Rule 23d(c) EPC (now Rule 28(c) EPC 2000).⁹⁶

The EPO began examining and granting patents in accordance with the principles set out by the Directive when the new provisions entered into force on 1 September 1999.⁹⁷ The EPO’s willingness to transpose the provisions of the Directive was not shared by all EU Member States. Even after the adoption of the Directive in 1998, the compromise that was eventually brokered was still not acceptable to all countries.⁹⁸ Due to the strong and diverging opinions surrounding the ‘patents of life’ issue, the process of implementation was severely protracted in many Member States.⁹⁹ Several EU Member States defied EU law by failing to create national laws to implement the Directive by the deadline.¹⁰⁰ In the Council, the Netherlands, who refused to apply patent law to living biotechnological material,¹⁰¹ had voted against the Directive, and Belgium and Italy had abstained.¹⁰² Upon enactment the legality of the Directive was immediately challenged by the Member States before the Court of Justice of the European Communities (ECJ).

i. *Netherlands v Parliament and Council*

In *The Kingdom of the Netherlands v European Parliament and Council*¹⁰³ the government of the Netherlands, joined by Italy and Norway, sought to annul the Directive in its entirety. The Netherlands put forward six arguments, namely that Article 100(a) of the EC Treaty was the incorrect legal basis for the Directive, breach of the principles of subsidiarity, breach of the principle of legal certainty, breach of obligations in international law, breach of the fundamental right to respect for human dignity, and

⁹¹ EC, *Commission Directive 98/44/EC of 6 July 1998*, [1998] OJ L213/13 at art 5.

⁹² EC, *Commission Directive 98/44/EC of 6 July 1998*, [1998] OJ L213/13 at art 18.

⁹³ EC, *Commission Directive 98/44/EC of 6 July 1998*, [1998] OJ L213/13 at art 15.

⁹⁴ Now Chapter V.

⁹⁵ (1999) OJ EPO 437; (1999) OJ EPO 574.

⁹⁶ EPC 2000 revises Article 53 to bring it into line with Article 27(2) of the Agreement on Trade-Related Aspects of Intellectual Property Rights.

⁹⁷ G Porter, *supra* note 8 at 16.

⁹⁸ *Ibid.*

⁹⁹ A Hellstadius, *supra* note 51 at 120.

¹⁰⁰ M Bagley, *supra* note 56 at 334.

¹⁰¹ M Risjsdijk, ‘*ECJ Affirms Biotech Directive*’ (2002) *Managing Intellectual Property*, online: *Managing IP* <<http://www.managingip.com/Article.aspx?ArticleID=1321875>>.

¹⁰² Press Release, Environmental Council, 2106th Session, June 1998.

¹⁰³ Case C-377/98, [2001] ECR I-07079.

breach of the procedural rules in the adoption of the Commission's proposal.¹⁰⁴ In rejecting the applicants' submissions that Article 5(1) of the Directive, in providing for the patentability of isolated elements of the human body, undermined human dignity, the Court took note of its obligations to ensure respect within the EC for the fundamental right to human dignity and integrity, but found that Article 5(1) was framed in stringent enough terms to ensure that the human body is unavailable for patenting and inalienable and to safeguard human dignity. There was, the Court reasoned, a difference between the discovery of a DNA sequence or of an element of the human body, neither of which would, as such, be patentable under the Directive, and inventions combining one of these natural elements with a technical process or application.

The Netherlands argued that Article 6(1) of the Directive infringes the principle of legal certainty on the grounds that it gives insufficient guidance and is too general and equivocal in determining whether there is an infringement of *ordre public* or morality. AG Jacob stated:

It is common ground that this provision allows the administrative authorities and courts of the Member State a wide scope for maneuver in applying this exclusion. However that scope for maneuver is necessary to take account of the particular difficulties to which the use of certain patents may give rise in the social and cultural context of each Member State, a context which the national legislative, administrative and court authorities are better placed to understand than the Community authorities.¹⁰⁵

The Directive, therefore, does not infringe the principle of legal certainty because, among other things, the application by national authorities of the concepts of *ordre public* and morality will always be subject to review by the Court. Attention was also drawn to Article 6(2).¹⁰⁶ The Court concluded that 'as regards living matter of human origin, the Directive frames the law on patents in a manner sufficiently rigorous to ensure that the human body effectively remains unavailable and inalienable and that human dignity is thus safeguarded.'¹⁰⁷ Under the *Netherlands reasoning Howard Florey/H2 Relaxin* may be decided differently under the Biotechnology Directive.¹⁰⁸

The ECJ upheld the legality of the Directive, but opposition to the Directive was so fierce that despite losing the legal challenge, eight of the fifteen EU Member States (Austria, Belgium, France, Germany, Italy, Luxemburg, the Netherlands, and Sweden) had not incorporated the Directive into their national laws by the end of 2003,¹⁰⁹ and

¹⁰⁴ M Risjsdijk, *supra* note 101.

¹⁰⁵ At paras 37-38.

¹⁰⁶ J Kokott & T Diehn, "The Kingdom of the Netherlands v European Parliament and Council 2002" 96 Am J Int'l L 950.

¹⁰⁷ Case C-377/98 *Kingdom of the Netherlands v European Parliament and Council*, [2002] FSR 36

¹⁰⁸ O Mills, *supra* note 9 at 147.

¹⁰⁹ M Habeck, "Brussels Takes EU States to Court over Biopatent Law" (2003) 21:9 Nature Biotechnology 960.

four were still out of compliance in early 2005.¹¹⁰ The Commission took action against Italy.

ii. *Commission v Italy*

The leading ECJ case on the interpretation of the illustrative list of exclusions in Article 6(2) of the Directive describes the correct interpretative approach.¹¹¹ In *Commission v. Italy*¹¹² the ECJ ruled:

Unlike Article 6(1) of the Directive, which allows the administrative authorities and courts of Member States a wide discretion in applying the general moral exclusion on inventions whose commercial exploitation would be contrary to *ordre public* and morality, Article 6(2) allows Member States no discretion in the implementation of the specific exclusions, since the very purpose of this provision is to give definition to the exclusion laid down in Article 6(1).¹¹³

The critical aspect of the ruling is the Court's insistence that the test to be applied to the interpretation of the list of specific exclusions under Article 6(2) is definitional, not moral. The implication is that, when reading and interpreting the specific exclusion, the words have to be given their natural meaning. Additional words should not be imported to vary, broaden, or narrow the exclusion in order to instantiate the alleged underlying moral consensus since, as stated by the Court, the specific exclusion is already illustrative of the principle.¹¹⁴

The specific list of exclusions, the ECJ reasoned, reflect the legislative consensus on inventions considered by the drafters to be morally unpatentable at the time.¹¹⁵ The wording of Article 6(2)(c) specifically excludes from patentability 'uses of human embryos for industrial or commercial purposes', not patents for inventions involving destruction of a human embryo. The fact that a wording precluding patents on uses/involving destruction of human embryos was not agreed upon at the time is both significant and not surprising in the light of the fact that the Directive was not intended to alter existing patent law¹¹⁶ and render unpatentable inventions based on activities

¹¹⁰ The Directive was not implemented into national law by all Member States until 2007.

¹¹¹ In *Monsanto Technology LLC v Cefetra BV and the State of Argentina*, Case No. C-428/08, AG Mengozzi stated the 'Directive constitutes an exhaustive body of rules governing the protection to be recognized in the EU as accruing to a biotechnology invention and precludes national legislation from conferring protection which is wider'. The Opinion is not binding on the ECJ and judgment will be given at a later date. Court of Justice Press Release No 24/10, March 2010.

¹¹² *Commission v Italy*, Case C-456/03, [2005] ECR I.

¹¹³ *Ibid* at para 78.

¹¹⁴ A Plomer, *Towards Systemic Legal Conflict: Article 6(2)(c) of the EU Directive on Biotechnological Inventions*, in A Plomer & P Torremans, eds, *Embryonic Stem Cell Patents: European Law and Ethics* (New York: Oxford University Press, 2009) at 189.

¹¹⁵ A Plomer, *supra* note 114 at 187-8.

¹¹⁶ Recital 8.

which were considered morally permissible and were lawful in Member States at the time.¹¹⁷ Supportive of this stance is the statement from Rothley¹¹⁸ (the rapporteur):

In relation to the use of embryos, the Council has set some limitations: they are not to be used for industrial or commercial purposes. But I would only ask you to remember that this was done with the UK in mind. We cannot as European legislators decree that something which does not contravene the underlying legal principles of all Member States is a contravention of public order, and we cannot brand something that we do not jointly regard as abhorrent as a contravention to common decency. That is not acceptable.¹¹⁹

When viewed in this light the legislative history of the provision may therefore actually constitute as yet a relevant aspect of the argumentation in favour of a narrow reading of Article 6(2)(c).¹²⁰ An analysis of the drafting history of the Directive indicates that the drafters did not specifically consider the question of the patenting of hESC related inventions,¹²¹ and therefore how Articles 5, 6(1), and 6(2)(c) would be applied to hESC technology.¹²² This is despite the fact that there had been some mention of the hypothetical use of hESCs as the next progression from primate ESC research carried out from 1995 onwards.¹²³

IV. THE EMERGENCE OF hESC TECHNOLOGY

The first isolation of hESCs by Wisconsin biologist and inventor James Thomson was reported in November 1998, four months after the Directive's adoption.¹²⁴ Therefore, controversy over the patentability of hESCs in Europe emerged as the wording of Article 6(2)(c) was thrown into question by rapid scientific advances.¹²⁵ The first formal question to the Commission on the applicability of the Directive to hESC patents was posed on the 7th December 1998 by Doeke Eisma of the European Liberal Democratic and Reform Party.¹²⁶ The written question requested that the Commission clarify

¹¹⁷ The UK had in force since 1990, the Human Fertilization and Embryology Act, which permitted research involving destruction of human embryos.

¹¹⁸ The 1997 Rothley "Report on the Proposal for a European Parliament and Council Directive on the Legal Protection of Biotechnological Inventions", COM (95) OJ C286/7.

¹¹⁹ Debates of the European Parliament, May 1998. Legal Protection of Biotechnological Inventions.

¹²⁰ M Rowlandson, "WARF/Stem Cells (G2/06): the ordre public and morality exception and its impact on the patentability of human embryonic stem cells" EIPR 2010, 32:2, 67 at 72

¹²¹ G Porter, *supra* note 8 at 24.

¹²² G Porter et al, *supra* note 25.

¹²³ J Thomson et al, "Isolation of a Primate Embryonic Stem Cell Line" (1995) 92:17 Proc Nat'l Acad Sci USA. 7844.

¹²⁴ J Thomson et al, "Embryonic Stem Cell Lines Derived from Human Blastocysts" (1998) Science 282, 1145.

¹²⁵ G Porter, *supra* note 8 at 26.

¹²⁶ Question No3668/98 "Applicability of the Directive on the Legal Protection of Biotechnological Inventions to Human Research with Embryonic Tissue", (1998) OJ C325/024.

whether Article 5 of the Directive would prohibit the patenting of the invention of a method of growing hESCs in a laboratory. The Commission's reply, of 16 February 1999, stated that although the patenting of hESC related technology might engage Articles 5 and 6(2)(c), it did not have jurisdiction over this particular question, and should the issue arise, it would be the patent offices of the Member States and the national judges before whom the matter was brought that would decide.¹²⁷ In fact, it was not cases before national patent offices and courts, but rather patent applications at the EPO that would initially trigger debate on the patenting of hESCs.¹²⁸

i. The Edinburgh Patent

The *Edinburgh Patent*¹²⁹ application to the EPO 'involved removing stem cells from human embryos, genetically manipulating these cells and cultivating genetically manipulated embryos from them'.¹³⁰ The Examining Division granted the patent. There was opposition against the patent by the governments of Germany, Italy and the Netherlands.¹³¹ In contrast to this opposition, a Report by the EGE¹³² concluded that there was no ethical obstacle to patentability attached to processes involving hESCs whatever their source.¹³³ The Opposition Division, in one of the first decisions to consider the new provisions under Rule 23d(c), acknowledged there was no uniform approach with regard to hESCs reflected in legislation or in other conventionally accepted standards of conduct in European culture, and decided to maintain the patent with amended claims, including claims to stem cells *per se*, but with a disclaimer to human or animal embryonic stem cells removing same from the scope of the patent.

The Opposition Division observed that the exclusion under Rule 23d(c) could be interpreted in either a narrow or a broad fashion.¹³⁴ Under the narrow interpretation only commercial uses of embryos as such would be excluded from patentability. The broad interpretation would mean that patents would be precluded not only on industrial and commercial uses of human embryos, but also on hESCs retrieved by the destruction of human embryos, irrespective of whether the application discloses direct use of the human embryo or not. According to the Opposition Division, Rule 23d(c) had to be construed broadly. This was because embryos as such are already 'protected' by Rule 23(e) (the equivalent of Article 5(1) of the Directive) and therefore interpreting Rule 23d(c) in the same way as Rule 23(e) would result in redundancy that would undermine the intention of the legislator.¹³⁵ In 2005, the President of the EPO suspended the issue

¹²⁷ G Porter, *supra* note 8 at 25.

¹²⁸ *Ibid.*

¹²⁹ EP No EP0695351.

¹³⁰ L Bently & B Sherman, *supra* note 20 at 460.

¹³¹ O Mills, *supra* note 9 at 61.

¹³² Report No. 16, May, 2002. The Commission has at its disposal an expert European Group on Ethics in Science and New Technologies (EGE). Article 7 of the Directive confirms the EGE may reach opinions about human genetic research that is relevant to the question of property rights.

¹³³ W Cornish & D Llewelyn, *Intellectual Property: Patents, Copyright, Trade Marks and Allied Rights* (London: Thomson Sweet and Maxwell, 2007) at 885.

¹³⁴ G Porter, *supra* note 8 at 25.

¹³⁵ *Ibid.*

of new patents in respect of hESC technology because ‘there are too many ethical aspects that have not been resolved at the political level’.¹³⁶

Notwithstanding the amendment to the patent claims, Edinburgh still appealed. After a decade of legal battle, this longstanding appeal was withdrawn during oral proceedings before the EPO Board of Appeal in November 2007.¹³⁷ The decision in *Edinburgh* is significant in terms of the moral provisions in European patent law as it is a clear departure from the EPO’s *pre Directive* ‘morality rulings’ where it held that exceptions to patentability must be interpreted narrowly.¹³⁸ The decision set a precedent, which informed the recent decision in *Wisconsin Alumni Research Foundation (WARF)*.¹³⁹

ii. WARF

The application filed by *WARF*, based on research carried out by James Thomson,¹⁴⁰ concerned a method for obtaining embryonic stem cell cultures from a primate embryo as well as the cell cultures themselves.¹⁴¹ In 2004, the Examining Division held the claims that could be extended to hESCs must be rejected on the grounds of morality, as even though the isolated hESCs are not themselves ‘embryos’, hESCs cannot be obtained without an embryo’s prior destruction.¹⁴² *WARF* appealed the decision to the TBA and also requested that the Enlarged Board of Appeal (EBA) should refer the issue of the interpretation of the Directive to the ECJ as it involved the application of EU law.¹⁴³

The TBA expressed doubts of the ethicality of approaching an Article 53(a) EPC assessment of hESC related inventions by means of applying the balancing test as set out in the *Onco-Mouse* decision.¹⁴⁴ ‘The Board has doubts, whether, when it comes to human life, it would be ethically acceptable to make a decision by weighing the interests of human beings which could potentially benefit from the exploitations of the technology against a right, if any, of human embryos’.¹⁴⁵

In 2005, the TBA in accordance with Article 112(a) EPC referred a series of questions relating to the interpretation of Rule 23d(c) to the EBA. At the end of 2008, the EBA issued its eagerly awaited decision.¹⁴⁶ The EBA refused *WARF*’s request to make a reference to the ECJ as there was a lack of any legal and institutional link between the EPO and the EU and there was no mechanism for making a reference to the Court. The ruling therefore distinguishes the EPO from the EU. The EPO sees itself as an international organization: in its view the EPC contracting states, not all of who are EU

¹³⁶ S Schubert, “Europe Halts *Decisions* on Stem Cell Patents” (2005) 435 *Nature* 720 at 721.

¹³⁷ EPO, “Edinburg Patent appeal Withdrawn” (Press Release, November 2007).

¹³⁸ *Ibid.*

¹³⁹ G2/06 25 November 2008.

¹⁴⁰ R Fitt, *supra* note 38 at 338.

¹⁴¹ *Ibid.*

¹⁴² G Porter, *supra* note 8 at 26.

¹⁴³ R Fitt, *supra* note 38 at 338.

¹⁴⁴ M Rowlandson, *supra* note 120 at 70.

¹⁴⁵ T1374/04, Reasons for Decisions, point 55.

¹⁴⁶ R Fitt, *supra* note 38 at 338.

Member States, cannot be presumed to have conferred jurisdiction to the ECJ.¹⁴⁷ The EBA proceeded to consider the four questions referred by the TBA.¹⁴⁸

1. Did the prohibition in respect of biotechnological inventions concerning the use of human embryos for industrial or commercial purposes apply retrospectively to applications filed before the implementation of the Directive into the EPC?
2. If the answer to Question 1 was yes, did it make any difference to the validity of the application that the method involving the destruction of embryos did not form part of the claim?
3. If the answer to Question 1 or 2 was no, did the prohibition under the EPC to inventions contrary to morality apply?
4. In the context of Question 2 and 3, did it make any difference that after the filing date the products claimed could have been obtained without using the method that involved the destruction of human embryos?

On assessing Question 1, the EBA noted that no transitional provisions were made when the Directive was implemented by the EPO and there was no indication that the commercial exploitation of embryos had previously been regarded as patentable. Therefore, the prohibition concerning the use of human embryos for industrial or commercial purposes applied to all pending applications retrospectively.¹⁴⁹

For Question 2, the EBA noted that the aim of the implementing rules was to align the EPC with the Directive and that the Directive was to be used as a supplementary means of interpretation. As the invention described in the *WARF* application could be performed only by destroying human embryos, and the invention was of commercial and or industrial benefit, it clearly fell within the scope of the prohibition on using human embryos for industrial or commercial purposes. The Board went on to turn down *WARF's* argument that the legislative history of the provision indicated a narrowing of the provision given its amended wording. On the contrary, the Board argued that the legislator's choice to lastly include the reference to industrial and commercial purposes does not evidence such narrowing. Instead of evidencing narrowing of the provision's application, the Board relied upon the legislative history of Article 23d(c) in the course of arguing in favour of a broad interpretation of the reference to industrial or commercial purposes.¹⁵⁰ Thus, the EBA concluded that the exception for inventions for therapeutic or diagnostic purposes which are applied to the human embryo and useful to it did not apply, as the invention had to benefit the embryo itself, and this was not the case in the present application as the embryos used to perform the invention were destroyed.¹⁵¹

¹⁴⁷ *Ibid.*

¹⁴⁸ *Ibid.*

¹⁴⁹ R Fitt, *supra* note 38 at 339.

¹⁵⁰ M Rowlandson, *supra* note 120 at 71.

¹⁵¹ R Fitt, *supra* note 38 at 339.

Given that the answers to Question 1 and 2 were yes, the EBA decided it was not necessary to answer Question 3. With respect to Question 4, the EBA ruled the technical developments that became publicly available only after the filing date could not be taken into consideration. Therefore, it was irrelevant that after the filing date the same products could have been obtained without having to use the method that necessarily involved the destruction of human embryos.

The EBA decision is potentially open to two interpretations. On a narrow interpretation of the ruling, drawing on the EBA's concluding statement that the decision is confined to the facts of the case and not concerned with the patentability of hESCs in general, the exclusion would be restricted to inventions the practice of which involves direct destruction of human embryos in the practice of the invention.¹⁵² Patent protection for methods and for human stem cells *per se* based upon cells derived from existing cell lines would appear to be unaffected by the ruling.¹⁵³ Given recent advances in stem cell technology, the ruling could not reasonably be extended to induced *pluripotent* stem cells, or to those methods of obtaining hESCs that do not require destruction of a viable embryo.¹⁵⁴ A narrow interpretation of the EBA's decision should therefore allow patents to be granted for hESC research where a stem cell bank rather than an embryo is identified in the patent as the source.¹⁵⁵ Indeed, the Geron Corporation,¹⁵⁶ the exclusive licensee of the *WARF* patents, commented that the EBA ruling should not adversely effect its patent applications relating to research performed using existing hESC lines available from stem cell banks.¹⁵⁷

On the broadest interpretation, the exclusion would reach to all downstream inventions based on the original 'morally tainted' inventions involving destructive use of human embryos.¹⁵⁸ The broad interpretation is based upon three key elements.¹⁵⁹ Firstly, the moral prohibition relates not to the act of patenting, but to the performing of the invention, which includes a step (the use involving its destruction of a human embryo) that has to be considered to contravene those concepts. The logical implication of this approach, which does indeed stand out as the most plausible, particularly in light of Article 38 of the Preamble, is that there must be an alignment between moral norms applied within patent law and the moral norms outside patent law, as implied by Recital 39 of the Directive. The second element is the finding that the nature of the immoral act attending the invention is the destruction of human embryos. The third and final element is the conflation and collapse of the distinction between industrial and commercial uses of human embryos into the making of the invention. In response to the applicant's

¹⁵² A Plomer, *supra* note 114 at 177.

¹⁵³ R Fitt, *supra* note 38 at 339.

¹⁵⁴ G Bahadur & M Morrison, *supra* note 21 at 5.

¹⁵⁵ D Rickard & C Murphy, *supra* note 29.

¹⁵⁶ Geron is a private U.S. biopharmaceutical company with a portfolio of 240 stem cell patents, focusing on developing and commercializing products for application in regenerative medicine.

¹⁵⁷ R Fitt, *supra* note 38 at 339.

¹⁵⁸ M Burda & M Grund, "G2/06 WARF EPO upholds a policy of refusing European patents for inventions covering products that can only be obtained via the destruction of human embryos" 9:6 *Bioscience Law Review* 239.

¹⁵⁹ A Plomer, *supra* note 114 at 178.

submission that some uses of embryos do not fit the categories of 'industrial' or 'commercial', the EBA ruled that whilst the wording of the exclusion in Article 23d(c) alluded specifically to uses of embryos which are 'industrial' or 'commercial', and stated that making the claimed product remains commercial or industrial exploitation of the invention even where there is an intention to use that product for further research.¹⁶⁰

The EBA's construction draws on EU sources such as the drafting history of the Directive and funding policy of the Commission under the Framework Programs excluding funding for research involving destructive use of human embryos to justify the scope of the exclusion.¹⁶¹ As the judgment of a supreme tribunal purporting to pronounce on European patent law, the EBA's ruling is singularly isolationist and bereft of references to the interpretation and application of similar principles by other supreme courts, most notably in this instance, the ECJ.¹⁶² Looking to the broader backdrop of the EU legal order, a broad exclusionary approach to Article 23d(c) is arguably untenable as it brings into conflict moral exclusions on patents in the Directive with the moral parameters of existing legislative controls on the practice of inventions involving human embryos and hESCs outside patent law in other EU Directives and Regulations. Since 2004, the use of human embryonic tissue in the context of inventions with a research purpose falls to be regulated by the Directive on Human Tissue and Cells.¹⁶³ The Regulation on Advanced Therapies and Medicinal Products¹⁶⁴ was specifically targeted at 'Regenerative medicine', i.e. the use of genes, cells, and tissues which are anticipated to offer huge therapeutic potential, notably diseases like Alzheimer's and Parkinson's which are of high prevalence in an ageing population.¹⁶⁵ Indeed, Recital 17 of the Biotechnology Directive is expressly aimed at encouraging the development of regenerative therapies.

The analysis of EU legislation on advanced therapies indicates that the industrial and commercial exploitation of hESC and tissue based products in Europe is not only *not* prohibited, whether destructive of human embryos or not, but was considered by the EU legislator as conferring important potential economic and health benefits to citizens in Europe. The implications for patent law are critical, as the combined body of EU legislation on the licensing and marketing of medicinal products on human tissue and cells, including hESCs, clearly indicate that industrial and commercial uses of such products are subject to *morally permissive* regulatory controls.¹⁶⁶ If the EBA's construction of Article 23d(c) is correct, then there is a systemic conflict within EU law

¹⁶⁰ *Ibid.*

¹⁶¹ The Sixth and Seventh Framework (2007-2013), [2006] OJ L400/86, Programs for Research and Technological Development of the European Commission (The Programs set up the framework for the European Human Embryonic Stem Cell Registry hESCReg and for the funding of stem cell research).

¹⁶² A Plomer, *supra* note 114 at 178.

¹⁶³ EC, *Commission Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004*. Recital 7: 'This Directive should apply to tissues and cells including...embryonic stem cells.'

¹⁶⁴ Regulation EC No 1394/2007, [2007] OJ L324.

¹⁶⁵ Communication from the Commission, "Safe, Innovative and Accessible Medicines: a Renewed Vision for the Pharmaceutical Sector", Brussels, COM (08) 666 final, December 2008.

¹⁶⁶ A Plomer, *supra* note 114 at 186.

between legislation which permits the conduct of activities involving destructive uses of human embryos, including product development on an industrial and commercial basis, yet precludes the grant of property rights on the related inventions as ‘immoral’. An interpretation introducing this level of conflict between patent law and national/EU laws outside patent law creates systemic incoherence and ultimately violates the principle of legal certainty. It also looks suspiciously like a subversion of Article 14 of the Preamble of the Biotechnology Directive.¹⁶⁷ A better approach is to construe the scope of the rights granted and excluded on moral grounds in the Biotechnology Directive consistently with the moral consensus evidenced in the cognate EU legislation on moral exclusions, as well as jurisprudence of the ECJ on the Directive, thereby aligning moral controls within patent law with moral controls outside patent law and in this way achieve legal certainty whilst preserving the integrity of the EU legal order.¹⁶⁸

The EPO is not the only institution authorized to issue patents within Europe. National patent offices grant patents that are valid within their own national jurisdictions, and may offer an alternative route to obtaining protection.¹⁶⁹

V. THE PATENTABILITY OF hESCS AT NATIONAL LEVEL

An overview of EU Member States reveals a patchwork of divergent regulatory policies towards patenting of hESCs.¹⁷⁰ There is, however, consensus among Member States, in view of the potentiality of totipotent hESCs, that such cells are not patentable because the human body at various stages of its formation and development cannot constitute patentable inventions under Article 5(1)¹⁷¹ of the Directive.¹⁷² In contrast, the picture across Europe is altogether different in regard to the patentability of pluripotent hESCs with contrasting approaches.¹⁷³

i. The United Kingdom

The UK Intellectual Property Office (UKIPO) is a patent office with a liberal approach towards hESC inventions. In 2009, the UKIPO revised its practice on hESCs to take account of the ruling in *WARF*.¹⁷⁴ The revised practice introduces a new condition under which patents on pluripotent hESCs will be granted provided they satisfy the normal requirement for patentability and that ‘at the filing or priority date, the invention could be obtained by means other than the destruction of human embryos’. Revision of the

¹⁶⁷ *Ibid.*

¹⁶⁸ *Ibid.*

¹⁶⁹ G Porter *et al*, *supra* note 25.

¹⁷⁰ G Porter, *supra* note 8 at 23.

¹⁷¹ Recital 38 provides that ‘totipotent cells of humans are excluded from patentability’.

¹⁷² Final Report from the Commission to the European Parliament and the Council, ‘*Developments and Implications of Patent Law in the Field of Biotechnology and Genetic Engineering*’ COM (2005) 312.

¹⁷³ G Porter *et al*, *supra* note 25.

¹⁷⁴ The 2009 Practice Notice supersedes the 2003 Notice.

UKIPO policy was seemingly in response to recent judicial dicta in the English higher courts calling for an alignment of national patent law with EPO law.¹⁷⁵

Strictly, the wording of the restriction suffers from the same defect as the EBA ruling in *WARF*, in that it does not indicate clearly whether the exclusion applies only to inventions the practice of which necessitates direct use (involving destruction) of a human embryo, or whether the exclusion also reaches to downstream inventions involving, for instance, differentiation of established hESC lines whose original derivation necessitated destruction of a human embryo.¹⁷⁶ In contrast to the EPO, the UKIPO practice hitherto has been to grant patents on downstream hESC derivatives.¹⁷⁷ A survey of stem cell patents granted in January 2009 shows that the UKIPO had granted just under 100 patents to both UK and non-UK residents and there were four times as many applications as grants.¹⁷⁸ It has been noted that applicants have taken advantage of this more sympathetic forum.¹⁷⁹ For example, one German company, Axiogenesis (Germany), has filed a hESC related patent application¹⁸⁰ at the UKIPO in addition to its application to the EPO.¹⁸¹

ii. Sweden

The Swedish Act on Ethics Review of Research Involving Humans¹⁸² sets up a mandatory system for pre-examination of research on humans by regional ethical committees. The institutional framework of research ethics review has a practical influence on the application of the patent morality clause by the Swedish Patent and Registration Office (SPRO) when examining patent applications. The SPRO has adopted the view that a patent application on subject matter resulting from research given permission after pre-ethical examination renders unnecessary further evaluation by the patent examiner from an *ordre public* or morality perspective. On the other hand, disapproved research is likely to be held unpatentable. This is an example of a functioning relationship between ethical legislation and the ethical provisions in patent law, ensuring coherence between permissible research and patentable subject matter. The practical application of this framework has also been confirmed in Sweden's attitude towards the application of the embryo exclusion.¹⁸³ The SPRO has granted a *WARF* patent concerning an invention consisting of a method for differentiation of hESCs into hematopoietic cells.¹⁸⁴ When granting this patent the subject of whether such claims

¹⁷⁵ *Kirin Amgen Inc and Others v Hoechst Marion Roussel Limited and Others*, [2004] UKHL 46; *Actavis UK Limited v Merck & Co, Inc*, [2008] EWCA Civ 444.

¹⁷⁶ A Plomer, *supra* note 114 at 196.

¹⁷⁷ GB 2427876A regarding methods for generating neuronal cells from hESCs and uses thereof published at September 1, 2007; GB 2428044A regarding a method of forming mesenchymal stem cells from hESCs as published on September 17, 2007.

¹⁷⁸ A Plomer, *Stem Cells and the European Patent System* (Berkeley Centre for Business, Law and Ethics, University of California at Berkeley, January 2009).

¹⁷⁹ G Porter *et al*, *supra* note 25.

¹⁸⁰ GB 2386609.

¹⁸¹ G Porter *et al*, *supra* note 25.

¹⁸² Lag om etikprovning som avser manniskor (2003:460).

¹⁸³ A Hellstadius, *supra* note 51 at 131.

¹⁸⁴ Swedish Patent Number SE526490 (U.S. priority: 1999-11-08 09/435578).

complied with the Swedish Patent Act, s1.c.3 (the implementation of Article 6(2)(c)) was considered. The conclusion was that it did, for the following reasons:

To produce hESCs, human embryos are required. However, the present method does not require that the stem cells need to be produced from embryos as a consequence of the invention, since the method can be performed using already existing (deposited) stem cells.¹⁸⁵

Thus, the Swedish view was that the commercial exploitation of this method does not need the use of a human embryo - the stem cells may have been isolated long before the invention was made. The object of the provision in Article 6(2)(c) was to avoid a repetitive use of the humans or parts of humans such as embryos, thus leading to an instrumentation of humans/embryos. This invention is not directly linked to the use of an embryo and moreover does not repeatedly need human embryos. Accordingly, the Swedish concept of morality did not hinder the grant of the *WARF* patent.¹⁸⁶ The reasoning has been confirmed in a later decision.¹⁸⁷

iii. Germany

The German Patents Act contains, in s.2, the morality clause as well as the exemplifying list.¹⁸⁸ According to the last sentence of s.2, relevant provisions of the Embryo Protection Act (EPA) are applicable to s.2(2) 1-3 of the Patents Act, including the embryo exclusion. The EPA¹⁸⁹ regulates the use of reproduction technology and the handling of human embryos in Germany. The reference establishes a connection between the strict regulations in the EPA and the relevant exclusions in the Patents Act.¹⁹⁰

The EPA prohibits the disposal of, hand over, acquire, or use of a human embryo produced outside the human body with a purpose not serving its preservation, notwithstanding how the embryo was extracted.¹⁹¹ S.2(2) further prohibits the development of a human embryo outside the body for any purpose other than assisted reproduction. The Act establishes an absolute ban on embryo-consuming techniques and consequently also on the production of hESCs and stem cell lines.¹⁹² The creation of embryos for research purposes, and the use of supernumerary IVF embryos for research are strictly forbidden. The strict provisions of the EPA limit the possible industrial,

¹⁸⁵ P Torremans, *The Construction of the Directives Moral Exclusions under the EPC*, in A Plomer and P Torremans *Embryonic Stem Cell Patents: European Law and Ethics* (New York: Oxford University Press, 2009) at 148.

¹⁸⁶ *Ibid.*

¹⁸⁷ Swedish Patent SE 529427: 'Endothelial cells derived from primate embryonic stem cells'.

¹⁸⁸ Patentgesetz, BGBI. 1981 I S. I, as amended by Article 2 of the Act of July 2008 (BGBI I p 1191).

¹⁸⁹ Gesetz zum Schutz von Embryonen (ESchG), BGBI I 1990, 2746.

¹⁹⁰ A Hellstadius, *supra* note 51 at 124.

¹⁹¹ s 2(1).

¹⁹² ss 1, 2, 6, 9, 11.

commercial, therapeutic or diagnostic uses of human embryos in Germany to an absolute minimum.¹⁹³

hESCs in general do not literally fall under the provisions of the EPA, since this Act specifically regulates the uses of human embryos. The definition of a human embryo is found in s.8 of the Act, and is based upon the capability of the material to develop into a human being. With this decisive factor not only embryos are covered by the scope of the Act, but also totipotent cells. An *e contrario* interpretation of the definition would exclude pluripotent cells from its range, arriving at the conclusion that the handling of and research on pluripotent hESCs as such is not prohibited by the Act. It therefore remains unclear to what extent the patenting of pluripotent hESCs *per se* is possible in Germany. Ultimately it will be a matter for the courts to decide.¹⁹⁴

The legal situation becomes more complicated when considering other relevant legislation. Even though it is impossible to establish hESC lines in Germany due to the EPA, ongoing research on hESC lines is in fact conducted within the Federal Republic. This apparent legal and practical contradiction is possible because the Stem Cell Act 2002 permits the importation of externally established stem cell lines into Germany.¹⁹⁵ The term ‘embryonic stem cells’ is defined in the Stem Cell Act as ‘pluripotent stem cells derived from embryos’.¹⁹⁶ It has been argued that the patenting of hESC lines produced outside Germany, lines derived from them, or modifications of both of these, if imported legally and in compliance with the Stem Cell Act, would be at least theoretically possible, because the decisive ground for the prohibition of patenting does not apply in these cases.¹⁹⁷ This situation, however, overlooks the impact of the reference from the Patents Act to the EPA. The latter is used to limit the patentable area and to interpret the embryo exclusion and, in that sense, the origin of the material should be of a subordinate nature. The patenting of inventions involving hESCs is in fact dependent on the invention in question and whether the use of human embryos for industrial or commercial purposes is required for the exploitation of the invention, and not on the origin of the cells.¹⁹⁸ This has also been the position of a recent court decision.

In 2006, the German Federal Patent Court¹⁹⁹ (GFPC) gave judgment in *Brüstle v Greenpeace*²⁰⁰ relating to biotechnological research undertaken by the German neuroscientist Dr. Oliver Brüstle. In 1999, the German Patent Office granted Brüstle a national patent that claims the use of hESCs for the treatment of neural deficiencies such as Parkinson’s disease and Multiple Sclerosis.²⁰¹ The Examining Division of the EPO

¹⁹³ A Hellstadius, *supra* note 51 at 125.

¹⁹⁴ *Ibid.*

¹⁹⁵ Gesetz zur Sicherstellung des Embryonenschutzes im Zusammenhang mit Einfuhr und Verwendung menschlicher embryonaler Stammzellen (StZG), Stammzellgesetz vom 28. Juni 2002 (BGBl. I S. 2277).

¹⁹⁶ A Hellstadius, *supra* note 51 at 126.

¹⁹⁷ *The Patenting of Biotechnological Inventions Involving the use of Biological Material of Human Origin*, opinion by the German National Ethics Council (Berlin 2005) at 31.

¹⁹⁸ Asa Hellstadius, *supra* note 51 at 127.

¹⁹⁹ Bundespatentgericht, BPatG.

²⁰⁰ BPatGt of 5 December 2006, 3 Ni 42/04.

²⁰¹ German Patent No. DE 197 56 864.

also granted, in 2006, a European patent on hESC derivatives to Brüstle.²⁰² The claims of the European patent are indistinguishable from the national patent except for a qualification that has been inserted throughout the claims stating that the procedures do not involve the destruction of human embryos.²⁰³ Greenpeace brought nullity proceedings against the national patent asserting that it was against public order and morality arguing the fact that the stem cells had been long cultivated outside the human body is irrelevant: at the beginning of the chain an embryo had to be killed to harvest the cells. Greenpeace stated that human life starts with the fusion of sperm and ovum, and blastocysts are embryos in the sense of the law. Brüstle counters that in the patent claims the use of stem cell lines which were harvested from blastocysts 4-5 days after fertilization, and therefore before the blastocyst can be rightfully called an embryo.

The GFPC invalidated the national patent as contrary to Article 6(2)(c) notwithstanding the grant of the European patent only six months earlier.²⁰⁴ According to the GFPC, it did not matter whether the cells in the application were pluripotent or totipotent, since the invention necessitated the use (by destruction) of the human embryos, although none of the claims related to the production of ESC from human embryos but only encompassed hESCs that were readily available from existing cell lines. According to the GFPC, the patent did not reveal any other ways of using the invention, which did not lead to the destruction of human embryos.²⁰⁵ The decision seems to pay less attention to the origin of the stem cells than to the technical teaching of the invention and the characteristics of the subject matter involved.

If this decision is upheld it would make a strong argument that the origin of the material has no impact on the patentability of hESC inventions in Germany, despite the distinction made in the applicable legislation with respect to the origin of the stem cells.²⁰⁶ The reasoning of the Court is in line with the approach adopted thus far by the EPO decisions in both *Edinburgh* and *WARF*, focusing on the making of the claimed product as an integral part of the invention.²⁰⁷ It is debatable whether such an enquiry should be part of the examination.²⁰⁸ As the ECJ noted in the *Netherlands* case, the Directive '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'.²⁰⁹

Dr. Brüstle is appealing against the GFPC ruling in the national courts, and because of the potential Constitutional issues raised by the case, on 21 January 2010 the German Supreme Court referred to the ECJ questions regarding the interpretation of Article 6(2)(c) of Directive. From the perspective of EU law, on the natural reading of Article

²⁰² Specifically a patent on neural precursor cells and methods for the production and use thereof in neural defect therapy: EP 10485B9.

²⁰³ A Plomer, *supra* note 114 at 193.

²⁰⁴ Grund et al, 'National Reports: Germany' 2005/2006 Bioscience Law Review 164.

²⁰⁵ A Hellstadius, *supra* note 51 at 128.

²⁰⁶ *Ibid* at 127.

²⁰⁷ G 2/06, 25 November 2008. Reasons for the Decision, para 21.

²⁰⁸ Grund et al, *supra* note 204.

²⁰⁹ *Netherlands v European Parliament and Council*, [2001] ECR I-07079 at para 79.

6(2)(c), the *Brüstle* patent would not involve a violation of Article 6(2)(c) since the claims are not to industrial and commercial uses of human embryos.²¹⁰ The ECJ will ultimately have to determine whether Germany may refuse patent protection to hESC inventions under Article 6(1) in recognition of fundamental principles of the German Constitution.²¹¹ In addition, the ECJ will now have to rule on the interpretation of ‘human embryo’ in the sense of Article 6(2)(c). Is a stem cell derived from a *blastocyst*, which has lost its ability to develop into a human still an embryo? If so, is a *blastocyst* a human embryo? If so, is purely therapeutic use of stem cells a ‘commercial or industrial purpose’ in the sense of Article 6? The ruling could make or break biotechnology patent applications claiming the use of hESCs with ramifications for the biotechnology industry in Europe.²¹² In the increasingly complex European patent map, the corresponding European *Brüstle* patent is being opposed at the EPO by the Geron Corporation.²¹³ The question now arises as to whether the European *Brüstle* patent is consistent with the EBA ruling within the EPC. On a ‘narrow’ reading of the EBA’s *WARF* ruling, the *Brüstle* application could conceivably be distinguished from the *WARF* application on the grounds that the claims to the isolation and differentiation of the neuroprogenitor cells do not involve destruction of a human embryo, as repeated throughout the European application.²¹⁴

VI. THE PATENTING OF hESCS IN THE UNITED STATES

Article I, § 8, clause 8 of the U.S. Constitution grants Congress broad power to legislate ‘to promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.’ The First Congress enacted the Patent Act 1790 that, in addition to novelty, required the invention to be ‘sufficiently useful and important’.²¹⁵ The relevant legislative history of the second U.S. Patent Act, the Patent Act of 1793, supports a broad construction of patent law, defining statutory subject matter as ‘any new and useful art, machine, manufacture, or composition of matter, or any new or useful improvement thereof’. The Act embodied Thomas Jefferson’s philosophy that ‘ingenuity should receive a liberal encouragement’.²¹⁶ In 1952, when patent laws were re-codified, Congress replaced the word ‘art’ with ‘process’ in Title 35 U.S. Code (U.S.C.) s101, but otherwise left Jefferson’s language intact.²¹⁷ Today, Title 35 U.S.C. s101 of the Patent Act 1952 still governs U.S. patent law. This is not to suggest that s101 has no limits or that it embraces every discovery. The laws of nature, physical phenomena, and abstract ideas are

²¹⁰ A Plomer, *supra* note 114 at 195.

²¹¹ A Plomer, *Human Dignity, Human Rights, and Article 6(1) of the EU Directive on Biotechnological Inventions*, in A Plomer and P Torremans, *Embryonic Stem Cell Patents: European Law and Ethics* (New York: Oxford University Press, 2009) at 225.

²¹² Online: IPKAT <<http://ipkitten.blogspot.com/2010/03/what-is-human-embryo-answers-please-by.html>>.

²¹³ A Plomer, *supra* note 114 at 194.

²¹⁴ *Ibid* at 195.

²¹⁵ M Adelman et al, *Patent Law in a Nutshell* (St. Paul: Thomson West, 2009) at 4.

²¹⁶ Writings of Thomas Jefferson 75-75 (Washington Edition), 1871.

²¹⁷ M Adelman et al, *supra* note 215 at 61.

categories of subject matter outside of s101. Such discoveries are ‘manifestations of nature, free to all men and reserved exclusively to none’.²¹⁸ The four classes of statutory subject matter (i.e. any art, machine, manufacture or composition of matter) under s101 are flexible, with the U.S. Supreme Court, in *Kewanee Oil Co. v Bicron Corp.*,²¹⁹ asserting that patent law was an evolving legal science designed to cover all emerging technologies.²²⁰

i. The Link Between Utility and Morality

Courts in the U.S. were often willing to withhold patents for inventions they considered immoral, such as inventions used to defraud buyers and machines used for gambling. Although U.S. patent law has no morality clause *per se*, because moral norms were often enforced in the courts by means of the utility requirement, the link between ‘utility’ and ‘morality’ is important.²²¹ The U.S. concept of utility is both broader and narrower than the notion of industrial application under the EPC.²²² It is a broader concept in that the same word encompasses elements such as morality and illegality. It is narrower in that pure research is not held to equal a practical utility.²²³

The principle of utility was judicially laid down in the 1817 decision of Justice Story in *Lowell v Lewis*.²²⁴ In that decision, he explained that ‘all that the law requires is that the invention should not be frivolous or injurious to the well-being, good policy, or sound morals of society. The word ‘useful’, therefore, is incorporated into the Act²²⁵ in contradistinction to mischievous or immoral’.²²⁶ Unfortunately, however, Justice Story could not have anticipated the wonders of modern science.²²⁷

ii. *Diamond v Chakrabarty* – U.S. Patent Liberalization

In *Diamond v. Chakrabarty*²²⁸ the U.S. Supreme Court held that Title 35 U.S.C. s101 is to be interpreted broadly due to the deliberate use of ‘any’ in conjunction with expansive terms such as ‘manufacture’ and ‘composition of matter’ found in the provision. The decision, taking into consideration the legislative intention of Congress under the 1952 Act,²²⁹ has been widely interpreted to hold that ‘anything under the sun that is made by

²¹⁸ *Funk Brothers Seed Co v Kalo Inoculant Co*, 333 U.S. 127, 130 (1948).

²¹⁹ 416 U.S. 470 (1974) at 480-481.

²²⁰ O Mills, *supra* note 9 at 116.

²²¹ *Ibid.*

²²² M Llewelyn, “Industrial Applicability/Utility and Genetic Engineering: Current Practices in Europe and the United States”, 1994 11 EIPR 473 at 474.

²²³ O Mills, *supra* note 9 at 45.

²²⁴ 15F Cas 1018 (no. 8568), Circuit Court, Massachusetts 1817.

²²⁵ *The Patent Act* 1793 and s112 of the *Patent Act* 1952.

²²⁶ G Hagen & S Gittens, “Patenting Part-Human Chimeras, Transgenics and Stem Cells for Transplantation in the United States, Canada, and Europe” (2008) 14 Rich. JL & Tech 35.

²²⁷ O Mills, *supra* note 9 at 46.

²²⁸ *Diamond v Chakrabarty*, 447 U.S. 303 (1980) at 308.

²²⁹ S.Rep No.1979, 82d Cong., 2d Sess., 5 (1952); H.R.Rep. No 1923, 82d Cong., 2d Sess 6 (1952).

man' is patentable.²³⁰ The Court gave a green light to biotech researchers and investors by confirming that 'life' can comprise patent-eligible subject matter. Acknowledging the possible repercussions of its decision, the Court noted the 'gruesome parade of horrors' identified by the USPTO and *amici* as potentially resulting from biotechnology patents. The Court, however, declared itself to be 'without competence' even to entertain such morality-laden 'high policy' arguments. In broadly construing s101, the Court identified its role as 'the narrow one of determining what Congress meant by the words it used in the statute; once that is done, our powers are exhausted.'²³¹

Consequently, the s101 subject matter prong of patent eligibility does not provide a bar to the patenting of morally controversial biotech subject matter.²³² The *Chakrabarty* decision is important in appreciating the Courts emphasis on limiting judicially created exceptions to patentable subject matter under s101.²³³ As a result living biological materials have been patented in the U.S.

Shortly after the *Chakrabarty* decision, the Court of Appeals for the Federal Circuit (CAFC) was created to promote greater uniformity in the application of U.S. patent law, and to reduce the possibility of forum shopping by parties seeking favorable courts.²³⁴ The CAFC now has exclusive jurisdiction over all appeals in patent cases. From its creation, the CAFC has been decidedly 'pro-patent'. The CAFC has provided much needed clarification of standards for interpreting patent rights and increased predictability in the application of patent laws. Clearly, such a development is welcome. By contrast, because the EPO is not an EU institution, legislative reform of this nature is not possible.²³⁵

iii. Property in Human Beings and the Thirteenth Amendment

The USPTO in response to the Board of Patent Appeals *Ex Parte Allen*²³⁶ decision regarding the patenting of multi-cellular animals, issued a notice stating explicitly that it considered 'a claim directed to or including within its scope a human being will not be considered to be patentable subject matter under s101. The grant of a limited, but exclusive property right in a human being is prohibited by the Constitution.'²³⁷ This Constitutional reference was to the prohibition of slavery under the Thirteenth Amendment of the Constitution, which states that 'neither slavery nor involuntary servitude, except as punishment for crime whereof the party shall have been duly convicted, shall exist within the U.S., or any place subject to their jurisdiction.'²³⁸

²³⁰ G Hagen and S Gittens, *supra* note 237 at 31.

²³¹ *Diamond*, *supra* note 228 at 318.

²³² M Bagley, *supra* note 56 at 319.

²³³ The Supreme Court, in *J.E.M. Ag Supply, Inc v Pioneer Hi-Bred International*, 534 US 124 (2001), confirmed its earlier ruling in *Diamond v Chakrabarty*.

²³⁴ J Wright, "Implications of Recent Patent Law Changes on Biotechnology Research and the Biotechnology Industry", 1997 1 Va JL & Tech 1.

²³⁵ O Mills, *supra* note 9 at 45.

²³⁶ *Ex Parte Allen* 2 USPQ 2d (BNA) 1425 (BPAI 1987).

²³⁷ USPTO, Manual of Patent Examining Procedure 2105 (2007), online: USPTO <http://www.uspto.gov/web/offices/pac/mpep/mpep_e8r3_2100.pdf>.

²³⁸ United States Constitution, Amendment XIII, s1.

Bagley suggests *Roe v. Wade*²³⁹ holds that at their earliest stages of development, embryos are not constitutionally protected as ‘persons.’²⁴⁰ This holding suggests that, at a minimum, the Thirteenth Amendment would not bar patents on human embryos.²⁴¹

Whilst the USPTO’s response to *Ex Parte Allen* clarified its position regarding the patenting of non-human multi-cellular organisms, it did nothing to reconcile its treatment of ‘isolated human biological material’ with that of ‘human beings’. This weakness was exploited when, in 1997, Jeremy Rifkin, a prominent opponent of biotechnology, and Dr. Stuart Newman, a cellular biologist at New York Medical College, filed a patent application covering the production of human-animal chimeras by inserting the genetic material from one species into an embryo of another to create, in effect, ‘human-animal’ chimeras.²⁴² The objective in filing the application was to ‘raise these ethical issues before the public and the legal system in a particularly dramatic fashion.’²⁴³ Because Newman had failed to place limits on the percentage of human cells in the invention, the USPTO found that the invention could embrace a human being and issued a rejection of the patent in 1999.²⁴⁴ In a media advisory released in response to the public outcry associated with the Newman application, the USPTO relied on the moral utility doctrine stating that the Newman chimeras could not be patentable because they would fail to meet the public policy and morality aspects of the utility requirement.²⁴⁵ The Newman-Rifkin patent application represents an instance where, arguably, the USPTO asked morality questions first, but lacked the authority to do so.²⁴⁶ By issuing the press release, the USPTO showed that it is willing to continue to rely on Justice Story’s formulation of utility in *Lowell v Lewis*. The Newman application suggests the link between ‘utility’ and ‘morality’ is especially relevant for modern biotechnological inventions.²⁴⁷

iv. Rejection of the Doctrine of Moral Utility

The reference by the USPTO to the moral utility doctrine is curious for a number of reasons. Firstly, when releasing ‘Utility Guidelines’ in 1998, the USPTO Commissioner stated that ‘if an applicant presents a scientifically plausible use for the claimed invention, it will be sufficient to satisfy the utility requirement.’²⁴⁸ This is in line with

²³⁹ 410 US 113 (1973) at 158, 163–165.

²⁴⁰ M Bagley, “Patent First, Ask Questions Later: Morality and Biotechnology in Patent Law”, (2003-2004) 45 Wm & Mary L Rev 469.

²⁴¹ *Ibid*.

²⁴² S Newman, *Chimeric Embryos and Animals Containing Human Cells*, US Patent Application No 08/993, 564.

²⁴³ S Newman, “The Legal Column: The Human Chimera Patent Initiative” (2002) 9 Lahey Clinic Med Ethics 1 at 4, online: NYMC <www.nymc.edu/sanewman/PDFs/Lahey_Winter_2002.pdf>.

²⁴⁴ Office Action Summary from USPTO Examiner D Clark to Applicant S Newman, USPTO Final Rejection Letter, (October 29, 1999) at 7.

²⁴⁵ USPTO Media Advisory No 98-6, *Facts on Patenting Life Forms Having A Relationship with Humans* (April 1998).

²⁴⁶ M Bagley, *supra* note 56 at 324.

²⁴⁷ O Mills, *supra* note 9 at 49.

²⁴⁸ K Dunleavy & M Vinnola, “A Comparative Review of Patenting of Biotechnological Inventions in the U.S. and Europe”, (2000) 3 J World Intellectual Property 65 at 74.

the 1952 Act,²⁴⁹ which provides that a person is entitled to a patent if his or her invention meets the statutory patentability requirements specified in the Act.²⁵⁰ Secondly, the 2001 Examination Guidelines for the Utility Requirement make no mention of morality or, indeed, public policy issues.²⁵¹ Thirdly, the decision in *Juicy Whip Inc. v Orange Bang Inc.*²⁵² explicitly sounded the death-knell for the moral utility requirement.²⁵³ Thus, a combination of the demise of the moral utility doctrine, along with the expansive judicial interpretations of the scope of patent-eligible subject matter, has resulted in virtually no basis on which the USPTO or courts can deny patent protection to morally controversial, but otherwise patentable, subject matter.²⁵⁴

In 2001, in contrast to Europe, the USPTO granted the equivalent *WARF* patent based on the same claims and work carried out by James Thomson.²⁵⁵ By 2004, a number of patents had been issued with claims to hESC products or processes.²⁵⁶ For example, the patent issued to the Geron Corporation for ‘methods and materials for the growth of primate-derived primordial stem cells in feeder-free culture’²⁵⁷ claims a cellular composition comprising undifferentiated primate primordial stem cells, which includes both pluripotent and totipotent primate stem cells, but does not exclude human primate stem cells. It appears then that, in the U.S., human pluripotent and totipotent stem cells are patentable, despite the fact that human beings at any stage of development are not patentable.²⁵⁸ By 2006, the USPTO had granted in excess of forty-one patents that claim hESCs in their title and front pages.²⁵⁹ These include patents on culture methods, differentiated cells derived from hESCs and even hESCs *per se*.²⁶⁰ Indeed the Geron Corporation has recently announced that it has received clearance from the U.S. Food and Drug Administration to begin the world’s first human clinical trial of hESC based therapy for patients with acute spinal cord injury.²⁶¹

v. The Full Frontal Attack on Biotechnology Patents

In *Association for Molecular Pathology et al. v USPTO et al., (Myriad)*²⁶² a U.S. District Court Judge recently struck down seven patents related to two genes linked to breast and ovarian cancer. The decision, if upheld, could throw into doubt patents covering

²⁴⁹ ss 101-102.

²⁵⁰ M Bagley, *supra* note 56 at 318.

²⁵¹ Federal Register, Vol.66 No.4, 5 January 2001.

²⁵² 185 F 3d 1364, 1999.

²⁵³ M Bagley, *supra* note 56 at 321.

²⁵⁴ M Bagley, *supra* note 240 at 469-503.

²⁵⁵ G Bahadur and M Morrison, *supra* note 21 at 1.

²⁵⁶ R Mandra & A Russo, “Stem Cells and Patenting and Related Regulatory Issues: A U.S. Perspective”, (2004-2005) 7 Bio-Science L R 143 at 144-45.

²⁵⁷ US Patent No. 6,800,480.

²⁵⁸ USPTO 2007 Manual of Patent Examining Procedure.

²⁵⁹ G Porter et al, *supra* note 25 at 653.

²⁶⁰ *Ibid.*

²⁶¹ R Fitt, *supra* note 38 at 339.

²⁶² 09 Civ. 4515, S.D.N.Y. 29 March 2010.

thousands of human genes and reshape the law of intellectual property in the U.S.²⁶³ In his opinion,²⁶⁴ Sweet J., noting the Supreme Court judgment in *Diamond v. Chakrabarty*, stated this broad reading of 35 U.S.C. s.101 and statutory patent eligibility is not without limits. Sweet J. agreed with the plaintiff's basic argument that the 'isolated' DNA that *Myriad* claimed to have patented is still a product of nature, and cannot be covered by patents. If upheld in the event of an appeal, the USPTO will need to make sure its practices conform to the decision, and avoid issuing patents related to isolated DNA. That leaves a big 'if,' considering that the next level, the U.S. Court of Appeals for the Federal Circuit, is a court that is considered patent-friendly and likely to reject, or at least narrow, such a broad challenge to gene patents.²⁶⁵

With a final resolution to *Myriad* likely several years away, a variety of other legal developments are slowly but surely reshaping the biotechnology patent landscape in the U.S.²⁶⁶ A perfect example of this is the decision of April 28 2010 by the Board of Patent Appeals of the USPTO to invalidate one²⁶⁷ of *WARF's* patents on stem cell cultures.²⁶⁸ This archetypal example of a 'broad patent' on hESCs raised criticism of market abuse and was the subject of an unsuccessful review following a challenge brought by the Foundation Taxpayer and Consumer Rights and the Public Patent Foundation.²⁶⁹ The challenge to the *WARF* patent is particularly noteworthy in that the motivation was undoubtedly 'moral' and driven by concerns that the USPTO had been overgenerous in granting the patent. But, crucially, the challenge did not take place in the realm of morality, but was focused instead on the USPTO's application of the technical criteria of novelty and inventive step/non-obviousness.²⁷⁰ The Board ruled that the *WARF* claims were anticipated by a 1992 patent and were obvious in light of 'significant guideposts' in the prior art. After some additional USPTO proceedings, there may be an appeal to the Federal Circuit.

vi. Reinstatement of Federal Funding for hESC Research

In March 2009, President Barrack Obama, in one of his first Executive Orders²⁷¹ reversed the Bush era ethics-driven ban on U.S. federal funding for hESC research.²⁷²

²⁶³ J Schwartz & A Pollack, *Judge Invalidates Human Gene Patent*, New York Times, 29 March 2010, online: NYtimes <<http://www.nytimes.com/2010/03/30/business/30gene.html>>.

²⁶⁴ Electronic filing, Online: NYtimes <http://graphics8.nytimes.com/packages/pdf/national/20100329_patent_opinion.pdf>.

²⁶⁵ *In ACLU Suit, Judge Rules Myriad's Genetic Patents Invalid*, The Prior Art, 29 March 2010, online: The Prior Art <http://thepriorart.typepad.com/the_prior_art/2010/03/aclu-v-myriad-judge-rules-gene-patents-are-invalid.html>.

²⁶⁶ *WARF Reexamination Takes Another Bite Out of Biotech Patents*, Genomics Law Report May 19 2010, online: Genomics <<http://www.genomicslawreport.com/index.php/2010/05/19/warf-biotech-patents>>.

²⁶⁷ *WARF* holds 64 stem cell lines, including extensive rights to five unmodified stem cell lines.

²⁶⁸ *Foundation for Taxpayer and Consumer Rights v WARF*, (BPAI) No. 2010-001854 (4/28/2010)

²⁶⁹ Public Patent Foundation, October 2006, online: PubPat <<http://pubpat.org/warfstemcellgranted.htm>> accessed 28 July 2010.

²⁷⁰ A Plomer, *supra* note 114 at 200.

²⁷¹ (Executive Order) 13505: Removing Barriers to Responsible Scientific Research Involving Human Stem Cells.

President Obama stated that ‘the purpose of this order is to remove limitations on scientific inquiry, to expand support for the exploration of human stem cell research, and in so doing to enhance the contribution of America's scientists to important new discoveries and new therapies for the benefit of humankind.’²⁷³ This is good news for anyone hoping for a cure for spinal cord injuries and degenerative diseases,²⁷⁴ but not for the EU biotechnology industry.²⁷⁵

CONCLUSION

The Commission’s aim of establishing a consistent and unified approach towards the patenting of biotechnological inventions within Europe has not been achieved. The inconsistent application of the moral exclusion clause under the Biotechnology Directive has led to legal uncertainty surrounding biotechnology inventions claiming hESCs within Europe. The uncertainty lies in the absence of a common European morality and a uniform legal definition of the human embryo. To add to this uncertainty, patent protection in Europe operates on three levels with differing institutional connections – the EPO, the EU, and the national states.²⁷⁶ Whilst the ECJ is the court vested with supreme authority over the interpretation of the Directive, the fragmented institutional framework in Europe on the examination and grant of European patents and the post-grant determination of their validity, means the whilst the EPO acts as a first filter on European patents, the legal validity of the patent is subject to review in the national courts.²⁷⁷ The biggest hurdle to achieving true European integration in patent protection is the absence of a centralized litigation system with a single judicial body able to rule definitely on the validity and infringements of European patents. The co-existence of a plethora of national enforcement mechanisms is not only extremely costly and lengthy but leads to forum shopping, complex cross-border litigation and considerable legal uncertainty. There is support for the establishment of a European Patent Court with a Court of First Instance and a Court of Appeal similar to that in the U.S.²⁷⁸

Given that a European Patent Court is a long way off, the EPO, who does not have the legitimacy to act as an arbiter of European morality, must consider the U.S. model of patenting first and asking questions later. A return to the ‘public abhorrence’ test set out in *Howard Florey*, invoking the moral exclusion in rare circumstances, would provide a greater degree of legal certainty for biotechnological inventions within Europe. Article 6(1) may constitute the legal basis for a Member State to invalidate a patent once it is transformed into a national patent if their view upon the human embryo dictates such action. It seems even more appropriate to allow each Member State decide upon whether

²⁷² D Rickard & C Murphy, *supra* note 29.

²⁷³ Online: Stanford <<http://ora.stanford.edu/hesc/default.asp>>.

²⁷⁴ Kiessling and Anderson, *Human Embryonic Stem Cells: An Introduction to the Science and Therapeutic Potential* (New York: Jones and Bartlett 2003) at 10.

²⁷⁵ D Rickard & C Murphy, *supra* note 29.

²⁷⁶ A Hellstadius, *supra* note 51 at 118.

²⁷⁷ A Plomer, *supra* note 211 at 225

²⁷⁸ H MacQueen et al, *supra* note 24 at 390.

or not the destruction of the human embryo constitutes a valid criterion in regard to the application of Article 6(2)(c).²⁷⁹

The decision in *WARF* has added to the uncertainty surrounding the moral exclusion in Europe.²⁸⁰ It is a missed opportunity to clarify the law regarding the patentability of hESCs within Europe and therefore also a missed opportunity to restore the legal credibility of the EPO who will eventually have to decide upon the issue of patents claiming hESC lines and new technology for extracting hESCs without destroying the embryo.²⁸¹ The incentive offered by U.S. patent law is particularly important for biotechnology inventions.²⁸² The past success of its patent system is a direct result of its ability to evolve and adapt to changing times and new technologies as they arise.²⁸³ This has the effect of giving international corporations an additional incentive to seek protection first in the U.S. where morality is not a factor.²⁸⁴ Now that the U.S. has started to dismantle its barriers to investment in hESC research, Europe needs to get its act together, and quickly, as the inconsistent application of the Biotechnology Directive's moral exclusion clause could undermine investor confidence in Europe, providing a competitive advantage to the U.S.²⁸⁵

²⁷⁹ M Rowlandson, *supra* note 120 at 67.

²⁸⁰ *Ibid* at 70.

²⁸¹ P Torremans, *supra* note 185 at 169.

²⁸² O Mills, *supra* note 9 at 41.

²⁸³ *Ibid* at 44.

²⁸⁴ M Adelman *et al*, *supra* note 215 at 131.

²⁸⁵ D Rickard & C Murphy, *supra* note 29.