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Commentary

Time-lapse microscopy patent upheld in Europe: response to Pearce

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A B S T R A C T

In this piece, we comment on the article by Pearce earlier in this journal. As Pearce correctly points out, what is fundamentally at issue in ESHRE et al's opposition to Stanford University's European patent on time-lapse microscopy is whether an exclusion from patentability, here of methods of medical diagnosis, should be interpreted narrowly or not. In the present case, the dominant piece of case law from the European Patent Office (EPO) gives a narrow interpretation of what a method of diagnosis must be in order not to be patentable. In their submissions to the EPO, ESHRE et al. have argued that this narrow interpretation is unfounded and incorrect.

This issue of *Reproducive BioMedicine Online* includes two articles on the subject of Stanford University's European Patent for the technique of time-lapse microscopy. The first of these (Sterckx et al., 2016) is by the present authors and describes the current status of their application to have the Stanford patent revoked on the grounds that it is directed to a method of medical diagnosis that is excluded from patent-eligibility by the European Patent Convention (EPC). The second article, by Dr David Pearce (Pearce, 2016), also summarizes this opposition to the Stanford patent and presents the author's opinion that the attempt by the present authors and the European Society of Human Reproduction and Embryology (ESHRE) 'to effectively change the law will fail.'

The opposition by ESHRE et al. to the Stanford patent is based on the objection that it is the current interpretation of the EPC by the European Patent Office (EPO) Boards of Appeal that is incorrect and they are not arguing that the law itself needs to be changed.

As Pearce correctly points out, what is fundamentally at issue is whether an exclusion from patentability, here of methods of medical diagnosis, should be interpreted narrowly or not. In the present case, the dominant piece of case law from the EPO, G-1/04 *Diagnostic methods* (EPO, 2006a), gives a narrow interpretation of what a method of diagnosis must be in order not to be patentable. More specifically, in G-1/04 the Enlarged Board of Appeal (i.e. the highest instance) of the EPO required that only methods relating to curable diseases could be excluded. A later decision by a lower instance of the EPO, T-143/04 Beth Israel Hospital Association (EPO, 2006b) did find a method of diagnosing Alzheimer's disease to be excluded, but the question of whether or not Alzheimer's was curable was not considered or commented upon by the Appeal Board in that case. Hence the Enlarged Board's narrow interpretation does not appear to be challenged by this later decision. Accordingly, in their submissions to the EPO, ESHRE et al. have argued that this narrow interpretation is unfounded and incorrect.

The EPC contains two sets of exclusions from patentability: one in Article 52(2) EPC, the other in Article 53 EPC. In accordance with Article 52(2) EPC, certain categories of subject-matter are deemed simply not to be inventions (and thus not to be capable of being patented), but these exclusions are softened by Article 52(3) EPC, which provides that it is only the subject-matter recited in Article 52(2) EPC 'as such' that is excluded. Thus, for example, although 'discoveries' are excluded as not being inventions, inventions based on, or using a discovery, are not. Other categories of subject matter excluded by Article 52(2) EPC include, for example, mental acts, aesthetic creations, computer programs, and presentations of information.

The Article 53 EPC exclusion does not contain such softening 'as such' language and the subject matter excluded by this article is not excluded because it is deemed not to be an invention but instead because the legislators considered that, for social, political or ethical

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reasons, it was not appropriate for monopolization by a patent. Examples of subject matter excluded by this article include methods of surgery, treatment and diagnosis, and inventions the commercial exploitation of which would be contrary to morality.

From the earliest days of the operation of the EPO, the patent community has sought to have the exclusions from patentability interpreted narrowly, resulting in comments such as the following from Law Professor Peter Drahos and British Judge Sir Robin Jacob:

> The effect of the assumption [that exceptions to patentability have to be narrowly construed] is to make the restrictions on patentability function weakly, if at all. . . . A crucial aspect to the expansion of [the concept of patentability] has been the development of juridical arguments and theories that have enabled [patent applicants] to overcome existing bars. One of the interesting things is that, while these arguments are often analytically weak, they have been readily accepted by the patent community . . . (Drahos, 1999, pp. 442–3)

> [I]t by no means follows that because of pressure from applicants, the grant of patents for excluded categories should be allowed or that the excluded categories . . . should be construed narrowly. Just as with arms, merely because people want them is not sufficient reason for giving them. (Jacob, 2006, para. 19)

For many years, the Appeal Boards of the EPO gave in to the demands of applicants and patentees to interpret the exclusions narrowly, almost to the extent that it became received wisdom that exclusions had to be interpreted narrowly, for example finding that, although, as mentioned earlier, computer programs and discoveries are excluded from patentability, computer programs are not excluded if claimed on a carrier, and that a newly found naturally occurring substance ceases to be a discovery when isolated or purified. Shortly before the question of the patent-eligibility of human embryonic stem cells was put to the Enlarged Board of Appeal of the EPO in the G-2/06 *Use of embryos*/WARF (EPO, 2009) case, the Enlarged Board included a comment in its G-1/04 *Diagnostic methods* opinion to the effect that a narrow interpretation was not in fact a foregone conclusion. In the decision referring the WARF case to the Enlarged Board, it was observed that only one Enlarged Board decision existed, which addressed the issue of whether exceptions to patentability had to be interpreted narrowly, namely G-1/04 *Diagnostic methods*, where the Enlarged Board had said that the frequently cited principle according to which exclusion clauses from patentability laid down in the EPC were to be construed in a restrictive manner, did not apply without exception. The referring Board in the WARF case rightly noted that the 'breadth' of an exclusion clause should be determined on the basis of an intensive analysis of the clause in question, an analysis which involves 'all the usual methods of legal interpretation', i.e. considering 'the wording, the object and purpose of the provision, the interests involved, the consequences of a narrow or broad interpretation, respectively, and the aspect of legal certainty.' (EPO, 2005).

Since G-1/04 *Diagnostic methods*, the Enlarged Board has gone further in making it clear that narrow interpretations of exclusions may not be correct, not only in its decision in G-2/06 *Use of embryos*/WARF, but also at the oral hearing in G-2/08 *Dosage regime*/Abbott Respiratory (EPO, 2010) where one of its members, legal expert Brigitte Günzel, pointed out that nothing could be derived from either the travaux préparatoires for the EPC or the EPC itself that indicates that any of the provisions of Article 53 EPC ought to be construed narrowly.

The G-1/04 *Diagnostic methods* opinion, which is at the heart of the Stanford case, confirmed three aspects of the way in which the exclusion of diagnostic methods was to be construed narrowly. First, the human body must be present for at least part of the method (thereby confirming that in-vitro clinical laboratory tests were not excluded). Second, the actual step of diagnosis and not the preceding information-gathering step alone must be recited (thereby confirming that medical imaging techniques such as MR imaging were not excluded). Third, to be excluded the diagnosis must be of a curable disease.

The first two points were central to the conflict that led to the referral of G-1/04 to the Enlarged Board and to the submissions made in *amicus* briefs by interested parties (for the most part members of the patent community). The third point seems to have crept in barely noticed and was not discussed or challenged, and it is this third, totally unsupported, narrowing that ESHRE et al. are asking to have reviewed.

As Pearce rightly notes, the question of whether or not ESHRE et al. will be successful hangs on whether or not this is a point of fundamental importance. If methods of diagnosis of conditions that are not curable diseases are patentable, then performing such methods may cause the physician to infringe patents, i.e. she cannot take an action which, in her professional opinion, may be essential for the well-being of patient or society. For the current authors, it is crystal clear that this is of fundamental importance.

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REFERENCES

Drahos, P., 1999. Biotechnology patents, markets and morality. Eur. Intellect. Prop. Rev. 21, 441–449.
EPO, 2005. T-1374/04 *Stem cells*/WARF, decision of the Technical Board of Appeal of 18 November 2005. www.epo.org. (Accessed 31 August 2016).
EPO, 2006a. G-1/04. *Diagnostic methods*. OJ EPO 334.
EPO, 2006b. T-143/04 BETH ISRAEL HOSPITAL, decision of the Technical Board of Appeal of 12 September 2006. www.epo.org. (Accessed 31 August 2016).
EPO, 2009. G-2/06 *Use of embryos*/WARF. OJ EPO 306.
EPO, 2010. G-2/08 *Dosage regime*/ABBOTT LABORATORIES. OJ EPO 456.
Jacob, R., 2006. *Aerotel Ltd. v. Telco Holdings & Ors* (UK-CA), [2006] *EWCA* Civ 1371.
Pearce, D., 2016. Time-lapse microscopy patent upheld in Europe. Reprod. Biomed. Online 34, 169–171.
Sterckx, S., Cockbain, J., Pennings, G., 2016. Patenting medical diagnosis methods in Europe – Stanford University and time lapse microscopy. Reprod. Biomed. Online 34, 166–168.