Stem Cell Patenting in the European Union

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As a European intellectual property lawyer, the author is often struck by the amount of comparative analysis in the area of intellectual property which adopts US intellectual property laws, rather than European ones, as their point of comparison. This seems strange when in many respects US intellectual property laws have their own unique features and when European such laws are often more closely aligned with the laws of most other countries in the world. This series of articles aims to expand knowledge of and to explain something of European intellectual property laws; how they got to their present state, what are current hot topics in them, where they are heading and why they matter. This third article in the series will focus on stem cell patenting in the European Union.

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On 20 October 2011, the Court of Justice of the EU (CJEU), the highest court in the European Union, gave judgment in the case C-34/10 Brustle. The judgment will have the effect of rendering many inventions based on human embryonic stem cells, and which would be patentable elsewhere in the world, invalid in the EU and perhaps the rest of Europe. This article discusses how this situation came about, and what it tells us about the relationship between two European organizations each established under international treaties, with no formal link between them, but with competences which overlap in the EU to a limited degree in the field of patents: namely the European Patent Organization, established by the European Patent Convention (EPC) and whose public manifestation is the European Patent Office (EPO), and the EU itself. The former comprises all the countries of the latter, together with many other countries in and around Europe that are not members of the EU, including such economically important countries as Switzerland and Turkey.

The CJEU rarely gets to opine on patent matters. This is because, and in contrast to most other areas of intellectual property, it lacks constitutional competence in most areas of patent law, except in so far as patent exploitation or enforcement touches on the EU Treaties. This has left most of the substantive law of patents in the EU in the hands of EU Member States as well as the EPO, as the body that grants ‘European’ patents, which despite their name have the effect in practice of a bundle of national patent rights. In such role the EPO also has an important norm setting function, and the pronouncements of its Boards of Appeal are treated as authoritative in the EPO Member States. One notable exception to the CJEU lack of competence over patent law is however the area of biotechnology, where as a result of the Biotechnology Directive, the EU, and thus the CJEU, has such competence, but only in so far as patents claim ‘biological material’ which is defined as ‘any material containing genetic information and capable of reproducing itself or being reproduced in a biological system.’ Thus although a DNA sequence will be ‘biological material’ so defined, the proteins for which such DNA sequences code and which actually exert effects on the body are not. Naturally, however the definition of biological material will extend also to all types of cells that are capable of replicating, including stem cells.

The passage of the Biotechnology Directive in the 1990s was long drawn out and contentious, but in retrospect it can be seen as resolving, or in many cases, confirming the previous resolution by the EPO, of many of the controversies that surround biotechnology patenting, such as those most recently encountered in the USA in the Myriad litigation; thus a challenge in Europe on one of the bases mounted in this litigation, and that succeeded at first instance, would have been bound to fail, because Article 3(2) of the Directive provides that ‘[b]iological material

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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.’ Although the Biotechnology Directive is only legally binding on EU Member States, which are obliged to conform their national laws with it, and not on the EPO, the EPO amended its implementing regulations to conform with it, taking the view that the Directive essentially reflected EPO practice anyway.

One area which the Biotechnology Directive did not directly address, because the technology simply did not exist at the time, was that of stem cell therapy. Article 6 of the Directive indirectly addressed this in one of the specific examples it gave of inventions that were to be considered unpatentable because ‘their commercial exploitation would be contrary to ‘ordre public’ or morality’, an exclusion from patentability that is found in Article 53(a) EPC and is permitted by Article 27(2) TRIPS Agreement. One such example, at Article 6(2)(c), renders ‘uses of human embryos for industrial or commercial purposes’ unpatentable.\(^4\) This raises the question as to the patentability of inventions in the area of human embryonic stem cells, because the derivation of such stem cells typically involves the destruction of human embryos.

Stem cells have therapeutic potential and research into, and most uses of, human embryonic stem cells in Europe is regulated at a national, rather than at EU, level. This is because of the major cultural and religious differences that exist between various countries of Europe, reflected for example in their differing views on abortion. Thus some countries ban work on human embryonic stem cells totally, but others, such as the UK, are much more permissive. Against this background, how should public policy principles be applied to inventions in this field, and what is the effect of Article 6(2)(c) of the Biotechnology Directive on these?

The Enlarged Board of Appeal of the EPO, the highest legal authority within the EPO, was faced with this issue in reference to it by an EPO Technical Board of Appeal in Case G2/06.\(^5\) It held that the provision of the EPC implementing regulations that had been amended to conform to Article 6(2)(c) of the Biotechnology Directive forbade ‘the patenting of claims directed to products which – as described in the application – at the filing date could be prepared exclusively by a method which necessarily involved the destruction of the human embryos from which the said products are derived, even if the said method is not part of the claims’.

In the light of this decision, the UK Intellectual Property Office (IPO), which is responsible for examining applications for UK patents and also has jurisdiction as to the UK designations of ones granted by the EPO, amended its previous practice note on the subject and issued a new one in which it observed:\(^6\)

‘… Although there is some opposition in the United Kingdom to research involving embryonic stem cells, a number of reports from influential UK political, medical and scientific bodies\(^7\) in recent years have emphasised the enormous potential of stem cell research, including embryonic stem cell research, to deliver new treatments for a wide range of serious diseases. This indicates that on balance the commercial exploitation of inventions concerning human embryonic pluripotent stem cells would not be contrary to public policy or morality in the United Kingdom. Thus, the IPO is ready to grant patents for inventions involving such cells provided they satisfy the normal requirements for patentability and provided that, at the filing or priority date, the invention could be obtained by means other than the destruction of human embryos.’

In Case G2/06, the EPO Enlarged Board had also considered a request that it seek a preliminary ruling on the issues before it, from the CJEU. It held that, unlike national courts in the EU, it had no power to do so because the EPO made no provision for making such a reference. It took a different case, a couple of years later, referred from the German Patent Court, and in the context of an application by the environmental pressure group Greenpeace to revoke a national German patent granted to the stem cell researcher, Oliver Brüstle, to provide the CJEU with an opportunity to consider the issue.

In Case C-34/10, Brüstle v Greenpeace eV\(^7\) the CJEU held that Article 6(2)(c) of the Biotechnology Directive rendered an invention unpatentable ‘where the technical teaching which is the subject of the patent application requires the prior destruction of human embryos or their use as base material, whatever the stage at which that takes place and even if the description of the technical teaching claimed does not refer to the use of human embryos.’ It noted that Article 6(2)(c) also rendered unpatentable the use of human embryos for purposes of scientific research, with the exception only of ‘use for therapeutic or diagnostic purposes which are applied to the human
COOK: STEM CELL PATENTING IN THE EUROPEAN UNION

embryo and are useful to it’. The CJEU also provided guidance to national courts as to what was to be regarded as a ‘human embryo’ for this purpose, despite submissions by certain EU Member States that this should be matter for discretion at a Member State level.8

Because the patents in issue and the questions that arose in the cases before the Enlarged Board of Appeal of the EPO and the CJEU differed, the latter appears to have gone rather further in its decision in limiting the patentability of inventions relating to human stem cells than did the Enlarged Board. The immediate consequences and wider implications have however yet to be determined. Thus the German Patents Court has yet to apply the decision to the Brüstle patent, and it is notable that the UK IPO has not yet felt the need to further revise its practice note, although the CJEU decision is binding throughout the EU. Neither is it clear what the response of the EPO will be, although it has since even before the decision of its own Enlarged Board of Appeal taken a restrictive approach to patents in this field.

But this may not matter since whilst all this has been happening the science has moved on, in that the technology now exists (although it did not do so at the date of the Brüstle patent) to make human embryonic stem cell-lines that preserve the viability of the donor embryo.9 Neither would it appear that the decision has any effect on the patentability of inventions involving human induced pluripotent stem cells that are not derived from embryos but from other human tissue, and so also have a more favourable regulatory status. Finally, the business seems also to have moved on, in that the main company seeking to commercialize therapeutic applications for human embryonic stem cells, Geron, terminated its research program in the area in November 2011 for reasons unconnected with this decision.

Thus the wider implications of the present dispute may be more limited than might otherwise have been the case. But they well demonstrate the complex and uneasy relationship that exists in Europe as between the CJEU and the EPO. The degree to which their competences overlap in the EU is at present limited to biotechnological inventions. In the event that the proposals currently under discussions for a unitary European patent come to fruition the overlap will extend to all areas of patent law.

References
1 It is for example, in the EU Treaties that the principle of ‘exhaustion of rights’ within the EU finds basis, and by which trade within the EU in an article first placed on the market within the EU by or with the consent of the patentee cannot be impeded by parallel patent rights.
3 Association for Molecular Pathology v USPTO (Fed Cir 29 July 2011).
4 The others are (a) ‘processes for cloning human beings’, (b) ‘processes for modifying the germ line identity of human beings’ and (d) ‘processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.’
5 G2/06, Use of embryos / WARF (EPO Enlarged Board of Appeal 25 November 2008) [2009] OJEPO pages 306–332. T-522/04 Stem Cells/CALEFORNIA [2009] EPO 450A applied this and found that a disclaimer ‘not derived from or by destruction of an embryo’ did not save a claim that was otherwise invalid for this reason as this constituted an addition of matter; Sterckx Sigrid and Cockbain Julian, Assessing the morality of the commercial exploitation of inventions concerning uses of human embryos and the relevance of moral complicity: Comments on the EPO’s WARF decision, SCRIPTed, 7 (1) (2010) 83–103.
6 Inventions involving human embryonic stem cells, IPO Practice Notice dated 3 February 2009.
7 Case C-34/10, Brüstle v Greenpeace eV (CJEU 18 October 2011).
8 It has also been suggested by scientists that the definition adopted by the CJEU is scientifically flawed, Green et al., European stem-cell ruling is misleading, Nature, 479 (7371) (2011) 41.