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Case Comment

Dignity, plurality and patentability: the unfinished story of *Brüstle v Greenpeace*

Shawn H.E. Harmon and Graeme Laurie

Aidan Courtney

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Case: [Brüstle v Greenpeace eV \(C-34/10\) \[2012\] All E.R. \(EC\) 809 \(ECJ \(Grand Chamber\)\)](#)

****E.L. Rev. 92** The patenting of living materials has been the subject of extensive controversy, and [Brüstle v Greenpeace](#) represents yet another skirmish over the patentability of inventions reliant on human embryos. This article examines the Court of Justice's decision in [Brüstle](#) from the legal and scientific/commercial angles, which are the two fields where it is proving to be most disruptive. We examine its legal and theoretical implications and shortcomings, focusing on the European law with which it failed to engage, and then its claimed, actual, and possible scientific and commercial consequences. We conclude that this important case, while already having obvious research funding consequences, will have more subtle commercial implications and potentially far-reaching legal consequences, as its questionable definition of the human embryo spills over into other fields.*

Introduction

The patenting of living materials has been the subject of extensive political and policy disagreement and legal confrontation across Europe and beyond. For example, note the controversy that surrounded the adoption of EU Biotechnology Patenting Directive (Biotech Directive),¹ and the many cases that have grappled with the propriety and validity of so-called "life patents" (i.e. patents for inventions based on **E.L. Rev. 93* living material).² The recent case of [Brüstle v Greenpeace eV \(Brüstle\)](#)³ represents yet another skirmish in the ongoing conflict over stem cell based patents and the interaction of the life sciences and intellectual property more generally. It is the first time that the question of the patentability of inventions reliant on the destruction of embryos has come directly and explicitly before the European Court of Justice (ECJ).

In the following article, we examine the [Brüstle](#) case from two perspectives, the legal and the scientific/commercial, for it is these two fields where it is proving to be most controversial and will likely prove to be most disruptive. After outlining the facts of the case and the questions posed to the ECJ, we examine the case's legal and theoretical implications and shortcomings, focusing on the European law with which it failed to engage and questioning the wisdom of its ultimate finding on the meaning of "human embryo". Secondly, we consider the claimed, actual, and possible longer-term scientific and commercial consequences of the decision (i.e. its potential impact for research on the ground).

In the end, we suggest that [Brüstle](#) has some deep legal implications and will have consequences for the development of European law. We also suggest that [Brüstle](#) will have some very practical scientific and commercial implications, and indeed is already doing so. However, this latter impact should not be overstated. Indeed, it is too early to predict with any confidence how these impacts will play out.

The [Brüstle](#) case

Facts

On December 19, 1997, Dr Oliver Brüstle, director of the Institute of Reconstructive Neurobiology at the University of Bonn, Germany, filed a patent concerning isolated and purified neural precursor cells, processes for their production from embryonic stem cells (ESCs), and their use for treatment of neural defects. The patent application claimed that:

- immature precursor cells exist primarily during the brain's development phase;
 - controversies around the use of embryo brain tissue has limited the availability of immature precursor cells for transplantation;
 - ESCs offer new prospects for the production of immature precursor cells for transplantation/treatment;
 - the pluripotency of ESCs can be maintained for many passages, thereby permitting production of almost unlimited quantities of isolated and purified precursor cells having neural or glial properties.
- *E.L. Rev. 94**

Ultimately, it was claimed that the transplantation of cerebral cells derived from embryos into the nervous system will allow for the treatment of numerous neurological injuries and conditions/diseases, including Parkinson's disease, preliminary clinical applications for which have already been developed.

Greenpeace brought an application for revocation of the patent on the grounds that certain claims relied on cells obtained from human ESCs (hESCs), thereby rendering the invention unpatentable under art.2 of the *Patentgesetz* (Patent Law).⁴ This provision implements art.6(1) and (2) of the Biotech Directive, which stipulate that patents may not be granted for inventions whose commercial exploitation would be contrary to *ordre public* or morality, and that, in particular, patents may not be granted for uses of human embryos for industrial or commercial purposes. This provision—which builds on the morality provision contained in art.53 of the European Patenting Convention 1973, as amended, and which mirrors reg.28 of the Implementing Regulations of the European Patent Office—is compatible with provisions in the *Embryonenschutzgesetz* (Protection of Embryos Law).⁵ The latter defines as a criminal offence, inter alia, the artificial fertilisation of ova for purposes other than inducing pregnancy in the woman from whom they originate, and the in vitro development of human embryos for purposes other than inducing pregnancy. Additionally, provisions in the *Gesetz zur Sicherstellung des Embryonenschutzes im Zusammenhang mit Einfuhr und Verwendung menschlicher embryonaler Stammzellen* (Protection of Embryos in Connection with the Importation and Use of Human Embryonic Stem Cells Law)⁶ state that the importation and use of pluripotent ESCs are prohibited unless they and their acquisition meet a range of stated conditions.

The Bundespatentgericht (German Patent Court) allowed the application in part, declaring the patent invalid insofar as the first claim relates to precursor cells obtained from hESCs and the 12th and 16th claims relate to processes for the production of precursor cells derived therefrom. Brüstle appealed the decision.

Questions

In November 2009, the *Bundesgerichtshof* (German Supreme Court) requested a clarification of the legal definition of “human embryos” in relation to patentability. The following questions were referred to the ECJ:

1. What is meant by the term “human embryos” in art.6(2)(c)?
2. What is meant by the expression “uses of human embryos for industrial or commercial purposes”? Does it include any commercial exploitation within the meaning of art.6(1), especially use for the purposes of scientific research?
3. Is technical teaching to be considered unpatentable pursuant to art.6(2)(c) even if the use of human embryos does not form part of the technical teaching claimed within the patent, but is a necessary precondition for the application of that teaching because (a) the patent concerns a product whose production necessitates the prior destruction of human embryos, or (b) the patent concerns a process for which such a product is needed as base material?

In essence, the ECJ was asked, for the first time, whether hESCs are properly described as an “embryo” (which would extend the term to that entity which exists from the moment of conception), or,

alternatively, as a “collection of cells” (which would delay the application of the term until the entity reached a subsequent but identifiable and defined stage of development). If the former, it was then asked whether hESC-based inventions are properly banned under art.6 of the Biotech Directive. **E.L. Rev. 95*

Opinion of the Advocate General

In his Opinion, A.G. Bot prefaced the decision with several foundational observations.⁷ In addition to opining that the legal analysis in this and other controversial science settings must be based on objective, up-to-date and accepted scientific information, he held as follows:

- While the questions posed are difficult legal questions, they are coloured by morality, ethics and notions of *ordre public*.
- The European Union is much more than a market to be regulated; it is a society with (shared) values such as human dignity, which must be vindicated.

These findings *should* have alerted the ECJ to the fact that both morality (and moral values, including dignity) and human rights (especially those founded on dignity), particularly “European” values and rights, should be important to the disposition of the case. These observations reflect the EU constitutional arrangement insofar as the Treaty of Lisbon requires the European Union to accede to the European Convention on Human Rights (ECHR),⁸ and recognises the Charter of Fundamental Rights of the European Union (Charter) as both important to EU functioning and equivalent to the Treaties in practical effect.⁹ They also reflect the view held in previous ECJ jurisprudence to the effect that EU directives and regulations generally, and the Biotech Directive specifically, must comply with fundamental human rights.¹⁰

The legal position—an ambitious mistake

On October 18, 2011, the Grand Chamber of the ECJ handed down its decision. In this part, we critique that decision on the basis of its interaction (or lack thereof) with fundamental guiding values and principles, structuring our comments around the questions posed to the ECJ.

Definition of “human embryos”

On the first question, the proper definition of “embryo”, the ECJ openly acknowledged that a “degree of sensitivity” was warranted stemming from the varied traditions and value systems across the European Union.¹¹ In short, it recognised socio-moral diversity around questions of when life begins, what entities deserve legal protection and who can be viewed as exhibiting moral agency.

This diversity is exemplified by the fact that there is no agreed definition of “embryo” among Member States, nor is there any consensus as to the appropriate moral status to be assigned to an entity so labelled. In some jurisdictions, the prevailing view is that an embryo forms and gains full moral status at conception, whereas in others it is that an embryo forms later, or, regardless of when it forms, the subject entity has limited moral status and accumulates greater moral status with the passage of time and the acquisition of **E.L. Rev. 96* certain traits.¹² The unsolvable “moral status” debate has, to some extent, given way to an equally intractable debate about the “proper valuing” of the embryo.¹³

Importantly, this diversity of positions in relation to the embryo has resulted in the recognition of a wide “margin of appreciation” for Member States over questions about when life begins, who can enforce rights, and when they can do so. Such was explicitly held by the European Court of Human Rights (ECtHR) in *Vo v France*,¹⁴ and *Evans v United Kingdom*.¹⁵ Indeed, looking back, it was the combination of this diversity and the operation of the margin of appreciation that resulted in the Biotech Directive eschewing a definition of the term “embryo” in the first place.¹⁶ Further, in *Netherlands v European Parliament and Council*,¹⁷ a case before the ECJ which specifically considered the Biotech Directive, the Court held that art.6(1) of that Directive allows Member States “a wide scope of manoeuvre and discretion” in applying the exclusion so as to take into account “the particular difficulties to which the use of certain patents may give rise in the social and cultural context of each Member State”.¹⁸ This admonition was obviously forgotten by the panel which decided [Brüstle](#).

In any event, and curiously, the ECJ sidestepped any engagement with this sensitive moral debate (that it readily acknowledged) by simply denying that it was being asked a medical or ethical question.

So, despite the fact that it was being asked to interpret an explicitly morally grounded provision aimed at excluding patents where morality and *ordre public* demand, it claimed that it was rather being asked a purely legal question; it was being asked to provide a legal interpretation of a legislative provision contained within a Community instrument aimed at both promoting biotech investment and protecting fundamental rights. As such, it characterised its function as defining a term for purposes of European patent law, which definition must be cognisant of the aims of the instrument and the rights considered fundamental to European society. However, again curiously, and quite aside from the rich body of socio-moral work that it ignored, the ECJ failed to engage with any *legal* authorities on, for example, the implicated human rights or the concept of human dignity, which is specifically referenced in the Biotech Directive, the EU constitutional order and the jurisprudence of the ECtHR, all of which must surely be relevant to the ECJ's consideration in this case.¹⁹

Rather, the ECJ merely stipulated that all terms of EU law which do not reference the law of a specific Member State must be given an independent and uniform interpretation throughout the European Union, and that the term "embryo", as used in the Biotech Directive, is such a term and so falls within this general rule.²⁰ It then went on to offer such a uniform definition. And contrary to the Advocate General's caution that the legal analysis should be based on objective, up-to-date and accepted scientific information, it offered a strict and bewilderingly broad definition that has been criticised as ignoring scientific subtleties.²¹ Moreover, despite its neglect of any deep theoretical moral or legal inquiry into "human dignity", which **E.L. Rev. 97* can be characterised as elusive,²² it relied on "human dignity" to claim that the aim of art.6 (i.e. to prevent any possibility of patentability where respect for human dignity could be affected) demanded that the term "embryo" be interpreted in a wide sense.²³

In the result, the ECJ defined "embryo" as²⁴ :

1. any human ovum after fertilisation;
2. any non-fertilised human ovum into which the cell nucleus from a mature human cell has been transplanted; and
3. any non-fertilised human ovum whose division and further development have been stimulated by parthenogenesis.

Although these latter entities have not been fertilised, it reasoned, they are nonetheless capable of commencing development into a human being and so must be excluded from patentability.²⁵

In essence, the ECJ has held that "human dignity" (and we are not given much instruction on what this concept means because it was hardly discussed) should be extended to entities that in no way resemble human beings, or even fertilised human embryos awaiting implantation into a female uterus. It made a finding of equality between fully formed humans and individual somatic cells in (or from) the human body. This rather bold finding is made all the more bold (and troubling) by the absence of any prefacing value-based or morally cognisant deliberation. The decision evinced no deep understanding of the meaning or purpose of the important socio-moral concept that is human dignity, nor of its scope or deployment in other socio-legal settings which might influence science and commercialisation (and vice versa). It did not apparently take into account how the concept of human dignity referenced in the Biotech Directive might colour its evaluation by supporting the development of treatments from hESC to positively aid the human dignity of those suffering from long-term illnesses, and how this should or could be balanced. It did not address itself to any *other* values that might be important to the field (or to their definition), nor did it seem to recognise any of the jurisdictions within Europe that consider the destruction of spare embryos and/or embryos specifically created for research to be morally and legally permissible.²⁶ Finally, it failed to acknowledge the ECtHR jurisprudence on the level of protection warranted to pre-natal entities under human rights law.²⁷

All told, the ECJ's definition of "embryo" in [Brüstle](#) is problematic (i.e. subject to severe and justified criticism from scientific, theoretical and practical perspectives). On the latter point, the imposition of a judicially constructed definition, particularly a surprisingly broad and inclusive one, in the face of social **E.L. Rev. 98* and political disagreement seems contrary to both constitutional authority and the Biotech Directive itself, particularly Recital 8 of the Preamble, which states that legal protection of inventions does not necessitate the creation of a separate body of law in place of national patent law.²⁸ Indeed, it has been argued that no court can legitimately impose uniform moral exclusions based on human dignity where the reality points to a diversity of moral positions and legal cultures, and to do so threatens not only the legitimate autonomy of Member States in a pluralistic Europe, but also the

integrity and unity of the Union itself.²⁹

Meaning of “uses for industrial or commercial purposes”

On the second question—whether embryos used in research trigger the “industrial and commercial uses” criteria in the patenting prohibition—the Court held that they do. Only if the invention has therapeutic or diagnostic purposes useful to the embryo might it be saved from this industrial and commercial characterisation.³⁰

In justifying its view, the Court reiterated that definitions assigned to the Biotech Directive are limited to the field of patenting and commercialisation and are not meant to fetter Member States in their regulation of scientific research (and the use of embryos therein)³¹; the regulation of science is separate from the patenting (or commercialisation) of inventions, and they have separate regulatory regimes. The patent system only speaks to the propriety of the science when an invention based on that science becomes the subject-matter of a patent application.³² While this sentiment demonstrates an awareness of the important conceptual separation between patent law and science regulation (discussed further below), the Court's limited engagement with this issue evinces a blinkered view of how patent law operates in the real world. It is well known that the possibility of obtaining a patent (a commercial monopoly) in a technical area has a significant impact on whether and how research organisations move into an area.³³

The ECJ's position also, worryingly, evinces an impoverished view of how patent law should interact with, and be shaped by, other more fundamental legal regimes such as the human rights regime. As noted elsewhere,³⁴ the right to the enjoyment of property is rather settled in the context of the ECHR, and while a wide margin of appreciation is extended to states in relation to defining that right,³⁵ “property” has been held to include intellectual property rights and patents.³⁶ Any limitation of the right to hold and use property is thus subject to “proportionality”; a limitation of the right must not have a disproportionate impact on the individual in relation to the end sought or achieved by the limitation. The ECJ made no reference to this principle, and indeed seems to have breached it insofar as it has fettered rights to property through an interpretation of the prohibition against the “industrial and commercial use of embryos” that includes use of cells, cell lines or products whose derivation requires destruction of an embryo. **E.L. Rev. 99*

While no margin of appreciation is afforded with regard to transposition into Member State domestic law of the list of patent exclusions in art.6(2),³⁷ the exclusions within that list were always understood to be narrow. The “industrial and commercial uses” exclusion in particular was intended to leave as patentable inventions and uses of human embryos that were lawful in Member States.³⁸ The ECJ seems to have dismissed this settled understanding.

Patentability of the invention

The third question put to the ECJ was whether an invention is patentable if it necessitates the destruction of human embryos. Recognising the possible negative consequences arising from the “instrumentalisation and commercialisation” of embryos,³⁹ the ECJ opined that an invention is unpatentable if its production requires either the prior destruction of human embryos or their use as base material, even if the patent application does not refer to the use of human embryos.⁴⁰ It stated:

“The fact that destruction [of the human embryo] may occur at a stage long before the implementation of the invention, as in the case of the production of embryonic stem cells from a lineage of stem cells the mere production of which implied the destruction of human embryos is, in that regard, irrelevant.”⁴¹

Thus any invention reliant on SCs obtained from the destruction of an embryo, whenever that destruction occurred, is unpatentable. Put another way, any invention not based on non-destructive techniques is excluded from patentability.⁴² The ECJ felt entitled to and did reach back as far as necessary to determine the nature of the use of embryos, and has empowered (indeed required) Patent Offices to do the same.

While this is not an entirely surprising approach given that, in WARF/Primate Embryonic Stem Cells ,⁴³ the Enlarged Board of Appeal of the European Patent Office held that inventions reliant on methods of production that necessitated the destruction of an embryo are unpatentable even if the method is not claimed for protection, it means that use of hESCs from biobanks, for example, would also be caught, thereby putting their use by anyone with commercial designs in jeopardy. While proving the

provenance of SCs in any given invention should not be a particularly onerous task (and is, in truth, to be welcomed and, indeed, should be extended to any tissue), this precedent could lead to practical difficulties, particularly if this approach is applied to all applications of the morality provision in the EPC. How far back into the development of an invention are examiners or adjudicators expected to delve when ascertaining patentability? How should research results derived from unethical practices be treated downstream, and should derived products be rendered unpatentable (even if they only rely on the “tainted” element to a small degree)? **E.L. Rev. 100*⁴⁴

Ultimately, the long-term impacts of this approach on both the existence and use of SC banks as well as on the general interpretation of the morality provision are matters for further inquiry.

Summation

We do not object to the ECJ pronouncing on matters of morality that are necessarily implicated by instruments it is called upon to interpret; it is essentially a constitutional court empowered to interpret and apply EU instruments, including the Charter, which clearly anchors European society in a collection of socio-moral values (and associated or derivative rights). However, we are entitled to expect that the ECJ will pursue those forays into the moral directly and honestly. The ECJ’s denial in [Brüstle](#) that it was dealing with moral issues, when clearly (whether directly or indirectly) it was, was disingenuous and disappointing. Even though it was interpreting a provision of patent law, it was interpreting a provision explicitly implicating the moral, and some greater exposition of both the moral and the interaction between the commercial and human rights regimes was warranted; a deeper consideration of human dignity and of how far this “patent law interpretation” was expected to travel (i.e. to interact with other fundamental values and rights and patent law relevant practices in associated fields, etc.) was well within its purview.

The commercial consequences—too early to tell

We have been very critical of the legal foundation and reasoning in [Brüstle](#), but what about its impact on science and commercial activities around science? This is the focus of the following section. At the outset, we acknowledge that the case will be no great boon to the advancement of cellular therapies research and the development of nascent products or their commercialisation in the European Union. Having said that, it need not be fatal to them either. The following pages outline the initial reactions and the basis for more measured responses.

Reactionary responses lending weight to predictions of disaster

Unsurprisingly, there has been extensive reaction to both the Advocate General’s Opinion and the ECJ’s judgment in [Brüstle](#). The most common and emphatically proclaimed view of stakeholders post-decision was that [Brüstle](#) will have a serious negative impact on science, potentially signalling the demise of hESC research in Europe. In this respect, it was predicted that (1) antagonists will be emboldened to pressure for public funding cuts; (2) companies will shift their investment to less restrictive jurisdictions; and (3) translation of discoveries will be realised elsewhere to the dire detriment of European patients and the European science economy.⁴⁵

We do not suggest that these predictions are utterly without merit. Certainly the first one—that antagonists will be emboldened to pressure for public funding cuts—is being played out. For example, the European Parliamentary Committee on Legal Affairs has issued a Draft Opinion on the Horizon 2020 Programme in which it states:

“The rapporteur also draws attention ... to a recent judgment of the Court of Justice which states that human embryonic stem cells are not patentable. If the results of research cannot be patented, this affects the profitability of research and thus the public interest in funding it. **E.L. Rev. 101*

The rapporteur therefore proposes that research which either involves the destruction of human embryos or which uses human embryonic stem cells should be completely excluded from EU funding. It would thus be up to individual Member States to decide, in line with their ethical rules, whether to fund such research from their own budgets.”⁴⁶

In essence, the Committee has adopted the position that public research should be commercialised and that funding decisions should be made on the availability of traditional market tools such as patents.⁴⁷ Parenthetically, we suggest that one should question the wisdom of tying publicly funded research, even EU-funded research, to commercial interests and restrictions. In any event,

stakeholders antagonistic to hESC research have definitely taken succour from [Brüstle](#) :

- COMECE, in an opinion that fails to appreciate the ECJ's limitation of its holding to the commercialisation and IP setting, has "aligned" itself with [Brüstle](#) and called for hESC research to be excluded from EU funding⁴⁸ ; and
- MEPs have threatened to challenge the Horizon 2020 Programme if the views of hESC research antagonists do not carry the day.⁴⁹

In response to these moves, hESC research protagonists have also taken the field.⁵⁰ Ultimately, while the other two predictions have not (yet) come to pass, the point is that the "alarmists" are not without their references.

A plea to more measured responses

Importantly for assessing the overall impact of [Brüstle](#) , it should be noted that the decision leaves whole swathes of current and emerging SC-based research unscathed, and some stakeholders have welcomed the possibility that an absence of patents might accelerate SC research in Europe, possibly even attracting scientists from abroad who might now be less concerned about infringement actions.⁵¹ Consideration of the practical issues suggests that there *may* be (and ought to be) less to be concerned about than initially feared, and that the chilling effect of this case need not be so great. To properly assess the (appropriate) potential impact of [Brüstle](#) , one needs an appreciation of: ***E.L. Rev. 102**

1. the complexity of stem cell biology and the extent to which that complexity provides a rich environment from which to develop medical therapies and technologies in the form of patentable inventions in ancillary fields;
2. the complexity and limits of patent law; and
3. the complexity of the innovation processes and academic/industry interactions, and the multi-factoral assessments that drive commercial investment in the science (and indeed the science itself).

Expertise in any one of these fields (cell biology, intellectual property law, commercial investment) does not properly equip one to see the broader picture of how patents may affect progress across a field. On balance, despite moves like that exemplified by the Draft Opinion, we remain cautiously sceptical about whether [Brüstle](#) will have a major impact on either the practice of ESC research or the commercialisation of ESC technologies in Europe. We are supported by (1) the difference between science regulation and intellectual property; (2) the limits of the decision in light of technological developments; and (3) the legal and practical alternatives to patenting that remain available to investors and inventors.

Science regulation v intellectual property

First, it is wrong to suggest that a ban on patenting under the morality and *ordre public* provision is the same as a ban on the science, investment in the science by governments, charities or private investors, or the commercialisation of products derived from the science. Research (and its regulation) and commercialisation (and its regulation via patenting law) *are* capable of dissociation from one another. Declaring certain types of inventions unpatentable is not the same as prohibiting the development, production, sale or use of such inventions. To fully appreciate this, it is important to understand what a patent is and does, and what the ECJ said in its judgment.

A patent is merely a statutorily created artefact which evidences a right enforceable by an inventor (or patent holder where they are not the same) when an invention meets the technical/legal criteria of novelty, inventiveness, and industrial applicability. That right entitles the patent holder to block others from marketing/using the invention. It is a negative right. It does not give the patent holder any additional rights relating to the use or exploitation of the invention (which may be subject to any number of regulatory regimes and stipulations). Indeed, it is quite possible to hold a patent on an invention but be blocked from making and/or marketing the invention by virtue of other patents which, for example, cover technologies required for exploitation. The law leaves it to the patent holders to negotiate whatever arrangement is achievable to alleviate such gridlock.

In its decision, the ECJ has offered definitions relevant to the interpretation and application of the

Biotech Directive, which is aimed at harmonising certain commercial practices across the European Union.⁵² It has said nothing about the propriety of pursuing hESC research, even that which might derive from material that necessitates the destruction of embryos. It has only said that *patenting* such inventions is prohibited under the Biotech Directive.⁵³ Member States remain free to authorise and fund research under a variety of reasonable conditions, and to authorise the marketing of medical devices and medicinal products based on them, and investors remain free to support such research and to profit from the sale of any products derived therefrom. Even if development work is carried out on human embryonic inventions *E.L. Rev. 103 outside the European Union, there is nothing in [Brüstle](#) (or the Draft Opinion) to prevent the importation or circulation of products or combination devices within the European Union.

The ban and emerging technical developments

As indicated, [Brüstle](#) prohibits the patenting of any invention that relies on or uses human embryos for “industrial or commercial purposes”. Inventions which involve or necessitate the destruction of a human embryo are prohibited from patenting regardless of how far removed the invention is from that original destruction; if the destruction is necessary for the invention to be made or used, the invention will be unpatentable.⁵⁴ Obviously, as noted above, this is a far-reaching approach. While complaints about the stifling effects of patents on research processes and tools *might* be alleviated by this decision, the fact remains that it goes further, holding that even eventual products will remain unpatentable.

However, and importantly, financial incentives to pursue this field have *not* been completely removed. While EU funding may be at risk,⁵⁵ funding from those Member States which are supportive of hESC research as well as private funding should still be available. Researchers may still see Europe (and particularly the United Kingdom) as an attractive place to undertake the research because of the robust regulatory regime that exists, especially in light of forthcoming reviews of the Directive on Medical Devices and Regulation on Advanced Therapy Medicinal Products. Additionally, if the manufacture or use of an invention can be achieved *without* the destruction of an embryo (or use of an ovum), then it remains patentable. If one could procure cells which had the same properties as hESCs but which used other starting material, or if one could produce hESCs without destroying the embryo, then many inventions which were hitherto linked to destructive methods could be decoupled from that process and become patentable.

Techniques that have emerged after Dr Brüstle’s patent application was filed should therefore be unaffected by the decision. For example:

- In 2006, data was published showing that a hESC line could be established from a single cell extracted from an embryo at the stage when it consists of only eight cells.⁵⁶ The technique employed to extract that cell (called a blastomere) was modelled on the existing medical technique used in pre-implantation genetic diagnosis (PGD), which is non-destructive insofar as it does not impair the ability of the embryo to develop, and it has been used clinically since 1990.⁵⁷
- In 2006 and 2007, it was demonstrated that adult skin cells (implicating neither ova nor embryos) can be reprogrammed to acquire a pluripotency similar to ESCs.⁵⁸ Whether such induced pluripotent stem cells (iPSCs) are the same (or as versatile or valuable) as hESCs *E.L. Rev. 104 remains a matter of scientific inquiry, but if they are, they will be just as useful as a starting material for the production of new cellular therapies as hESCs. Indeed, results have been published to demonstrate that iPSCs can be differentiated into neuronal precursor cells and could possibly be used in the type of cellular therapy originally envisaged by Dr Brüstle.⁵⁹ While this work is at least partially founded on an understanding of the biological processes underway in, and the functioning of, hESCs, it would be an extraordinary stretch for this foundation to support a conclusion that inventions which build on these scientific discoveries are unpatentable.

Of course, the development of iPSCs and single blastomere hESCs does not mean that hESCs are obsolete; hESCs are still regarded as the “gold standard” for pluripotency and the measure against which these other techniques are compared. Further, many scientific and regulatory questions remain to be addressed for these other techniques, not least their suitability for clinical use. Nonetheless, these and other developments illustrate how the continuation of fundamental research is likely to lead to sources of pluripotent SCs which can be used as the basis for patentable inventions notwithstanding [Brüstle](#) . One certain impact of [Brüstle](#) will be that researchers will seek patents for iPSC-based (and single blastomere hESC-based) inventions that build on fundamental research which started with (now) unpatentable hESCs.

Commercial and regulatory realities and opportunities

Importantly, patents are not the only tool in the inventor's or the investor's toolbox. As noted, they are but one limited and socially constructed piece of the commercialisation landscape. It has been reported that trade secrets, tax incentives and rapid innovation can be, and often are, as important as the availability of patents for encouraging activity in a specific field.⁶⁰ In fact, as alluded to above, *prohibiting* patents can *facilitate* the dissemination and use of knowledge or technologies in that field, and whether that would be the case in the SC field is an empirical question that remains open. Methods of medical treatment, including surgical procedures, for example, remain unpatentable in many jurisdictions, including Europe, not because of any desire to prohibit their use, but rather to address the concern that health practitioners should not be fettered in their choice of treatment methods. Many methods have thus been developed and disseminated.

Of course, embryo and hESC science constitute a nascent field which requires investment before broadly usable technologies (or products) will be developed, and it might therefore be differentiated from surgical procedures. One might argue that preventing patent-based monopolies undermines the rationale for commercial investment and thus indirectly undermines the development and use of embryo-derivative technologies because competitors could develop (and sell) almost identical "me too" products. While this is by no means an unfounded argument, it only goes so far, and this complaint against [Brüstle](#) is potentially overblown. Commercial investment is unlikely to stand or fall on the availability of a single patent (or the availability of a patent in a single or narrow field of innovation). Investment is based on an expectation of future profits and the ability to defend one's market from competition. While patents offer a well-established mechanism for achieving this, complex and highly regulated products such as cellular therapies might rely on other mechanisms, the most immediate of which is based on a combination of trade secrets and marketing demands.

In essence, controlling access to the cell-line that provides the starting material for the cellular therapy in question would represent a substantial barrier to competitors hoping to develop market diluting "me **E.L. Rev. 105* too" products, and therefore might reasonably encourage commercial investment in that cellular therapy. In jurisdictions like Europe and the United States, extensive and expensive pre-clinical and clinical trials are required before a therapy will be approved for clinical use (by the European Medicines Agency or the US Food and Drug Administration respectively).⁶¹ In the case of new cellular therapies, the data generated by these trials is necessarily specific to the cell-line used. Even if one accepts that a cellular therapy can have a "biosimilar" version (which is questionable), the "me too" product could not be approved in Europe for eight years post-original if that product relies on the same clinical data as the original, and it cannot be marketed in Europe for another two years.⁶² Use of another cell-line would require evidence of equivalence, the generation of which would be no trivial matter, and, in any case, access to the original cell-line for comparative studies would still be required. If the original cellular therapy qualifies for orphan status (and many cellular products will), then no application for marketing authorisation can be entertained for a "me too" product for 10 years post-designation.⁶³

In short, while competitors *could* develop similar therapies using alternative cell-lines and unique processes, the time and expense required to do so will be a significant deterrent for those considering entering the market several years later with a "me too" product. Obviously, this is not the same as direct patent protection, and the (economic) utility of this approach will rely to a great extent on the quality and efficacy of the domestic regulation of science and the market. Ultimately, the [Brüstle](#) decision forces (or should prompt) individual Member States to take steps to ensure that their regulatory environments around science, access to research resources and product authorisation are attuned to the commercial realities and are more joined up with respect to delivering a coherent set of objectives when it comes to supporting the research. Given that patenting is no longer (and should never be) the be all and end all, the focus of Member States should now shift to other means to promote and protect investment.⁶⁴

If investors can identify other mechanisms by which to grow and/or defend their market (i.e. other means of generating income, or other techniques for generating similar outcomes), then the fallout from [Brüstle](#) will not be catastrophic. The absence of patents on hESC-based products in Europe may even accelerate some elements of research. European researchers will now be entitled to make use of teachings in relevant US patents without the need of a licence, as they now have no fear of patent infringement actions.⁶⁵ This could encourage wider experimentation and testing of data, which might see the field develop toward new avenues of investigation that might have otherwise been viewed as uneconomical. Product development aside, it might also encourage the increased use of hESC-based

or cellular products and technologies in Europe. The invalidity of hESC-based patents may be seen as an invitation for **E.L. Rev. 106* companies to develop and introduce products which could not be marketed in other jurisdictions (where patentability persists). Indeed the “free rider” benefits of avoiding costly upfront investment in R & D may make Europe the “go-to” place for hESC-based products. Ultimately, investment in the field will be determined on a case-by-case basis and it would be rash to predict the overall impact of [Brüstle](#) at this time.

Summation

Importantly, science has moved on since Dr Brüstle filed his application. Pluripotent SCs no longer necessarily come from destroyed embryos; emerging techniques make the scope of [Brüstle](#) more limited than it might first appear. It does not stop researchers from conducting research, nor does it prevent them from seeking patents in other countries, and they need not relocate their research to avail themselves of that protection. Additionally, alternative regulatory protections, such as those associated with orphan drug designation, continue to offer a period of market exclusivity. Having said that, we would not wish to be viewed as saying that [Brüstle](#) will have no impact on the commercialisation of hESC technologies and therapies in Europe; this is patently not the case. Rather, aside from the rather blunt reactions of antagonists, the commercial impact (particularly as shaped by researchers and research organisations working in the field) will likely be more subtle than many might appreciate, and it will require a thoughtful reorientation of strategy towards the role of the Member State.

Conclusions

To state the obvious, [Brüstle](#) is an eminently noteworthy case. In addition to its real (if subtle) commercial implications—which we hope we have put into better perspective—the ECJ’s application of “human dignity” can be expected to generate extensive debate and probably more litigation. Indeed, it is this value-based aspect of the case that is most troubling and potentially impactful for Europe, not least because of the coupling that the ECJ made as between “industrial and commercial purposes” and “pure research”. The ECJ’s “patent law understanding” of human dignity—which betrayed little awareness of the underpinning reasons for, or the socio-legal consequences of, the social variation which it acknowledged in the decision—will interact with (and potentially shape) other policy and regulatory spheres, both Union and Member State, as we are already seeing via the Draft Opinion. The broad influence of EU institutions and their decisions cannot be denied, particularly given the “mission creep” the European Union exhibits in arenas such as health, which is notionally one of domestic competence. This understanding of human dignity will be picked up by stakeholders where battles are still being fought for recognition that ailing patients awaiting novel treatments deserve greater vindication of their human dignity and dignity-based rights than do individual cells from the body.

Shawn H.E. Harmon and Graeme Laurie

School of Law and J Kenyon Mason Institute for Medicine, Life Sciences and Law, University of Edinburgh

Aidan Courtney

Roslin Cells; J Kenyon Mason Institute for Medicine, Life Sciences and Law, University of Edinburgh

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1. Directive 98/44 on the legal protection of biotechnological inventions [1998] OJ L213/13. This is discussed in S. Harmon, “From Engagement to Engagement: The Expression of Moral Values in European Patent Proceedings, Present and Future” (2006) 31 E.L. Rev 642.
2. In the United Kingdom, [Genentech Inc’s Patent \[1989\] R.P.C. 147 CA \(Civ Div\)](#), and [Kirin-Amgen Inc v Hoechst Marion Roussel Ltd \[2004\] UKHL 46; \[2005\] R.P.C. 9](#) considered whether gene sequences are patentable “inventions” as opposed to unpatentable “discoveries”, holding that, standing alone, a gene sequence is a “discovery”, but, if on the basis of that discovery one can tell people how it can be usefully employed, then a patentable invention may result. In [Eli Lilly v Human Genome Sciences \[2011\] UKSC 51; \[2012\] R.P.C. 6](#), the UK Supreme Court adopted a relaxed approach to the “industrial application” condition for patenting, citing a need to align with other EPO members. Beyond these technical conflicts, controversies persist around patenting inventions the material for which originates in human embryos and their destruction: EDINBURGH/Animal Transgenic Stem Cells, Patent Application No.94913174.2, July

- 21, 2002, Opposition Division, and WARF/Primate Embryonic Stem Cells, Patent Application No.96903521.1-2401, July 13, 2004, Examination Division, appealed to the Technical Board of Appeal, which, by decision T-1274/04-3.3.08, dated November 18, 2005, referred the case to the Enlarged Board of Appeal, whose decision, Case G0002/06 dated November 25, 2008 is available at <http://www.epo.org/law-practice/case-law-appeals/recent/g060002ep1.html> [Accessed December 14, 2012].
3. [Brüstle v Greenpeace eV \(C-34/10\) \[2012\] 1 C.M.L.R. 41.](#)
 4. BGBl, 2005 I, p.2521.
 5. BGBl, 1990 I, p.2746.
 6. BGBl, 2002 I, p.2277.
 7. [Brüstle \(C-34/10\) \[2012\] 1 C.M.L.R. 41](#), Opinion of A.G. Bot, March 10, 2011.
 8. Article 6(1) of the Treaty on European Union, as amended by the Treaty of Lisbon [2007] OJ C306/1, in force on December 1, 2009 (TEU).
 9. Article 6(2) TEU. For more on this, see *P. Craig and G. de Búrca (eds), The Evolution of EU Law, 2nd edn (Oxford: Oxford University Press, 2011)* ; and S. Douglas-Scott, "The European Union and Human Rights After the Treaty of Lisbon" (2011) 11 Human Rights Law Review 645.
 10. In *Netherlands v European Parliament & Council (C-377/98)* [2001] E.C.R. I-7079; [2001] 3 C.M.L.R. 49, a previous ECJ case considering the compatibility of the Biotech Directive with human rights, A.G. Jacobs emphasised at [197] that respect for fundamental rights must be protected through EU law.
 11. [Brüstle \(C-34/10\) \[2012\] 1 C.M.L.R. 41](#) at [30].
 12. For more on this, see S. Harmon, "Emerging Technologies and Developing Countries: Stem Cell Research (and Cloning) Regulation and Argentina" (2008) 8 *Developing World Bioethics* 138; and A. Siegel, "Ethics of Stem Cell Research" in E. Zalta (ed.), *The Stanford Encyclopaedia of Philosophy (Stanford: Metaphysics Research Lab, 2008)*.
 13. See B. Farsides and R. Scott, "No Small Matter for Some: Practitioners' Views on the Moral Status and Treatment of Human Embryos" (2012) 20 *Med. Law Rev.* 90.
 14. [Vo v France \(2005\) 40 E.H.R.R. 12.](#)
 15. *Evans v United Kingdom* (2008) 48 E.H.R.R. 34.
 16. M. Rowlandson, "WARF / Stem Cells (G2/06): The Ordre Public and Morality Exception and its Impact on the Patentability of Human Embryonic Stem Cells" (2010) 32 *Euro. I.P. Rev.* 67.
 17. *Netherlands v European Parliament and Council (C-377/98)* [2001] E.C.R. I-7079; [2001] 3 C.M.L.R. 49.
 18. *Netherlands v European Parliament and Council (C-377/98)* [2001] E.C.R. I-7079 at [37]–[38].
 19. A point made in A. Plomer, "After Brüstle: EU Accession to the ECHR and the Future of European Patent Law" (2012) 2 *Queen Mary J. I. P.* 110.
 20. [Brüstle \(C-34/10\) \[2012\] 1 C.M.L.R. 41](#) at [25]–[29].
 21. K. Vrtovec and C. Scott, "The European Court of Justice Ruling in Brüstle v Greenpeace: The Impacts on Patenting of Human Induced Pluripotent Stem Cells in Europe" (2011) 9 *Cell: Stem Cell* 502.
 22. See *Omega Spielhallen und Automatenaufstellungs-GmbH v Oberbürgermeisterin der Bundesstadt Bonn (C-36/02)* [2004] E.C.R. I-9609; [2005] 1 C.M.L.R. 5. See also R. Macklin, "Dignity is a Useless Concept" (2003) 327 *B.M.J.* 1419; T. Caulfield and R. Brownsword, "Human Dignity: A Guide to Policymaking in the Biotechnology Era?" (2006) 7 *Nature Reviews Genetics* 72, and others.
 23. [Brüstle \(C-34/10\) \[2012\] 1 C.M.L.R. 41](#) at [34].
 24. [Brüstle \(C-34/10\) \[2012\] 1 C.M.L.R. 41](#) at [30]–[36].
 25. With regard to stem cells (SCs) obtained from a human embryo at the blastocyst stage, it directed the referring court to ascertain, having regard to the science in operation, whether they are capable of so developing and therefore constituting an "embryo" such that they should be excluded from patentability: [Brüstle \(C-34/10\) \[2012\] 1 C.M.L.R. 41](#) at [38].
 26. Indeed, efforts to include a ban on such conduct within the Biotech Directive failed, and both Directive 2004/23 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells [2004] OJ L102/48 and the Regulation on advanced therapy medicinal products [2007] OJ L324/121 adopt a permissive approach, deferring to Member States the evaluation of the moral and legal acceptability of such scientific and commercial uses: A. Plomer, "Article 6(2)(c) of the Directive — Towards Systemic

Legal Conflict" in A. Plomer and P. Torremans (eds), *Embryonic Stem Cell Patents: European Law and Ethics* (Oxford: Oxford University Press, 2009), pp.174–202.

27. As exemplified by [Vo v France \(2005\) 40 E.H.R.R. 12](#) ; Evans v United Kingdom (2008) 48 E.H.R.R. 34; and [A, B & C v Ireland \(2011\) 53 E.H.R.R. 13](#).
28. Plomer, "After Brüstle" (2012) 2 Queen Mary J.I.P. 110, 125.
29. A. Plomer, "Human Dignity, Human Rights and Article 6(1) of the EU Directive on Biotechnological Inventions" in *Embryonic Stem Cell Patents* (2009), pp.203–227.
30. [Brüstle \(C-34/10\) \[2012\] 1 C.M.L.R. 41](#) at [39]–[46].
31. [Brüstle \(C-34/10\)](#) at [40].
32. [Brüstle \(C-34/10\)](#) at [42]–[43] .
33. See R. Tijssen, "Global and Domestic Utilization of Industrial Relevant Science: Patent Citation Analysis of Science-Technology Interactions and Knowledge Flows" (2001) 30 Research Policy 35, and many others.
34. Plomer, "After Brüstle" (2012) 2 Queen Mary J.I.P. 110, at 130–132.
35. As contained in art.1 of the 2001 Protocol on the Enforcement of Certain Rights and Freedoms not included in the Convention.
36. See Smith Kline and French Laboratories Ltd v Netherlands (12633/87), October 4, 1990 (Commission), and Lenzing AG v United Kingdom (38817/97), September 9, 1998 (Commission).
37. The list must be implemented in full: see Commission of the European Communities v Italy (C-456/03) [2005] E.C.R. I-5335.
38. G. Porter, "The Drafting History of the European Biotechnology Directive" in *Embryonic Stem Cell Patents* (2009), pp.3–26.
39. See S. Sterckx, "The European Patent Convention and the (Non)Patentability of Human Embryonic Stem Cells — The WARF Case" (2008) 12 I.P.Q. 478.
40. [Brüstle \(C-34/10\) \[2012\] 1 C.M.L.R. 41](#) at [49]–[52].
41. [Brüstle \(C-34/10\) \[2012\] 1 C.M.L.R. 41](#) at [49].
42. The Advocate General opined that, if this were not the case, patent drafters could get around the provision by simply not mentioning in the application that embryos were used or destroyed: see [Brüstle \(C-34/10\) \[2012\] 1 C.M.L.R. 41 at \[108\]](#).
43. WARF/Primate Embryonic Stem Cells, Patent Application No.96903521.1-2401, Case G0002/06, November 25, 2008, Enlarged Board of Appeal, <http://www.epo.org/law-practice/case-law-appeals/recent/g060002ep1.html> [Accessed December 14, 2012].
44. E. Bonadio, "Stem Cells Industry and Beyond: What is the Aftermath of Brüstle?" (2012) 1 E.J.R.R. 93.
45. See A. Abbott, "European Court of Justice Rejects Stem-Cell Patents", *Nature News*, March 10, 2011, <http://www.nature.com/news/2011/110310/full/news.2011.152.html> [Accessed December 14, 2012]; A. Smith, "'No' to Ban on Stem Cell Patents" (2011) 472 Nature 418; A. Plomer's response to E. Callaway, "European Ban on Stem-Cell Patents has a Silver Lining" (2011) 478 Nature 441; A. Abbott, "Stem Cells: The Cell Division" (2012) 480 Nature 310; and the quotes offered by *Neuro Stemcell*, "European Court Bans Stem Cell Patents" (October 18, 2011), <http://www.neurostemcell.org/european-court-bans-stem-cell-patents/> [Accessed December 14, 2012].
46. *European Parliamentary Committee on Legal Affairs, Draft Opinion on the proposal for a regulation establishing Horizon 2020 — the Framework Programme for Research and Innovation (2014-2020)*, 2011/0401(COD), p.3.
47. Recall that much funding for basic science, which is (or should be) "pre-commercial", comes from public and charitable sources rather than private/commercial investment: see <http://www.guardian.co.uk/science/2010/oct/07/science-funding-cuts-firms-charities> [Accessed December 14, 2012]; and A. Stevens et al., "The Role of Public-Sector Research in the Discovery of Drugs and Vaccines" (2011) 364 N. E. J. M. 535. For more on the "commercial turn" in academic research, which is more often than not publicly funded, see T. Caulfield, S. Harmon and Y. Joly, "Open Science Versus Commercialisation: A Modern Research Conflict?" (2012) 4 Genome Medicine 17; and S. Harmon, T. Caulfield and Y. Joly, "Commercialisation v Open Science: Making Sense of the Message(s) in the Bottle" (2012) 12 Med. Law International 3.
48. *Commission of the Bishops' Conferences of the European Community, "Position Paper of the Secretariat of COMECE on some Ethical Aspects of Horizon 2020"*, <http://www.comece.org/site/en/press/pressreleases/newsletter.content/1483.html> [Accessed December 14, 2012].

49. A. Plomer, "Horizon 2020: EU Funding of hESC Research in the Balance" (October 24, 2012), *Eutopia Law*, <http://eutopialaw.com/2012/10/24/horizon-2020-eu-funding-of-hesc-research-in-the-balance/#more-1529> [Accessed December 14, 2012].
50. See *Coalition of Funders*, "Statement Supporting Funding for Stem Cell Research in Horizon 2020" , <http://www.mrc.ac.uk/consumption/groups/public/documents/content/MRC008737.pdf> [Accessed December 14, 2012] .
51. E. Callaway, "European Court Bans Patents Based on Embryonic Stem Cells" (October 18, 2011), *Nature News*, <http://www.nature.com/news/2011/111018/full/news.2011.597.html> [Accessed December 14, 2012]. It has long been known that patent thickets have discouraged some investigations: see J. Sulston, "Heritage of Humanity" (2002), <http://www.mondediplo.com/2002/12/15genome.pdf> [Accessed December 14, 2012].
52. This (limited) ambition is clearly stated in the Preamble to the Biotech Directive itself and is confirmed by the ECJ in *Netherlands v European Parliament & Council* (C-377/98) [2001] E.C.R. I-7079, and *Re Adolf Truley* (C-373/00) [2003] E.C.R. I-1931.
53. A fact emphasised in some responses to A.G. Bot's Opinion—see A. Denoon, "Brüstle v Greenpeace: Implications for Stem Cell Research" (2011) 6 (6 Suppl.) *Regen Med.* 85—and acknowledged in the ECJ's decision itself.
54. [Brüstle \(C-34/10\) \[2012\] 1 C.M.L.R. 41](#) at [47]–[52]. Note that, while the ECJ's definition of embryo relies on the condition that the entity be "capable of commencing the process of development of a human being", and therefore may be quite inclusive, its simultaneous reliance on the use of human ova may ultimately limit the scope of the ban.
55. *European Parliamentary Committee on Legal Affairs, Draft Opinion on the proposal for a regulation establishing Horizon 2020 — the Framework Programme for Research and Innovation (2014–2020)*, 2011/0401(COD).
56. I. Klimanskaya et al., "Human Embryonic Stem Cell Lines Derived from Single Blastomeres" (2006) 444 *Nature* 481.
57. One can imagine a couple using PGD within the context of their IVF treatment authorising their physician to allow the extracted single cell from the embryo to undergo a division before conducting the genetic analysis such that the second cell can be used to produce a hESC line which would be genetically identical to the implanted embryo. In this case, the production of the cell-line would not involve the destruction of the embryo, and would potentially be of great benefit to it.
58. S. Yamanaka et al., "Induction of Pluripotent Stem Cells from Mouse Embryonic and Adult Fibroblast Cultures by Defined Factors" (2006) 126 *Cell* 663; and J. Yu et al., "Induced Pluripotent Stem Cell Lines Derived from Human Somatic Cells" (2007) 318 *Science* 1917.
59. See M. Wernig et al., "Neurons derived from reprogrammed fibroblasts functionally integrate into the fetal brain and improve symptoms of rats with Parkinson's disease" (2008) 105 *Proc. National Academy of Science* 5856.
60. W. Lesser and M. Mutschler, "Lessons from Patenting of Plants" in M. Rotschild and S. Newman (eds), *Intellectual Property Rights in Animal Breeding and Genetics (United Kingdom: CABI, 2002)*, pp.103–118.
61. With regard to the EMA, see Regulation 1394/2007 on advanced therapy medicinal products [2007] OJ L324/121. With regard to the FDA, see *Good Tissue Practice for Blood and Biologics Companies, Code of Federal Regulations, Title 21, Vol.8, April 1, 2009 (21 CFR 1271)*.
62. So noted by A. Denoon, "Brüstle v Greenpeace: Implications for Stem Cell Research" (2011) 6 (6 Suppl.) *Regen Med.* 85.
63. A fact noted by J. Davies and A. Denoon, "Brüstle Decision is Unhelpful, but Not Catastrophic" (2011) 9 *Cell: Stem Cell* 501.
64. In the United Kingdom, the Human Fertilisation and Embryology Authority obliges all UK-derived hESC lines to be deposited in the UK Stem Cell Bank (UKSCB), and the UKSCB requires all cell-lines to be available for research purposes: *UKSCB, Code of Practice for the Use of Human Stem Cell Lines, Version 5 (Hertfordshire: UKSCB, 2010)*. While a competitor will not be able to access the cell-line under a commercial licence, the availability of the same starting material would enhance the developability of a competitive product with demonstrably similar characteristics to the original, which weakens a trade secret strategy. Thus it is incumbent on UK policy-makers to assess its regulatory setting, including that relating to the UKSCB, having reference to [Brüstle](#) . For more on this, see A. Courtney et al., "Balancing Open Source Stem Cell Science with Commercialisation" (2011) 29 *Nature Biotech* 115.
65. Of course, European researchers may still want to purchase a licence so that any therapies they develop can be sold in the markets where patents are held. In this way, the shadow of US patent law may exert a more direct extra-territorial effect in Europe.