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Exclusion of patentability of Embryonic stem cells in Europe: another restriction by the European Patent Office

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Main text:

The technical board of appeal of the European Patent Office (EPO) (here after the technical board) recently states in a case law involving Technion Research and Development Foundation (here after the *Technion* case) that it is not acceptable under the European patent Convention¹ (EPC) to patent inventions using human embryonic stem cells (hESC) obtained either by *de novo* destruction of human embryos, or from publicly available hESC lines initially derived by a process destroying the human embryo.² Doing so, it extends the scope of exclusions from patentability for uses of human embryos for industrial or commercial purposes, further than it did in the previous decision of the enlarged board of appeal of the EPO (here after the enlarged board) *Wisconsin Alumni Research Foundation* (here after the

WARF case).³ It also aligned with the decision of the Court of Justice of the European Union (CJEU) *Brüstle v Greenpeace eV* (here after the *Brüstle* case)⁴ that has been widely commented both by lawyers⁵ and scientists.⁶ The *Brüstle* case “troubled” most scientists acting in the field of hESC research as it prohibits patents of hESC that could be obtained in the USA or Asia.⁷ The *Technion* case goes further as it applies beyond the European Union (EU) to all the contracting States to the EPC. Moreover and particularly, it involves that inventions using hESC obtained from the existing hESC lines that are available worldwide are not patentable.

The case was brought up by Technion Research and Development Foundation LTD, an Israeli company that applied for a European patent on methods of maintaining hESC in an undifferentiated state and on a cell culture comprising both hESC and human foreskin cells. The examining division of the EPO refused to grant the patent on the basis that hESC lines referred to in the application and used to carry out the invention were not publicly available at the date of application’s filing. As a consequence, it considered destroying human embryos was the only possibility to realize the claimed method. The company appealed and the EPO’s technical board adopted its decision on 4 February 2014. Although it considered serious doubts remain regarding the public availability of the hESC lines described in the application, it based its decision on the more fundamental criterion of the previous destruction of a human embryo necessary to establish the cell lines.

A wide interpretation of the uses of human embryos for industrial or commercial purposes

On 25 November 2008, the enlarged board in the *WARF* case, decided that the exclusion from patentability for inventions using human embryos for industrial or commercial purposes prohibits to grant European patents with “claims directed to products which-as described in the application- could be prepared, at the filing date, exclusively by a method which necessarily involved the destruction of human embryos”. By declaring unpatentable the products prepared *exclusively* by a method destroying an embryo at the patent filing date, it appeared that the enlarged board chose to let a possibility for the patentability of products and methods involving the use of hESC obtained from previously derived hESC lines and available in biobanks.⁸

The argument of such “depository loophole”⁹ was exactly the one used by the company Technion calling on the methods it used are based on commercially or otherwise publicly available hESC lines which do not involve *de novo* destruction of human embryos, and as such are not excluded from patentability. It was rejected by the technical board even if there was no *de novo* destruction of human embryos for the production of hESC.

Examining the cell lines claimed to be publicly available at the date of application, the technical board noted they were all initially derived from the inner cell mass of blastocyst stage human embryos which resulted in the destruction of such human embryos. Even more, as regards as hESC lines allegedly available from the US NIH, no evidence on file proved that they were obtained by methods not involving the destruction of a human embryo.

The Technion company also argued it would go much too far in the exclusion if one were to take into account all the steps preceding an invention. Such argument was already raised in the *WARF* case and the Enlarged board considered it as “irrelevant”. The latter had a global view on the invention as it distinguished neither the different persons involved in the different steps preceding the invention nor the different points in time when the different steps leading to the invention took place. Referring to the enlarged board in *WARF*, the technical board

rejected the *Technion*'s argument and stated that all steps preceding the invention had to be considered as "a necessary precondition for carrying out the claimed invention". Therefore, the EPC disposals that forbid granting European patents for biotechnological inventions which concern uses of human embryos for industrial or commercial purposes have been interpreted widely by the EPO. In the *Technion* case closing the door let opened by the *WARF* case, the technical board states that "inventions which make use of [hESC] obtained by *de novo* destruction of human embryos or of publicly available hESC lines which were initially derived by a process resulting in the destruction of the human embryo" are excluded from patentability. Such extensive approach is in line with the *Brüstle* ruling of the CJEU.

The European Patent Organization and the European Union

On 18 October 2011, in the *Brüstle* case the CJEU gave an extensive interpretation of the human embryo as well as of the patent's exclusion for uses of human embryos for commercial or industrial purposes. It mainly ruled Article 6(2) (c) of the Directive on the legal protection of biotechnological inventions "excludes an invention from patentability where the technical teaching which is the subject-matter 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".¹⁰ With the *Technion* case, the EPO clearly chose to follow the CJEU's decision although it was not a legal obligation to do it.¹¹ Indeed, the European patent organization (that relies on the EPC and within which the EPO is the executive organ including an examining division to grant European patent, appeal's boards and the enlarged board of appeal) and the EU (within which the CJEU is the main legal Court) are two distinctive European organizations which are not bound together.¹² Moreover, although all the Member States of

the EU are contracting States to the EPC, the European patent organization is wider as it also includes nine non EU Member States. But in 1999, the contracting States to the EPC agreed to adopt the wording of the EU directive on the legal protection of biotechnological inventions to include it in the EPC and to use this directive as supplementary means of interpretation.

Thus, even though the technical board was not legally bound by the CJEU ruling, it considered the *Brüstle* case “as being persuasive” enough to be in line with it while acknowledging the need for uniformity in harmonized European patent law. One can wonder whether the EPO’s intent was solely the relevance of European patent law or if on the basis of the *Brüstle* case, the *Technion* decision of the EPO is a turning point to consider ethical consequences of patentability for biological material.

Surely the *Technion* case will have an impact on the organization of hESC innovation¹³ as it generally extends the *Brüstle* case to the whole Europe beyond the EU Member States. However, the *Technion* case has also direct and new legal consequences regarding the uniform interpretation of European patent law.

The uniformity of European patent law

With the *Technion* case, a better uniformity of European patent law is clearly and legally settled between the EPO and the EU. This could have been foreseen as long as, following the *Brüstle* case, the EPO President’s posted that “If the judges rule in favour of a restrictive interpretation of biotech patentability provisions, the EPO will immediately implement it”.¹⁴ Moreover, on 20 June 2012 the EPO adopted new guidelines that reflect the *Brüstle* ruling.¹⁵ Thus, the *Technion* case ensure such uniformity and it will be applied both for European patents under the EPC and for national patents within the EU Member States which have to

apply the *Brüstle* case that hESC technologies will not be patentable if the used hESC are obtained from the destruction of human embryos whenever is the point in time at which such destruction takes place. Importantly, it can be anticipated that such approach will also be retained to grant the future European patent with unitary effect. Indeed, the latter will be delivered by the EPO under the EPC as a European patent that will obtain a unitary effect, at the patentee's request, on the territories of the States participating to the 'enhanced cooperation' in the field of patent in the EU (all the EU Member States except Spain and Italy). Besides the national patents and the classical European patent, the unitary patent will be another option available from the entry into force of the agreement on a unified patent Court.¹⁶

Nevertheless, although the *Technion* case is in line with the *Brüstle* case, questions remain on the full uniformity of European patent law regarding hESC, especially on how to demonstrate the methods to obtain hESC do not involve the *prior* destruction of human embryo. Enforcing the CJUE ruling in *Brüstle* case, the German Federal Court ruled the German patent of Pr Brüstle could be maintained in an amended form. It notably held that inventions are admissible to patentability if there are methods to obtain hESC from human embryos without destroying them, irrespective of whether such methods are actually described in the patent claims.¹⁷ On the basis of such interpretation of the CJUE ruling in *Brüstle* and its implementation by the German Federal Court for his German patent, Pr Brüstle newly claimed for his European patent that hESC were obtained without *prior* destruction of human embryos. But the opposition division of the EPO revoked entirely his European patent on 11 April 2013 because the non-destruction of human embryos was not mentioned in the original patent application. Thus, the opposition division of the EPO astonishingly avoided the question of proving the use of permitted methods for harvesting hESC. It should be noted that

Pr Brüstle appealed in August 2013 but we are still waiting for the technical board's decision regarding this European patent.

With the *Technion* case, the EPO approach becomes stricter as it appears clearly that evidences on the methods to obtain hESC without the *prior* destruction of human embryos have to be part of the patent claims. This will have strong consequences on the potential patentability of hESC obtained from previously derived hESC lines currently stored in biobanks. In other words, regarding the EPO decision, utilization of such lines for patents could be problematic in the future as the grant of European patents will be refused if it cannot be demonstrated that there was no previous destruction of embryos. In order to help future demand it could be recommended to these biobanks to be clearer on the techniques used for deriving the lines and to make this information obviously available to researchers. Another possibility could be to require this information to be systematically described, as a standard, in the European hESC registry. Moreover, the EPO avoided the question of what is a human embryo and did not refer to the definition established by the CJEU in the *Brüstle* case (any human ovum after fertilization, and any non-fertilized human ovum into which the cell nucleus from a mature human cell has been transplanted or whose division and further development have been stimulated by parthenogenesis)¹⁸ while choosing to focus only on the destruction of the human embryo. It should be highlighted the definition of the human embryo, based on the ability to develop into a human being, has already been the object of diverging interpretations.¹⁹ On the one side, the German Federal Court considered organisms have both to commence and to finish the process of development into a human being to be covered by the definition of the human embryo.²⁰ On the other side, the UK Patent Office rejected two patents applications involving the parthenogenetic activations of oocytes for the production of hESC and pluripotent stem cells lines to derive corneal tissues.²¹ Although it appears parthenotes could not develop into an entirely viable human being, it interpreted the

Brüstle case as excluding parthenotes from patentability as soon as they can start the process of developing into a human being even if they are not able to finish it. Following the applicant's appeal (International Stem Cell Corporation), the case was brought before the UK High Court of Justice which referred the following question to the CJEU for preliminary ruling: "Are unfertilised human ova whose division and further development have been stimulated by parthenogenesis, and which, in contrast to fertilised ova, contain only pluripotent cells and are incapable of developing into human beings, included in the term 'human embryos' in Article 6(2)(c) of Directive 98/44/EC on the legal protection of biotechnological inventions?"²² The uniform interpretation of the definition of the human embryo relies again on the CJEU which should explain whether the start only or the completion of the process to develop into human being will have to be retained. It should be ensured and strengthened if the CJEU follows the opinion of Advocate General Cruz Villalon who considered that "unfertilised human ova whose division and further development have been stimulated by parthenogenesis are not included in the term 'human embryos' in Article 6(2)(c) of Directive 98/44/EC [...] as long as they are not capable of developing into a human being and have not been genetically manipulated to acquire such a capacity"²³.

Finally, the EPO would permit to patent invention based on hESC obtained without destroying embryo, as via biopsies, upon evidences. But, such possibility seems to be closed in the *Brüstle* case which prohibits not only the patentability of inventions that require the destruction of human embryos, but also those that used them as base material.

The EPO and the EU adopted a similar approach to provide legal safety for the patentability of biotechnological inventions through common limitations for many inventions based on biological elements obtained initially from an embryo that has been destructed. However, uncertainties remain regarding the interpretation of the definition of the human embryo²⁴ (hopefully the latter should be partially solved by the CJEU for parthenotes) and how to prove

hESC have been obtained without *prior* destruction of human embryo. This incomplete but global coherence at European legal level questions the consequences for patients' accessibility to such treatments in Europe so that other stakeholders than scientists, jurists and inventors entering the debate might be foreseen, notably patients' organizations.

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