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PATENTING STEM CELLS IN EUROPE: THE CHALLENGE OF MULTIPLICITY IN EUROPEAN UNION LAW

MARTON VARJU* and JUDIT SÁNDOR**

1. Introduction

This article examines the development of the law relating to the application of Directive 98/44/EC on the legal protection of biotechnological inventions¹ (hereafter: Biotechnology Directive) to patents on human embryonic stem cells (hES cells/hESC), a material (a research tool) promising unprecedented breakthrough in biomedicine. Our investigation was prompted by decisions under Article 6 of the Biotechnology Directive concerning the patentability of inventions consisting of or containing hES cells by the organs of the European Patent Organization (EPO),² on the national level by the German Federal Patent Court³ and by the EU Court of Justice in its recent judgment in the *Brüstle* case.⁴ The decisions, following a similar logic in interpreting the Biotechnology Directive, excluded the patentability of hES cells, erecting a significant obstacle to biopatenting in Europe.

Our central question is how the law managed to deal with the challenges of moral and legal pluralism dominating the relevant area, the patenting of human biological material in Europe. The Biotechnology Directive, establishing a common European framework for biotech patenting, operates in

* Law School, University of Hull and Research Associate at the Centre for Ethics and Law in Biomedicine (CELAB), Central European University, Budapest.

** Professor of Law and Political Science and Director of the Centre for Ethics and Law in Biomedicine (CELAB), Central European University, Budapest. The research leading to these results received funding from the European Union's Seventh Framework Programme ([FP7/2007–2013] [FP7/2007–2011]) under grant agreement n° 217180 (REMEDiE). For more information on REMEDiE, please visit <www.york.ac.uk/satsu/remedie>.

1. Directive 98/44/EC of the European Parliament and the Council of 6 July 1998 on the legal protection of biotechnological inventions, O.J. 1998, L 213/13.

2. EPO Enlarged board of appeal, decision G 2/06 of 25 Nov. 2008, OJ EPO, May 2009, 306; EPO boards of appeal, decision T 522/04 of 28 May 2009, nyr.

3. Judgment by the German federal patent court, AZ: 3 Ni 42/04 (5 Dec. 2006), <juris.bundespatentgericht.de/cgi-bin/rechtsprechung/document.py?Gericht=bpatg&Art=en&sid=061f0f9e4b6bfd679ba46c7b1fd93fcb&nr=1909&pos=0&anz=1&Blank=1.pdf> (last visited 11 Jan. 2012).

4. Case C-34/10, *Brüstle v. Greenpeace*, judgment of 18 Oct. 2011, nyr. For a specific analysis, and proposing a somewhat different appraisal, see case note by Spranger, in this *Review*, 1197.

an environment characterized by a multiplicity of viewpoints concerning the ethical boundaries of related human activity and by multiple loci of authority for regulating those boundaries and for the interpretation and application of the law. In the application of the Directive, attention must be paid to the differences in determining the value of human life in different value systems, to the conflict between value considerations and large scale economic and social priorities, and to the choices of direction made by the different legal forums when working with the bioethical principles introduced to European patent law by the Directive. The fundamental cause of complications was the engagement on the European level in the regulation of biotechnology also covering the commercialization of biotechnological inventions through patenting. The regulatory endeavours of the European Union brought to light the contested nature of human activity with human biological material. In order to delimit risk, protect research subjects, or ensure the successful translation and commercialization of research, such endeavours necessitated addressing the ethical implications of this activity and finding its boundaries in a complex regulatory setting.

Designing European regulation to secure the incorporation of the ethical principles applicable to biotechnological research is a perplexing task. Having regard to the multiplicity of viewpoints prevailing in biomedical ethics, it requires exploring a moral common ground among the Member States and/or producing regulatory solutions which would acknowledge and accommodate the diversity of ethical viewpoints in the Member States. The appropriate ethical calibration of European regulation is crucial considering that the EU's regulatory intrusion threatens the autonomy of Member States in expressing important value choices in relation to human activity in biosciences. The boundaries for regulating European ethical requirements are provided in a complex European matrix of bioethical principles, the Oviedo Convention on Human Rights and Biomedicine⁵ presenting the broadest framework. Following these, where agreement among the Member States is available, the laying down of European rules is permitted, and where a multiplicity of moral viewpoints prevails, European regulation must sustain the prevailing diversity. In the area of human embryonic and stem cell research, the notoriously slippery ethical principle of human dignity⁶ presents the main bioethical boundaries of European regulatory intervention.

5. Council of Europe Convention for the protection of human rights and dignity of the human being with regard to the application of biology and medicine. With a focus on the human rights limitations of biomedical research, it builds on the protection of human dignity and integrity and confirms the primacy of the human being over the interests of science and society (Arts. 1 and 2). Available through <conventions.coe.int/>.

6. See, *inter alia*, Harris, "Cloning and human dignity", 7 *Cambridge Quarterly of Healthcare Ethics* (1998), 163–167.

In this environment, European Union measures, pursuing a market creation and market integration agenda by aiming to overcome the problems associated with regulatory multiplicity and diversity among the Member States, must determine with precision how far harmonization may press and where value-based regulatory differences must be maintained. The creation by regulation of an integrated space for scientific and commercial activities in biotechnology in Europe must incorporate accurate, ethically informed regulatory distinctions. This is of constitutional importance in the European Union. First, its competences under the Founding Treaties to regulate the (bio)ethical aspects of the European economy and society are limited, in particular when regulation involves introducing bioethical principles to be applied uniformly in the Member States. Furthermore, European Union regulation, having regard to the requirements imposed in Articles 4 and 5 TEU, must demonstrate respect for national identities and for regulation at the national level, essential in an area with substantive overlaps between European and national regulation, such as the ethics of biomedical research. Finally, respect for variety at the national level is a central issue in the regulation of the internal market, as demonstrated by the provisions on the approximation of laws in the internal market (Art. 114 TFEU – providing the legal basis of the Biotechnology Directive) and by the jurisprudence on the derogations from the free movement provisions (Arts. 36, 52 and 62 TFEU), especially on public morality grounds.⁷ On this basis, determining whether uniform bioethical principles are available at the European level, or that a diversity of moral viewpoints should be sustained among the Member States is a question of constitutional obligations for the European Union.

Besides European value pluralism, the regulation of biotechnological research in Europe must have regard to a further source of multiplicity. It relates to the broader institutional and governance framework of European law, in our case European patent law, in which the application of the law must be ensured in a multi-layered system consisting of national patent systems (patent authorities and courts), the EPO and the European Union. The system was brought together by the Biotechnology Directive, and functions under the interpretative coordination of the EU Court of Justice. The link between the national level and the EU Court of Justice is provided by the procedure for preliminary rulings in which the Court is given an opportunity to assess the distinctions of the Biotechnology Directive based on the relevant bioethical principles. In interpreting these provisions, the Court must observe where the

7. See, *inter alia*, Case 121/85, *Conegate*, [1986] ECR 1007; Case C-275/92, *Schindler*, [1994] ECR I-1039; Case C-268/99, *Jany*, [2001] ECR I-8615; Case C-36/02, *Omega Spielhallen*, [2004] ECR I-9609.

Directive allows uniformity and where sustaining the multiplicity of moral positions among the Member States is required.

The participation of the EPO in the system, necessary for securing the influence of the Biotechnology Directive in European patent law, made its coordination a more complex task. After the voluntary incorporation of the Directive into the European Patent Convention (EPC),⁸ the EPO organs assumed competence to interpret and apply the provisions of the Directive adding a further competent forum to the system of governance under the Directive. There are no formal links between the EPO organs and the EU Court of Justice, although the possibility of turning to the Court of Justice using a preliminary reference system has been considered.⁹ In this construction, maintaining uniformity in the interpretation and application of the Directive and preserving the integrity and sustaining the coherence of the system of governance under the Directive are of paramount importance.

In the following, we will examine the broader policy and ethical background of the Biotechnology Directive, the legal and ethical framework and the crucial distinctions of the Directive relating to biopatenting and the patenting of stem cells in particular, and the application of the Directive to hESC patents by the EPO organs, the German Federal Patent Court and the EU Court of Justice. We will investigate how the Directive's solution for addressing moral multiplicity was treated before the different legal forums, especially whether the legislative blueprint provided by the Directive, incorporating legally relevant distinctions based on the relevant bioethical principles, was observed in its interpretation and application. It is questioned whether in light of the obligation to observe multiplicity and preserve local assessments in certain issues of public morality under the Directive, the treatment of hESC patents in European law is entirely justifiable.

2. Biotechnology, the market and ethics in Europe

On the basis of its preamble, the Biotechnology Directive subscribes to a clear market creation and market integration agenda. Its preamble uses terms such as “industrial development”, “investment”, “profitable”, “barriers to trade” and “smooth operation of the internal market”. Its regulatory rationale, the removing of regulatory differences among the Member States in the field of patenting which impede the development of a European biotechnology sector, suggests that the Directive is a classic instrument of European economic regulation. The sector addressed in the Directive,

8. Rules 26–29 (ex Rules 23b–e) of the Implementing Regulations of the EPC.

9. G 2/06, cited *supra* note 2, paras. 2–11.

biotechnology, is of strategic importance to the European Union economy; advancement in the sector is hoped to contribute to its increased global competitiveness.¹⁰ Beyond drafting strategies, European Union action in the field of biotechnology now involves a variety of hard and soft legal instruments and genuine governance systems¹¹ – the EU regulatory arsenal includes the Biotechnology Directive, the Tissue Directive¹² and the Advanced Therapies Regulation.¹³

Without ignoring the economic value, including lucrative intellectual property rights, generated by progress in biotechnology,¹⁴ the regulation of biotechnology from a purely economic perspective would be unsatisfactory. The scope of regulatory intervention, even in the form of European Union harmonization measures, must incorporate the broader social/ethical considerations related to a new form of technology.¹⁵ One of the most important ethical controversies surrounding biotechnology, which has an impact on the patentability of biotechnological inventions, is the use of human biological material, human tissues and cells, including human eggs and human stem cells, as “base material” for biomedical research and therapy. It evokes the principles of modern bioethics concerning the moral status of human beings, the human body and human biological material, respect for human dignity being the most fundamental of those principles. For the European Union, legislating in accordance with the requirements of human dignity (and integrity) follows from the Charter of Fundamental Rights (Arts. 1 and 3) and from the general principles of EU law.¹⁶

The presence of considerations beyond the primary aim of approximation of patent laws made the choice of a legal basis for the Biotechnology Directive rather complicated, as indicated in the legal challenge mounted by the

10. Communication from the Commission, Life sciences and biotechnology – A strategy for Europe (23 Jan. 2002) COM(2002)27 final.

11. Favale and Plomer, “Fundamental disjunctions in the EU legal order on human tissues, cells and advanced regenerative therapies”, 16 MJ (2009), 90.

12. Directive 2004/23/EC of the Parliament and the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells, O.J. 2004, L 102/48 and the related Directives.

13. Regulation (EC) 1394/2007 of the Parliament and the Council of 13 Nov. 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Reg. (EC) No 726/2004, O.J. 2007, L 324/121.

14. Rose, *The Politics of Life Itself* (Princeton Univ. Press, 2006), pp. 2 and 4.

15. In fact, opening an ethical perspective on European patent harmonization led the European Commission to realize that the regulatory divergence sought to be remedied by the Directive rested more in the regulation of the ethical aspects of biomedical advancement, Gold and Gallochat, “The European Biotech Directive: Past as prologue”, 7 ELJ (2001), p. 337.

16. Case C-377/98, *The Netherlands v. Parliament and Council*, [2001] ECR I-7079, para 70.

Netherlands against the Directive.¹⁷ Among other grounds, it was claimed that the Directive was adopted following the wrong legal basis, ex Article 100a EC (later Art. 95 EC, now Art. 114 TFEU), its chief aim being the promotion (and regulation) of industrial development and scientific research activity. The Court of Justice responded that the aims of legal harmonization and the promotion of research and enterprise are not exclusive, and since the approximation of legislation represents a means of overcoming the obstacles “likely to impede and disrupt research and development activity in that field”, Article 100a EC was available as a legal basis.¹⁸

The Biotechnology Directive, regulating the patenting of biotechnological inventions consisting of or containing human biological material, relies on human dignity as the key governing principle (Recital 16). Its incorporation into the Directive was imperative considering the inherently commercial nature of patent systems, defined as commodity systems through which inventions are introduced into the market for commercialization. In the case where human biological material is brought within the patent system, the prohibitions inherent in human dignity, especially the non-commodification principle, should be given effect. In Wilkinson’s terminology, commodification represents one form of wrongful exploitation of things which are not objects, and refers to social practices or legal arrangements which allow things to be bought and sold treating them as commodities.¹⁹ In a narrower, moral sense commodification and commercialization stand for the objectionable practice of treating other human beings, the human body and its parts as commodities, as fungible, interchangeable, not unique, as available for exchange for money.²⁰ A translation into law of these principles is provided in the Oviedo Convention, contending that the human body and its parts shall not give rise to financial gain (Art. 21).

By ensuring that the human dignity principle shall be observed, the Biotechnology Directive determines in what circumstances human biological material would constitute patentable subject matter and on what grounds inventions including human biological material may be excluded from patentability. The instruments used in this regard are concepts available in patent law: the discovery/invention distinction and the public policy (*ordre public*)/public morality exemption to patentability. A discovery is finding something as it exists in nature and an invention is creating something, which does not exist, by way of human intervention. Patent protection is only available for inventions. This provides an opportunity to exclude from the

17. Ibid.

18. Ibid., paras. 27–28.

19. Wilkinson, *Bodies for Sale* (Routledge, 2003), pp. 44–45.

20. Ibid.

scope of patent law human biological material, since it exists in nature, meeting the non-commodification requirement, and to acknowledge as patentable subject matter “inventions of” human biological material, objects created by human intervention, available under the human dignity principle to be treated as objects of value in the patent system.²¹ As allowed under Article 27 TRIPS, the Biotechnology Directive also contains a public policy/public morality clause capable of incorporating, in general or in more specific terms, the bioethical objections to certain biotechnological inventions and excluding their commercialization through the patent system. By producing a detailed regulation of these concepts in the Directive, the commercial exploitation of human biological material in European patent law was placed under the constraints of the applicable bioethical principles.

Incorporating human dignity into European patent law relating to biotechnological inventions presented an important complication for the regulatory construction of the Directive. Human dignity is a principle which attracts different interpretations in different value communities. If we follow the distinction introduced in relation to the functions of human dignity in bioethics, “human dignity as empowerment” and “human dignity as constraint”, representing respectively a universal requirement for the protection of individuals and a limit to human activity as dictated by the local value community,²² the European level regulation of human dignity needs to distinguish between situations when a uniform requirement may be imposed and those when respect for the multiplicity of moral viewpoints on the local level needs to be ensured. At the European level, the introduction of uniformly applicable rules derived from human dignity necessitates establishing a consensus among the Member States; if such consensus is lacking, the decision on the moral limits of biopatenting should be deferred to the national level, to the level of individual value-communities.

Inventions originating from research with human embryos, patent claims on hES cells in particular, presented the most significant challenge to the Directive’s provisions. The use of human embryos for research purposes raises bioethical questions, mainly associated with the moral status of human embryos, different from the main debate on commodification and the patenting of human biological material, addressed in separate biomedical research regulatory regimes in the Member States with considerable

21. It exists in an artificial setting and it could be regarded as an object (patentable subject matter) because it exists within that setting, Gold and Galloch, *op. cit. supra* note 15, p. 344.

22. Beyleveld and Brownsword, *Human Dignity in Bioethics and Biolaw* (OUP, 2001), p. 11.

differences regarding the morality of hESC research.²³ The principal objection to hES cells is that at the current state of art the derivation of these cells from the blastocyst would lead to the destruction of the human embryo. The Directive could be interpreted so as to accommodate this moral objection (e.g. under the general public morality clause). However, a decision under the Directive excluding patentability in order to ensure the protection of the human embryo must take account of the multiplicity of ethical viewpoints on the national level.

That multiplicity is recognized in the Oviedo Convention, with the holding that “where the law allows research on embryos in vitro, it shall ensure adequate protection of the embryo” (Art. 18(1)). European multiplicity regarding the moral status of human embryos has also been confirmed under the European Convention on Human Rights. Article 2 ECHR on the right to life attracted a deferential approach from the European Court of Human Rights when it faced the question whether the rights of an “unborn child” should be protected.²⁴ Under the ECHR, the moral status of human embryos was declared to fall within the margin of appreciation of the Contracting States.²⁵ Maintaining European moral pluralism was also a concern for the European Group on Ethics (EGE), the European Union ethical advisory body, which suggested that hESC derivation from human embryos must be assessed with a view to the variety in the Member States in regulating human embryonic research.²⁶

If it intends to express ethical objections against hES cells harvested from human embryos, beyond the narrower considerations of non-commodification/non-commercialization, European patent law has to address the regulatory issues arising from the “variation in norms and laws regulating biomedical research both within and outside Europe”.²⁷ Unless the European Union legislature is able to find consensus among the Member States, it appears that the ethical assessment of hESC patents needs to be deferred to the level of local value communities. With this crucial point in mind, we will now unveil the regulatory framework for biopatenting at the

23. See <www.stemgen.org/mapworld.cfm> (last visited 6 Nov. 2011) and Isasi and Knoppers, “Mind the gap: policy approaches to embryonic stem cells and cloning research in 50 countries”, 13 *European Journal of Health Law* (2006), 9–26.

24. *Brueggemann and Scheuten v. Germany*, (1981) 3 EHRR 244; *Paton v. UK*, (1981) 3 EHRR 408; *Open Door Counselling v. Ireland*, (1993) 15 EHRR 244; *Vo v. France*, ECHR 2004-VIII; *Evans v. UK*, App. 6339/05, nyr; *S.H. and Others v. Austria*, App. 57813/00, nyr.

25. *Evans*, paras. 54 and 56 and *S.H. and Others*, paras. 68, 69, 74 and 75–85, both cited *supra* note 24.

26. Opinion No. 15 (14 Nov. 2000) – *Ethical Aspects of Human Stem Cell Research and Use*, available at <ec.europa.eu/european_group_ethics/docs/avis15_en.pdf> (last visited 4 Sept 2009).

27. Plomer, *The Law and Ethics of Medical Research* (Routledge-Cavendish, 2005), p. 24.

European level as devised by the Biotechnology Directive and the boundaries therein relating to the patentability of hES cells.

3. Ethical distinctions and multiplicity: the Biotechnology Directive

The European level harmonization of patenting biotechnological inventions faced formidable regulatory challenges. It had to resolve the conflict between the main regulatory rationales, market creation and integration, on the one hand, and safeguarding non-economic values expressed in the relevant bioethical principles on the other. It had to navigate in the complex regulatory background provided by the principles of bioethics, the introduction of which into European patent law required distinguishing between principles which could be imposed at the European level and those which demand the recognition of value multiplicity among the Union's Member States. The drafters of the Biotechnology Directive, after a long gestation period, responded to these challenges by drawing up a firm and clear regulatory framework for the patenting of biotechnological inventions in Europe. The Council and the Parliament constructed a harmonization measure which identified the boundaries of the commercialization of human biological material through intellectual property rights by introducing crucial conceptual clarifications and distinctions.

From the perspective of the patentability of hES cells, the most relevant issues are the interpretation of Article 6 and the distinction between paragraphs 1 and 2 of that Article, determining whether hESC patents could be excluded on public morality grounds and whether this decision occurs at the European level, on the basis of a common understanding of the relevant ethical principles, or should be deferred to the national level, the level of local value-communities. Nevertheless, our analysis requires examining other relevant provisions of the Biotechnology Directive concerning the clarification whether biological material of human or other origin can be patentable subject matter in European patent law. Article 3 states that:

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

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

In this respect, the Directive relied on the legal distinction between discoveries and inventions, separated by the element of human intervention, and contended that as opposed to matter occurring in nature, biological material subjected to certain forms of human intervention, isolation or production by means of a technical process, constitutes patentable subject matter. With this, the Directive appears to have subscribed to the argument that an element of “human ingenuity”²⁸ would render biological material patentable under the regular provisions of patent law. Concerning human biological material, such as cells, tissues, organs, or the whole human body, the same distinction between discoveries and invention enabled the Directive to declare that elements “isolated from the human body or otherwise produced by means of a technical process”, such as hES cells derived from the blastocyst, constitute patentable subject matter and that the “simple discovery of” elements of the human body (cells, genes, tissues etc.) are excluded from patenting (Art. 5(1) and (2)).

The Biotechnology Directive also established that the availability of human biological material for patenting is not absolute. It contends that “the human body, at the various stages of its formation and development” is not patentable subject matter (Art. 5(1)). Evidently, this provision is based on respect for the bioethical constraints following from human dignity which universally, at least in Europe, prohibit the commercialization of the human body through the patent system.²⁹ The scope of this provision should cover the human embryo, the source of hES cells, without distinguishing between human embryos *in utero*, (supernumerary) human embryos created in a parental project (IVF), and human embryos created for research purposes.

The rationale of Articles 3 and 5 of the Directive must be sought beyond the categories used by patent law, such as the technical distinction between discoveries and inventions. With the help of these provisions, the Directive expressed a trade-off between the bioethical constraints relating to human activity with human biological material, and the utilitarian considerations which underline the use of human biological material in biomedical research, and which recognize the contribution of the patent system to encouraging further biomedical research (Recitals 17 and 18). The drafters made it clear that there is European consensus in allowing the commercialization through the patent system of human biological material, with the unyielding exception

28. For the origins of the “human ingenuity” argument see, *Diamond v. Chakrabarty*, 447 US 303 (1980) distinguishing between “products of nature” and “products of human ingenuity”.

29. *The Netherlands v. Parliament and Council*, cited *supra* note 16, paras. 70–77. It ensures “that the human body effectively remains unavailable and inalienable and that human dignity is thus safeguarded” (para 77).

concerning the human body, for the purpose of intensifying research in biomedicine.

Determining whether human biological material constitutes patentable subject matter, and could be treated as commodities, is only one aspect of incorporating the ethical considerations of biomedical research into European patent law. Beyond the non-commodification principle, European level consensus was discernible concerning certain human activities, human intervention with human life, regarding them as incompatible with the principles flowing from human dignity. These are listed under Article 6(2) of the Directive, determining the commercial exploitation of which inventions should be excluded on public policy or public morality grounds. The list is non-exhaustive, its purpose is to guide national patent offices and courts, and it identifies inventions for which patents must not be granted in European patent law, such as

- (a) processes for cloning human beings;
- (b) processes for modifying the germ line genetic identity of human beings;
- (c) uses of human embryos for industrial or commercial purposes.

The possibility to exclude the patentability of inventions besides those listed in Article 6(2) is provided under Article 6(1), which incorporates a general *ordre public* and public morality clause. It stipulates that “Inventions shall be considered unpatentable where their commercial exploitation would be contrary to *ordre public* or morality”. While Article 6(2), representing a consensus among European States, should be applied uniformly in the Member States and could give rise to excluding inventions from patentability at the European level, by the EPO or through the interpretation of the EU Court of Justice, account must be taken in the application of Article 6(1) of the diversity of viewpoints among the Member States regarding the moral acceptability of the particular biomedical invention.³⁰

The real difficulty with the Biotechnology Directive lies in the application of Article 6 in the multi-actor system of European patent governance. As indicated earlier, this consists of national patent offices and courts, the EU Court of Justice, endowed with the competence to provide the authoritative interpretation of the Directive, and the EPO with jurisdiction to grant a bundle of European patents enforceable in the EPO Contracting States. In this system,

30. Recital 39 of the Preamble, “*ordre public* and morality correspond in particular to ethical or moral principles recognized in a Member State” (emphasis added), and *Netherlands v. Parliament and Council*, cited *supra* note 16, para 37: it “allows the administrative authorities and courts of the Member States a wide scope for manoeuvre in applying this exclusion”. See further paras. 38–39.

Article 6(2) presents an attractive option as it dictates uniformly applicable exemptions to patentability on all levels (national and European) before all forums (patent offices and courts) from which no departure is permitted, depending on the particular legal, social and cultural context. In contrast, Article 6(1), which recognizes the possibility of differing ethical assessment of biotechnological inventions in different States, must be applied with the intention of accommodating the value judgements of different value communities. The obligation to recognize the multiplicity of local approaches may cause headaches at the European level, as it is capable of compromising the market creation and integration agenda of the Directive and jeopardize the integrity and coherence of the system of governance under the Directive.

Another complication ensuing from examination at the European level of whether an invention would be patentable under the general public morality clause, in the event that no moral consensus is discernible among Union Member States to trigger the application of the exemption, is that it leaves no other option than finding the invention morally acceptable and declaring the invention patentable, despite the fact that it would be rejected as ethically unacceptable in some of the States. In case of socially contested inventions, such as hES cells, for a European decision maker this reduces the attractiveness of Article 6(1) considerably.

When the explicit grounds of Article 6(2) are not available and no agreement on a common ethical standard among Union Member States can be revealed, European value pluralism presents a nearly impossible decisional situation for the EPO and the EU Court of Justice. The obligation to recognize the fact that the requirements of public morality attract different interpretations in different value communities means that the European level is driven to declare the invention patentable under Article 6(1), thus violating the bioethical constraints imposed on the human activity leading to that invention in certain States and religious or other social value communities. The alternative solution, declaring the invention incompatible with Article 6(1), would contravene the obligation to respect European bioethical pluralism, and would mean imposing uniform ethical requirements over Union Member States without the appropriate democratic authorization arising from EU legislation.

Escaping the conflict inherent in the decisional situation under Article 6(1) is only possible when the European forum is given the procedural avenue to defer the question of moral restraints on the patentability of biotechnological inventions to the State level and, as a result, avoid giving a green light to the patentability of an ethically controversial invention. This option is not available within the EPO system, but is open to the EU Court of Justice under the preliminary ruling procedure. The Court of Justice is entitled, having

described the legal parameters for the decision at the local level, to remit the decision on patentability to the national court which made the original reference for a preliminary ruling.

Besides the difficulties in its application, the interpretation of Article 6 of the Biotechnology Directive also represents a challenge in a multi-actor environment. Article 6 applies carefully constructed terms. Paragraph 1 speaks of inventions the commercial exploitation of which would breach the requirements of public morality. In light of Article 5 of the Directive, which by determining what may constitute patentable subject matter on grounds of the bioethical prohibitions concerning the commodification of human biological material, Article 6(1) should be read as not stipulating the ethical unacceptability of patenting of inventions consisting of or containing human biological material.³¹ Article 6(1) does not concern the commodification by the act of patenting of things which should not be treated as commodities. Instead, here the Directive refers to excluding the availability of certain inventions from the market, because their commercial exploitation would be incompatible with values prevailing in a particular value community.

In our interpretation, Article 6(1) expresses an objection against the patent system offering inventions to the market for commercialization, which is based on the ethical unacceptability of those inventions.³² This must be contrasted with the position, found attractive later by the relevant legal forums, that Article 6(1) focuses on the intention of the patent claimant and excludes the patentability of inventions on the ground that submitting a patent claim, reflecting a clear intention to commercialize the relevant invention, provides the commercial element required under Article 6(1) by constituting a commercial exploitation of the said invention.³³ This is unconvincing as the structure of Article 6 offers a different interpretative route.

The aim of Article 6(2) is to exclude the commercialization of ethically objectionable inventions in the market. This follows from the list of inventions under Article 6(2), mentioning interventions with human life and the human body that are regarded as ethically unacceptable throughout Europe because of the nature of the particular human activity, as suggested by Recital 40 in the Biotechnology Directive. The inevitable commercial orientation of submitting a patent claim relating to the activities mentioned under Article 6(2) is irrelevant. The patenting of human cloning is excluded because the availability in the market of such objectionable practices through the

31. See also Sterckx and Cockbain, "Assessing the morality of inventions concerning uses of human embryos and the relevance of moral complicity: Comments on the EPO's WARF decision", 7 *SCRIPTed* (2010), 95–98.

32. See the interpretation provided by the EPO Board of Appeal, *infra* note 45.

33. Moufang, "Patenting of human genes, cells and parts of the body, the ethical dimensions of patent law", 25 *International Review of Industrial Property and Copyright Law* (1994), 504.

mediation of the patent system would be ethically unacceptable. The commercial interest represented by the patent claim has no impact on the application of Article 6(2)(a). In the same vein, Article 6(2)(c) does not focus on the commercial orientation of a patent claim involving human embryos. Instead, it should be applied to prevent the ethically objectionable industrial or commercial exploitation of human embryos in a technology brought to the market through the patent system.

The same interpretative logic must apply to Article 6(1), the general clause on public policy and morality, providing the basis for the specific examples when the patentability of inventions should be excluded under considerations of public policy or morality under Article 6(2). On this basis, Article 6(1) would exclude the patentability of inventions which use material obtained in an ethically objectionable manner (e.g. the human tissue was procured from the “market”, the human tissue was obtained without the prior informed consent of the research subject, or the research subject (a human embryo) was killed or was subjected to inhumane treatment), and which for this reason should not be made available for commercialization in the market. In this regard, the position established in individual Member States concerning what may constitute ethically objectionable practices will be of relevance.

Article 6(2) contains uniformly applicable exemptions to the patentability of certain biotech inventions, reflecting a common understanding of the relevant bioethical principles in Europe. Recital 40 of the Directive states that the unequivocal exclusion from patentability under Article 6(2) of interventions in the human germ line and the cloning of human beings follows from a Europe-wide consensus that these practices offend against public policy and morality. This position may build upon the European consensus expressed in Chapter IV of the Oviedo Convention and the Cloning Protocol added to it. In the meaning of the Oviedo Convention, Article 6(2)(a) of the Directive should cover reproductive and research human cloning, also supported by Article 18 of the Oviedo Convention which prohibits the creation of human embryos for research purposes. The human embryo receives further protection from Article 6(2)(c), which excludes uses of human embryos for commercial and industrial purposes from patentability. The European consensus on this may be represented by the Oviedo Convention and its provisions on human dignity and the non-commercialization of the human body (Arts. 1 and 21).

The key exemption of Article 6(2)(c), the “industrial or commercial use clause”, represents a common belief that human embryos, an invaluable resource in biomedical research, should not be subjected to treatment by humans which deprives them of their value as living matter capable of developing into a full human being. In its interpretation and application, the

following distinctions are of relevance. Article 6(2)(c) does not express an objection to the commodification of human embryos in the patent system, treating them as fungible things. This was addressed in Article 5 of the Directive, under which human embryos and totipotent stem cells, constituting a phase of development of the human body, are excluded from patentable subject matter, but which recognizes biological material isolated from human embryos, such as human embryonic (pluripotent) stem cells, as patentable subject matter. Instead, Article 6(2)(c) enables an enquiry by patent offices and courts whether the invention *constitutes* an industrial or commercial use of human embryos and whether this should prevent its availability in the market through the patent system.

Article 6(2)(c) is intended to exclude inventions from the market on the ground that they constitute an ethically unacceptable use of human embryos within the meaning of the “industrial or commercial use clause”. The commercial intention associated with the patent claim is irrelevant – the ethical objection expressed in Article 6(2)(c) is more fundamental. Instead of examining the commercial hopes of patent claimants, under this provision it needs to be investigated whether the invention is linked to commercially focused activities, or activities on an industrial scale and following industrial methods³⁴ involving human embryos. In this reading, the ethical objection against destroying human embryos in biomedical research (in the process of deriving hES cells) must also be found irrelevant under Article 6(2)c. The “industrial or commercial use clause” encapsulates only specific uses of human embryos.

From the perspective of hESC patents, the most pressing interpretative dilemma under Article 6(2)(c) is whether isolated hES cells would constitute an industrial or commercial use of the human embryos from which they were derived. It must be noted that Article 6(2)(c), as opposed to Article 6(2)(a) on cloning, does not refer to a particular technology (i.e. hESC derivation/research),³⁵ and its application to a particular technology requires a bit of stretching of the “industrial or commercial use clause”. In searching for an answer, an investigation into the nature of hES cells and the place of commercial considerations in biomedical research is required. Our main

34. Defined as “market transactions in which products are traded for money or profit” and “direct, repetitive use of the human embryo as a raw material in a chemical, mechanical or technical process”, in Plomer (project coordinator), *Stem Cell Patents: European Patent Law and Ethics*, Report EU FP6 “Life sciences, genomics and biotechnology for health”, SSALSSB-CT-2004-005251 (2008), <www.nottingham.ac.uk/~llzwww/StemCellProject/project.report.pdf> (last visited 12 Dec. 2011), pp. 74–75.

35. At the time of the adoption of the Directive, human cloning was the dominant technology and the main concern for legislatures; hESC technology was still in its infancy.

contention is that at this stage the use of human embryos for the derivation of hES cells is far from having an outright industrial or commercial character and that the commercial elements of hESC research are inseparable from its dominant non-economic priorities.

hES cells are a basic research tool, an “essential facility”³⁶ in biomedical research, indispensable for further upstream and downstream research. They have significant prospective commercial and social value, considering that future healthcare products and therapies may be based on the patented basic research tool. However, in order to exclude the use of human embryos for the derivation of hES cells under Article 6(2)(c) a more direct link between the basic research tool harvested from human embryos and prospective marketable and commercially attractive products and therapies needs to be established. Currently, there is only a potential to develop commercially viable products or therapies from hES cells³⁷ as opposed to marketable biomedical inventions, such as biodegradable scaffolds or cryopreservation methods. Any decision in the patent system declaring that human embryos in hESC research are used for commercial or industrial purposes needs to rely on conclusive evidence that hESC derivation is performed (on an industrial scale) to meet the demand of the market.

A further complication in determining the nature of the use of human embryos in hESC research follows from the inability to separate in biomedical research the non-commercial values of protecting human health and human life from the commercial value of a certain product or therapy. A commercially relevant biotech patent may be based on public sector research and/or at least partially publicly funded research, such as the world-renowned hES cell patents of the Wisconsin Alumni Research Foundation (WARF).³⁸ There are clear public interest elements in such research and the effective commercialization of the results of public sector research is often seen as key to securing the achievements of those public interest objectives. Raising revenue, securing investment and finding commercial partners to develop products or therapies by way of patenting research results is a policy priority for public sector research pursuing non-economic agendas, enabled by regulation such as the US Bayh-Dole Act 1980.³⁹ The overlap between the commercial and non-commercial elements in biomedical research was also recognized by the Biotechnology Directive, which subscribes to a

36. Borrowed from Davis, “Patented embryonic stem cells: The quintessential ‘essential facility’?”, 94 *Georgetown Law Journal* (2005), 205.

37. See McKernan, McNeish and Smith, “Pharma’s developing interest in stem cells”, 6 *Cell Stem Cell* (2010), 517–520.

38. See Eisenberg and Rai, “Proprietary considerations”, in Lanza et al. (Eds.), *Handbook of Stem Cells. (Vol. 1)* (Elsevier, 2004), pp. 793–798.

39. Pub. L. No. 96-517, 35 USC 200–211.

combination of commercial and non-commercial priorities made visible in its preamble, which states that without patenting the economic *and* social benefits of innovation may not be realized.

Patenting entails another non-commercial benefit for public sector research and society at large. Without a direct link to investors and the market, public sector research may not be able to fill the innovation gap left by the private sector in areas like public health, where the priorities of the private and public sector may diverge considerably. The patent system could be able to secure public policy objectives in areas found unattractive by commercially oriented private sector activity by raising the interest of the market in public sector research and upstream activities (translation into healthcare products or therapies). In Schneider's equation, the public interest and the commercial nature of patenting is not mutually exclusive, as "patents equal innovation, equals economic development, equals therapeutic improvement, equals beneficence for general wealth, and thus benefit for the common good".⁴⁰

It appears that establishing that an invention constitutes an industrial or commercial use of human embryos requires an examination which extends beyond the narrow remit of applying for a patent in the innovation process. The commercial significance of patenting and patents, insofar as they offer a protected market position, promise the generation of returns and may attract investment and aid the marketing of the invention,⁴¹ is insufficient on its own to bring inventions under Article 6(2)c. The "industrial or commercial use clause" requires more than contending that the preparation of hES cells (their derivation from human embryos) to obtain a patent was inevitably driven by commercial considerations. In the application of the Directive, it needs to be established that a direct link exists between the invention and industrial and commercial uses of embryos, and that biomedical research and biomedical patenting in the area was driven by commercial priorities ignoring the non-commercial, public interest elements of biomedical research activity and its utilization of the patent system.

Theoretically, the application of hES cells in therapeutic products and therapies could lead to a commercial demand for hES cells which may require the organization of the derivation process from human embryos on an industrial scale. In such circumstances, patents relating to the mass production of stem cells lines from human embryos for the use of commercially oriented health care companies could fall under the exclusion of Article 6(2)c. Only the exception mentioned in Recital 42 of the Directive, referring to inventions for

40. Schneider, "Can patent legislation make a difference?", in Hauns et al. (Eds.), *Politics of Intellectual Property* (Edward Elgar, 2009), p. 134.

41. See, *inter alia*, Kitch, "The nature and function of the patent system", 20 *Journal of Law and Economics* (1977), 266–267.

therapeutic or diagnostic purposes which are applied to the human embryo and which are useful to it, could present an escape from the “industrial or commercial use clause”. Adopting this approach in the current circumstances to prevent the patentability of hES cells would be exceptionally cautious practice.

The final relevant bioethical consideration which may play a role in determining the patentability of hES cells concerns the act of destroying human embryos in the process of derivation of stem cells. It is connected to the debate on the moral status of human embryos and reaches beyond the scope of Article 5 and 6, which reflect the bioethical principles of non-commodification and non-commercialization. In fact, there is very little room under the Biotechnology Directive to accommodate a moral objection against the destruction of human embryos in biomedical research in Europe. While the destruction of human embryos could be relevant under the “industrial or commercial use clause”, it would be a forced reading of Article 6(2)(c) to give effect to a Europe-wide condemnation of embryo destruction in biomedical research. More importantly, imposing under Article 6(2)(c) a “uniform moral bar on patents on hESC whose derivation necessarily involves embryo destruction” has no legal basis under the Directive.⁴²

The only provision available in the Directive is the general public morality clause, which seeks to prevent the patenting of inventions the availability of which for commercialization in the market would be ethically unacceptable. As stated earlier, the difficulty with Article 6(1) of the Directive lies in its application at the European level. In order to exclude the patentability of hES cells, it is necessary to establish a European moral consensus on human embryonic research and hES cell derivation from human embryos. In the absence of such consensus, the European level, the EU Court of Justice and the EPO, will have to recognize the diversity of moral viewpoints among Member States on this matter. As a result, the European level will be prevented from excluding the patentability of hES cells on this basis and defer the question to the national level.

The key provisions of the Directive provide clear signposts for the European and local level in the process of patenting biotechnological inventions. These provisions incorporate the immediate ethical concerns of patenting in biotechnology and determine its boundaries with reference to those ethical principles.⁴³ The Directive introduced uniform rules where consensus among Member States can be established in relation to the relevant ethical principles and acknowledged value multiplicity where no such consensus is available.

42. Plomer, *op. cit. supra* note 34, p. 83.

43. As confirmed in *Netherlands v. Parliament and Council*, cited *supra* note 16, paras. 71–77.

The challenges arise from the complex task of applying and interpreting the Directive in a multi-actor system of governance, which will be discussed next.

4. Patenting human embryonic stem cells under the Biotechnology Directive: Legislative intent gone wrong?

The prudent distinctions of the Biotechnology Directive soon found themselves among growing controversy. For holders of key biomedical patents in the US and their European competitors, it was strategically important to obtain a European patent, a patent in biotechnologically advanced European States and the bundle of national patents from the EPO. This met with fervent opposition from the European objectors to “patents on life”. With Articles 3 and 5 of the Directive representing a core European agreement on enabling patenting in biotechnology, only Article 6 of the Directive was available to challenge on moral grounds the patentability of biotech inventions including hES cells. In the following, we will look at the practice emerging under the Directive and examine whether the interpretative efforts remained loyal to the system of distinctions introduced in the Directive.

4.1. Take one: The EPO’s practice under the Directive.

The vulnerability of the interpretative construction of the Biotechnology Directive came to light relatively early under EPO framework. Nevertheless, the EPO organs had no difficulty with establishing the relationship between the general public morality clause (Art. 53(a) EPC) and the list of inventions deemed unpatentable by Article 6(2) of the Directive.⁴⁴ They also managed to provide a sound interpretation of the general public morality clause, stating that it excludes “inventions the exploitation of which is not in conformity with the conventionally accepted standards of conduct pertaining to (the culture inherent in European society and civilization)” from patentability.⁴⁵ EPO practice adequately addressed the problem posed by the multiplicity of moral viewpoints under the general public morality clause when establishing that, when applying that clause, a common European understanding is required concerning what conduct and practices can be regarded as morally acceptable at the European (EPO) level, and that the plurality of moral viewpoints prevailing among Union Member States

44. EPO Boards of Appeal Decision T 0315/03 of 6 July 2004, OJ EPO, 2005, 209, para 10.1.

45. *Ibid.*, para 10.2.

prevents the European level from introducing a uniform ethical position on the patentability of biotechnological inventions.⁴⁶ In EPO practice, the application of the general public morality clause involves an examination of whether the moral objection against the invention is genuine and adequately represented in the different societies of the world and in European culture,⁴⁷ and focuses on establishing that moral objections against certain technologies or human intervention could be elevated “to the status of moral disapproval in European culture”.⁴⁸

The interpretation concerning the clause on the industrial or commercial use of human embryos,⁴⁹ however, proved to be genuinely controversial. In relation to the patentability of inventions consisting of or containing hES cells, EPO practice, having considered the general public morality clause as irrelevant, resorted to the “industrial or commercial use clause” and excluded their patentability. The origins of this approach can be found in the so-called “Edinburgh Patent Decision”.⁵⁰ In this decision, the Opposition Division had decided that in light of the aims of the Directive the “industrial or commercial use clause” must be given a broad interpretation and concluded that the clause excludes from patentability not only uses of human embryos but also hES cells derived from human embryos leading to the destruction of those embryos. Apparently, the decision placed embryo destruction in the centre of the “industrial or commercial use clause”.

The “Edinburgh Decision” was subsequently confirmed in the seminal Decision G 2/06 of the EPO Enlarged Board of Appeal on the WARF stem cell patent application (the “WARF Decision”). The authority of the *WARF* Decision is now supported by the “California Stem Cell Decision” the novelty of which was that it extended the interpretation of the clause to cover products *and* methods involving the destruction of human embryos.⁵¹ The EPO *WARF* Decision presented a new chapter in the history of the WARF cell lines, the first stem cell lines reported to be isolated in the world, subject to patents in the US.⁵² In the US, the challenges against WARF’s patents were mainly

46. *Ibid.*, paras. 10.3 and 10.4. See also, EPO Boards of Appeal Decision T 356/93 of 21 Feb. 1995, OJ EPO, 1995, 545, paras. 5–6. It matches the ECJ’s interpretation, cited *supra* note 30.

47. T 0315/03, paras. 13.2.14–13.2.21, cited *supra* note 44 and EPO Boards of Appeal Decision T 19/90 of 3 Oct. 1990, OJ EPO, 1990, 476.

48. *Ibid.*, para 13.2.21.

49. Rule 28(c) EPC/Art. 6(2)(c) of Directive.

50. The case concerning European Patent No. EP0695351, decided after oral hearings 22–24 July 2002.

51. “California Stem Cell Decision”, T 522/04, para 4, cited *supra* note 2.

52. Thomson et al., “Embryonic stem cell lines derived from human blastocysts”, 282 *Science* (1998), 1145–1147 (US Patent No. 5,843,780 (1996), 6,200,806 (1998) and 7,029,913 (2001)).

unsuccessful. They focused on technical questions of patent law – US patent law lacking an explicit reference to public morality as ground for the exclusion of patentability – and led to the invalidation of only one of the WARF patents, patent 7,029,913.⁵³ Whereas in Europe, the challenges mounted against the WARF patent application were based on the ethical acceptability of human embryonic research, in particular the derivation of hES cells, and resulted in excluding the patentability of the WARF cell lines under European patent law.

The key argument of Decision G 2/06 is that the performing of the invention (making the product with an intention to patent that product) constitutes the commercial element which entails the application of the “industrial or commercial use clause”. In consequence, any involvement of human embryos in the preparation of the invention, which may involve the destruction of those embryos, will be deemed as an “integral and essential part of the industrial or commercial exploitation of the claimed invention”.⁵⁴ The “use” of human embryos as stipulated by the Biotechnology Directive, in the case of hES cell patents, was equated with the act of derivation of the stem cell lines from human embryos (and the inevitable destruction of those embryos). The Decision, nevertheless, made it clear that it is not the commercial act of patenting which is considered to contravene Rule 28(c).⁵⁵

There are numerous indications that the interpretative construction of Decision G 2/06 was influenced by a more pressing moral concern than that relating to the commercial intent in performing the invention. Paragraph 29 of the Decision appears to suggest that *ordre public* and morality are violated by “performing the invention, which includes the step (of destroying a human embryo)”. The reference to Recital 42 of the Directive to contrast uses beneficial to the embryo with the destruction of the human embryo⁵⁶ implies that the element of destroying human embryos in the process of hES cell derivation played a significant role. This is more apparent in the “California Stem Cell Decision”, which holds that the destruction of human embryos in the derivation of hES cells is sufficient to have the patentability of inventions consisting of or containing hES cells excluded under the clause referring to the industrial or commercial use of human embryos.⁵⁷

The *WARF* Decision applied a contestable reading of the Biotechnology Directive. The commercial element for the purpose of the “industrial or commercial use clause” was found in the allegedly commercial act of

53. *Foundation for Taxpayer and Consumer Rights and Public Patent Foundation v. WARF*, B.P.A.I. No. 2010-001854, 28 April 2010.

54. G 2/06, para 25, cited *supra* note 2.

55. The clause on the industrial or commercial use of human embryos. *Ibid.*, para 29.

56. *Ibid.*, para 27 (“That this is not the case here is evident, since the embryos used to perform the invention are destroyed”).

57. T 522/04, para 7, cited *supra* note 2.

preparing an invention for patenting. Moreover, the Decision never clarified the impact on the interpretation and application of the clause of the ethically objectionable fact that the derivation of hES cells necessitates the destruction of human embryos. The application of the general public morality clause was not considered. In the view of commentators, this was the most serious shortcoming of the Decision, because the application of the general public morality clause may make the application of Rule 28(c) unjustifiable.⁵⁸

4.2. *Take two: A local interpretation of the Biotechnology Directive: the Brüstle stem cell patent in Germany*

The EPO's interpretation of the Directive found an unlikely follower at the national level in the decision of the German Federal Patent Court in a case concerning the stem cell patent⁵⁹ associated with the eminent researcher Oliver Brüstle. Brüstle's research requiring the use of human embryonic stem cells had been subject of serious controversy and led to the adoption of the German Stem Cell Act,⁶⁰ the legislation regulating stem cell research in Germany and an important element in the Patent Court's decision. In its judgment, the court held that the hESC patent in question was in breach of the "industrial or commercial use clause", as the destruction of human embryos was a "real and integral part of the invention".⁶¹ The court argued that the destruction of human embryos is a necessary preliminary activity of the said invention, and stated that with the "industrial or commercial use clause" the legislature had given supremacy to the constitutional protection of human embryos over the inherently commercial characteristics of inventions.

The interpretation of the Directive by the German court was directly influenced by the domestic legal environment relating to the regulation of human embryonic research. The judgment deliberately linked the morality provisions of the Directive to the ethical boundaries established in the Act on the Protection of the Human Embryo and the Stem Cell Act,⁶² the most relevant of which prohibits the improper uses of human embryos, including the use of human embryos for the derivation of hES cells, in German jurisdiction. The Stem Cell Act introduced a prohibitive regime for human embryonic stem cell research allowing research only on hES cells imported from other countries subject to a "cut-off date" requiring that the imported cell

58. Sterckx and Cockbain, *op. cit. supra* note 31, p. 96.

59. German patent number DE 197 56 864 (C1) and EPO patent number EP 1040185.

60. Taupitz, "The German stem cell Act", 11 *German Law Journal* (2010), 1373–1374.

61. Judgment AZ: 3 Ni 42/04, cited *supra* note 3.

62. <www.gesetze-im-internet.de/bundesrecht/eschg/gesamt.pdf> and <www.gesetze-im-internet.de/bundesrecht/stzg/gesamt.pdf> (last visited 8 May 2012).

lines were derived before 1 January 2002. The Act treats hES cells differently from other human biological material on the grounds that in the course of their derivation the destruction of human embryos is necessary; it permits their use (the use of imported cell lines) in research in extremely limited circumstances as a minimal concession to the constitutional right to freedom of research.⁶³

In light of the structure of the morality provisions of the Directive, reliance on domestic biomedical research regulation and the ethical viewpoints expressed therein is an acceptable approach in national patent jurisdictions, provided that we overlook the unfortunate selection of the “industrial or commercial use clause” as the legal basis of the decision. As opposed to the European level, decision makers at the national level under Article 6(1) of the Directive, the general public morality clause, may rely on the local determination of ethical boundaries relating to biomedical research, especially regarding the destruction of human embryos for research purposes. The “industrial or commercial use clause” of the Directive, based on European consensus, is not intended to accommodate local variation in the assessment of biomedical research practices.

4.3. *Take three: The Brüstle stem cell patent before the EU Court of Justice: Estranged multiplicity?*

The reference in *Brüstle* from the German Federal Court, proceeding in appeal from the Federal Patent Court to the EU Court of Justice, the ultimate forum to provide an authoritative interpretation of the Biotechnology Directive, presented the final opportunity to clarify how hESC patents should be treated under the interpretative blueprint provided by the Directive, and also how the moral objection to the destruction of human embryos could be accommodated at the European level under the Directive. To many, the judgment of the Court in *Brüstle* represents the triumph of clarity in the law over the contested and movable boundaries in bioethics of human activity in biomedicine. The Court favoured an interpretation of Article 6 of the Directive which applied the “industrial or commercial use clause” to hESC patents and which secured the uniform application of the law before all relevant forums. The application of Article 6(1) instead of Article 6(2)(c) in relation to hES cells, a genuine acknowledgement of value multiplicity and local diversity in determining the ethical acceptability of hESC research, was not considered.⁶⁴

63. Taupitz, *op. cit. supra* note 60, p. 1379.

64. The question from the referring court suggested that Art. 6(1) may play a role in determining the patentability of hES cells.

The Court held first that European patent law under the Biotechnology Directive operates with a uniform concept for the human embryo, covering the fertilized egg and the subsequent stages of embryonic development, SCNT embryos and parthenogenetic embryos. Second, the Court contended that under Article 6(2)(c) the patentability of inventions consisting of or containing hES cells must be excluded on the ground that applying for a patent with the intention to exploit the commercial rights derived from patents would mean that the invention, the relevant innovative human activity, acquired a commercial or industrial nature irrespective of whether the human activity in question, basic biomedical research, had an essentially non-commercial nature. Finally and least controversially, the Court ruled that examinations in the patenting process on grounds of public morality should look beyond the patent claim and consider the actual invention, in particular, the origin of the biological material used in the invention.

The interpretation by the Court of the “industrial or commercial use clause” in Article 6(2)(c) of the Biotechnology Directive, as admitted by the Court itself, is identical (or at least bears considerable resemblance) to that provided in the EPO *WARF* Decision.⁶⁵ Again, in determining whether biomedical research could be brought under Article 6(2)(c), the grant of a patent (entailing access to the protection provided by patent law), was in itself found sufficient to mean that the use of human embryos for scientific research represented an industrial or commercial use of those embryos.⁶⁶ The justification for the conclusion that patenting is “connected with acts of an industrial or commercial nature” was provided by Recital 14 of the Directive defining patents as entitling patent holders “to prohibit third parties from exploiting [the patent] for industrial or commercial purposes”,⁶⁷ which led to the final statement that

“Although the aim of scientific research must be distinguished from industrial or commercial purposes, the use of human embryos for the purposes of research which constitutes the subject-matter of a patent application cannot be separated from the patent itself and the rights attaching to it”.⁶⁸

The judgment, in the same way as the EPO’s *WARF* Decision, placed emphasis on the presumed commercial and industrial mindset of patent applicants. They both extended the assessment of patentability to the phase of producing the invention for patenting, and condemned hESC patents on the

65. *Brüstle*, para 45, cited *supra* note 4.

66. *Ibid.*, para 41.

67. *Ibid.*, para 42.

68. *Ibid.*, para 43.

basis of the commercial nature of the act of patenting including, in their interpretation, the activity of preparing the invention to obtain a patent. They correspond with the opinion of Rainer Moufang, member of the EPO Boards of Appeal, that “the intention of commercialization . . . is necessarily linked to a patent application”.⁶⁹

The destruction of human embryos in the derivation process of hES cells did not have a visible impact on the interpretation of the Court. By constructing the link perceived between producing an invention for patenting and the “industrial or commercial use clause”, the Court managed to distinguish the ethical objections expressed in Article 6(2)(c) from the ethical objections against the derivation of hES cells from embryos. The only indication that the Court took notice of the most significant ethical controversy surrounding human embryonic research can be found in its response to the third question, dealing with the gap between the technical teaching as provided in the patent claim and the actual invention. In paragraph 49 the Court held that

“an invention must be regarded as unpatentable, even if the claims of the patent do not concern the use of human embryos, where the implementation of the invention requires the destruction of human embryos. In that case too, the view must be taken that there is use of human embryos within the meaning of Article 6(2)(c) of the Directive”.

Contrasted with the reserved approach of the Court, the Opinion of the Advocate General in *Brüstle* was more open to concerns regarding the consequences of hESC derivation from human embryos.⁷⁰ Its main objection to patentability under Article 6(2)(c) was that (to make an industrial application of) inventions consisting of or containing hES cells “would amount to using human embryos as a simple base material”.⁷¹ The Opinion defined industrial or commercial use as “large-scale production”,⁷² presupposing “cell cultures intended for pharmaceutical laboratories with a view to the manufacture of medicines” and a technique for therapy which requires a large number of cells and embryos “created to be destroyed a few

69. Moufang, op. cit. *supra* note 33, p. 504.

70. Opinion of A.G. Bot delivered on 10 March 2011 in Case C-34/10, *Brüstle v. Greetpeace*, nyr, para 103, “it is not possible to ignore the origin of this pluripotent cell”; *ibid.*, para 104, the blastocyst is “one of the stages in the formation and the development of the human body which the removal will destroy”; *ibid.*, para 109, “inventions relating to pluripotent stem cells can be patentable only if they are not obtained to the detriment of an embryo, whether its destruction or its modification”.

71. *Ibid.*, para 110.

72. *Ibid.*, para 113.

days later”.⁷³ The prospect of commercially motivated industrial scale destruction of human embryos led the Advocate General to advise the Court to decline the patentability of stem cell lines and the related methods. The concluding interpretation of the Opinion of Article 6(2)(c) spoke of the prior destruction of human embryos *or* their use as base material as the main objections against the patentability of hES cells.⁷⁴

5. The view from here

It is difficult not to admire the simplicity of the now prevalent interpretation of the Biotechnology Directive in relation to hESC patents. Under this interpretation, the (preparation of an invention for an) act of patenting will suffice to establish that a commercial use of human embryos has taken place, investing an act of research with an instant commercial character. In our view, however, the underlying argument that biomedical research activity carried out with a view to patenting any invention produced from it represents an essentially commercial activity (i.e. the derivation of the hES cell lines by James Thomson at Wisconsin University was of commercial nature owing to the commercialization activities of WARF) is false. As discussed above in relation to the interpretative framework of the Directive, there are a number of reasons why the validity of the interpretative construction produced under the EPO framework and by the EU Court of Justice remains open to question.

First, this interpretation constitutes a crude simplification of biotechnological research design and the role of the patent system in innovation and research policy. It overlooks the desirability in basic research in biosciences of combining commercial and non-commercial elements for the purpose of achieving the predominantly non-commercial aims of that research; and it ignores the non-commercial benefits patenting may feed into research and innovation activity of public importance. Further, it ignores the considerable temporal and technological gap between deriving stem cell lines from human embryos, executed for the purpose of generating a research tool for further basic research, and the future exploitation of human embryos to produce stem cell lines for products and therapies available in the market. More importantly, it provides a reading of Article 6(2)(c) which impinges upon the interpretative framework of the Directive, as discussed above, placing emphasis on the irrelevant commercial mindset of patent applicants and failing to establish a link between the invention and genuine commercially

73. *Ibid.*, para 114.

74. *Ibid.*, para 117.

focused activities, or activities on an industrial scale and following industrial methods involving human embryos.

The interpretation which should follow from the Directive is a matter of establishing different boundaries of human activity in biotechnology. The EPO and the Court of Justice found the breach of the ethical principle prohibiting the commercialization of human embryos expressed in Article 6 of the Directive in carrying out a/any commercially meaningful activity involving human embryos (a patent claim on hES cells). In contrast, as we claimed earlier, it actually needs to be ascertained that the invention itself constitutes an industrial or commercial use of human embryos; and the examination under Article 6(2)(c) should focus on the commercial or industrial prospects of the invention being placed in the market through the patent system. Article 6 of the Directive was enacted to prevent certain inventions being put on the market for commercial exploitation on account of their incompatibility with public morality requirements,⁷⁵ and not to prevent the placing of human embryos in a commercial context by submitting a patent application. The interpretation by the EPO organs and the EU Court is a cautious and not entirely convincing solution. It fails to give appropriate consideration to the uncertainty of actual uses of hES cells outside the laboratory and to the fact that the intentions of the patent holder concerning the prospective commercialization of the invention are open to change; the whole environment is too dynamic to make future assumptions on the basis of current circumstances. Also, it inflates the importance of the commercial element of submitting a patent claim in the complex process of biomedical research and bio-patenting.

The cautious treatment of hESC patents under the Directive could be explained by the lack of an explicit provision in the Directive dealing with the bioethical implications of hESC technology in patent law. hESC patents raise serious bioethical concerns, so that an interpretation of a provision of the Directive needs to be found in which those concerns could be accommodated. The technology itself (hESC derivation) can not be tackled directly in the same way as human cloning is treated under Article 6(2)(a). In order to fill the gap, the relevant organs decided to address the use of hESC technology to achieve a particular aim, obtaining a patent on an invention consisting of or containing hES cells, and linked this to Article 6(2)(c) on the ground that the derivation of hESC cells for the purpose of obtaining a patent constitutes a commercial use of the embryos destroyed in the process of derivation.

The premature setting in patent law of the boundaries of human activity with embryos and hES cell lines leads to a further complication: extending examination under patent law to a segment of the research process which is

75. See the interpretation provided by the EPO Board of Appeal, *op. cit. supra* note 44.

regulated by a separate body of law answerable to a specific set of bioethical principles. The interpretation advocated by European fora passes an ethical judgement, based on a connection to patenting, on human activity which under the applicable provisions of biomedical research regulation was carried out for research purposes and was authorized as being compliant with the bioethical principles applicable to biomedical research. The interpretation of Article 6(2)(c) by the EPO organs and the EU court ignores national competences in regulating biomedical research.

Evidently, the relevant European fora, needing to deal with hESC patents, favoured a broad interpretation of the terms of the Biotechnology Directive. The advantages of this interpretative approach can be explained with reference to the difficulties of applying the Directive in a multi-actor environment, explained above in the general discussion on Article 6. Its effect of embracing the “highest moral standard” generates the least controversy in a European setting characterized by a multiplicity of viewpoints, and is capable of simplifying patent governance under the Directive in a multi-actor system.

Shifting interpretation towards the highest, most restrictive standard may be considered as the safest option for decision makers in an environment characterized by a plurality of moral viewpoints. The interpretation of Article 6(2)(c) advanced by European fora provides an early and high level of protection against the commercialization of human embryos and follows a precautionary approach wishing to avoid the slippery slope of ethical permissiveness. It has comparable advantages over the alternative solution of applying Article 6(1) and enabling local assessments in determining the moral boundaries of hESC patenting. Without European consensus available on this matter, European decision makers following Article 6(1) would have to give green light to hESC patents and accept the patentability of a socially highly contested invention. Article 6(1) creates an impossible decisional situation for European fora pressed towards Article 6(2)(c) to avoid controversy.

The connection between the interpretation given to Article 6(2)(c) and the destruction of human embryos in the process of deriving stem cells should also be considered in the discussion on the upwards adjustment of moral requirements. While its presence in the EU Court’s reasoning is less accentuated than in EPO practice, it remains open to debate whether the broad interpretation of the terms of the “industrial or commercial use clause” was prompted by concern for the treatment of human embryos in research. As indicated previously, an ethical objection against the harvesting of hES cells from human embryos has no role to play in determining whether an invention

constitutes an industrial or commercial use of embryos⁷⁶ and may only be considered under the general public morality clause under Article 6(1), applied to exclude, on ethical grounds, the availability of certain inventions for commercial exploitation. Considering the diversity of practices among Member States, this question needs to be deferred to the local level and decided in light of the applicable provisions of domestic law, as attempted not entirely reassuringly by the German Federal Patent Court in the domestic proceedings leading to *Brüstle*.

From a governance perspective, the now prevalent interpretation of Article 6(2)(c) of the Directive achieved a uniform treatment of hESC patents in Europe. Uniformity in a multi-layered and multi-actor system of governance characterized by value multiplicity regarding the limits of biomedical research provides certainty and maintains coherence in European patent governance. The alternative of recognizing a margin of moral appreciation at the local level would amplify diversity in the application of the law, jeopardize European control over patentability requirements, and lead to the fragmentation of the system created by the Directive, thus indeed threatening the achievement of its regulatory objectives.

Without suggesting a bias for uniformity before European fora, it is necessary to take into account the benefits of adopting at the European level a uniform legal solution for hESC patents. First, a uniformly applicable solution contributes to achieving the Directive's agenda of market creation and market integration and of establishing a single regulatory framework in Europe for biopatenting. Second, the uniform solution available under Article 6(2)(c) would match the approach developed in the EPO *WARF* Decision, and respond to the need for developing and maintaining uniform patenting practice under the Directive. With this, the broader harmonization efforts of the Directive in European patent law could be acknowledged and a harmonious relationship between the EU and the EPO could be ensured. Relying on the EPO in harmonizing and simplifying European patent law could be vital for the European Union after the recent setback the revived EU patent⁷⁷ suffered from Opinion 1/09⁷⁸ of the Court of Justice.

When discussing the attractiveness of a uniform solution at the European level, the record of the Court of Justice in upholding and managing legal and value multiplicity in Europe must not be left out of the account. In the law of

76. Applying the "embryo destruction" principle under Art. 6(2)c is legally indefensible and clashes with positions regarding the bioethical limits of biomedical research in the EU, under the ECHR and in the Member States, see Plomer, *op. cit. supra* note 34, pp. 83 and 116.

77. Its most recent revival: European Commission Proposal for a Regulation of the European Parliament and the Council implementing enhanced cooperation in the area of the creation of unitary patent protection, COM(2011)215/3.

78. Opinion 1/09 of the Court (Full Court) of 8 March 2011, *nyr*.

the internal market, where regulatory difference and multiplicity presents the most crucial problem, respecting local appraisal and sustaining the diversity of local regulatory solutions based on broader considerations, such as justice, equity, solidarity, or morality, are embedded in the legal framework and the jurisprudence of the Court. The Treaties provide for derogations from the free movement provisions in order to protect domestic regulation from the deregulatory pressures arising from EU law.⁷⁹ The principle of mutual recognition serves to manage regulatory diversity in the internal market in absence of harmonization.⁸⁰ The law of the internal market also acknowledges local appraisal in the protection of fundamental rights; deference to the local assessment of what respect for human dignity requires from regulators was the central element of the judgment in *Omega Spielhallen*.⁸¹ Against this background, developing an interpretation of Article 6 of the Directive which would recognize the multiplicity of viewpoints at the local level regarding the ethical acceptability of human embryonic and hESC research could have been a feasible option for the Court of Justice.

6. Conclusions

The foremost challenge in the harmonization of patenting biotechnological inventions in Europe has been multiplicity. It appears in numerous forms. The reduction of regulatory multiplicity and regulatory differences among the Member States was the main purpose of the Biotechnology Directive, which set out to achieve the objectives of European economic policy in the bioeconomy. The Directive was to recognize the relevant principles of bioethics, and with this, especially as dictated by the human dignity principle, the problem of European value multiplicity became embedded. This presented the additional dilemma of how to sustain and manage that value multiplicity in European governance, which consists of multiple actors in different layers. The tensions inherent in such a regulatory enterprise were brought to the fore by patent claims on a basic research tool, hES cells, an invention generating serious social controversy on account of the treatment of human embryos in the research process.

In applying the Directive to hESC patents, both the EPO organs and the Court of Justice offered a compact solution to a question of considerable ethical and legal complexity. The law as applied by the ECJ in *Brüstle* is clear,

79. Arts. 36, 45 and 52 TFEU.

80. See Armstrong, "Mutual recognition", in Barnard and Scott, *The Law of the Single European Market* (Hart, 2005), 225.

81. *Omega Spielhallen*, cited *supra* note 7.

indicating a cautious treatment of hESC patents and presenting a manageable task for European patent governance. The gap between hESC technology and the provisions of the Directive, and that between research activity with human embryos and the clause excluding from patentability industrial or commercial uses of embryos under Article 6(2)(c), was closed by giving legal relevance to the commercially significant act of applying for a patent (preparing the invention for patenting). The only concern is whether the solution is actually available under the interpretative framework of the Directive, which lays down boundaries in biopatenting as they follow from the principles of European bioethics. The role granted in European patent law to ethical objections against the derivation of stem cells from human embryos also remains to be reassuringly settled.

The *Brüstle* decision of the Court confirmed that the European market, as an exception from global practices, will be closed for hESC patents and holders of hESC patents elsewhere would not be able to exploit the benefits of the patent system in Europe. From the perspective of a globally competitive European bioeconomy, this means that a crucial basic research tool remains part of public science, unrestrained by the legal monopoly of patents and unaffected by the access problems⁸² associated with patenting in public science. In assessing the impact of *Brüstle*, it must not be neglected that last year *Geron Corp.* abandoned the first ever human clinical trials using hESC technology⁸³ and that an ethically less controversial technology is available.⁸⁴ Although Europe's cautious legal treatment of hESC patents will remain a significant chapter in the European bioethical discourse, its actual impact on biomedical research and the bioeconomy appears to have been reduced by technological progress in the field.

82. See, *inter alia*, Gallini, "The economics of patents: Lessons from recent US patent reform (2002)", in Merges et al. (Eds.), *Economics of Intellectual Property Law (Volume I)* (Edward Elgar, 2007), 68–69, and specifically, Joly, "Clinical translation of stem cell therapies – Intellectual property and anticipatory governance", 7 *SCRIPed* (2010), 268.

83. See <www.cirm.ca.gov/PressRelease_2011-11-14> (last visited 25 Jan. 2012).

84. In the form of iPS cells, pluripotent cells created by inducing somatic cells to redifferentiate. See, *inter alia*, <www.icems.kyoto-u.ac.jp/e/> and <www.wicell.org/index.php> (last visited 25 Jan. 2012).