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Commentary

Time-lapse microscopy patent upheld in Europe

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A B S T R A C T

A case for revoking Stanford University's European patent 2430454 on time-lapse microscopy was set out in *Reproductive BioMedicine Online* by Sterckx *et al.* in 2014, on the grounds that the patent claimed a method of diagnosis that was excluded under a provision of the European Patent Convention. An opposition at the European Patent Office in which this ground was raised has recently concluded with a decision that the patent is not excluded from patentability under European patent law and is to be upheld. An appeal from this decision has been filed, but the possibility of the decision being overturned is, in this author's opinion, very limited.

Introduction

In the February 2014 issue of *Reproductive BioMedicine Online*, Sterckx et al. (2014) put forward a case for revoking European patent 2430454, granted to Stanford University in 2013. The patent claimed a method for assessing good or poor developmental competence of a human embryo, based on specific timings of the first to third cell divisions that were to be measured by time-lapse microscopy. Sterckx et al. (2014) argued that the patent should not have been granted because it was contrary to Article 53(c) of the European Patent Convention (EPC), which states that patents shall not be granted to 'methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body'. Their argument was that the method was a diagnostic one practised on a human body (i.e. the embryo), the diagnosis being the assessment of good or poor developmental competence. An opposition to the patent was filed in October 2013 in the names of Sterckx *et al.*, together with the European Society of Human Reproduction and Embryology, in which the objection under Article 53(c) EPC was raised. This opposition was subsequently supported by observations filed by the Association of Irish Clinical Embryologists, the UK Association of Clinical Embryologists and the Royal College of Nursing.

In response to the Sterckx *et al.* 2014 article, I argued that the view that the patented method was excluded under European patent law was mistaken (Pearce, 2014), and indicated that I expected the opposition on this ground to be dismissed. The two key points that the opposition by Sterckx et al. would need to convincingly demonstrate in their opposition to have the patent revoked were as follows: a human embryo was to be defined as a human body; and the claimed method for assessing developmental competence was a diagnostic method, both within the meaning of Article 53(c) EPC. The arguments put forward by Sterckx et al. (2014) relied primarily on the former, for which there was support in the EPO case law as well as precedent from the EU Court of Justice. The latter point, however, was not well supported by case law and the arguments instead relied on assertions and opinion from experts in the field.

Is a human embryo a human body?

The main argument put forward by Sterckx et al. (2014) was that a human embryo should be considered to be a human body for the purposes of patent law, i.e. regardless of any other interpretation that may be applied in other areas of law. In this respect, there is plausible support from Rule 29(1) of the EPC and from Directive 98/44/EC (European Union, 1998) (known as the Biotech Directive), both of which refer to the human body at various stages of its formation and development, thereby at least implying that a human embryo should be considered to be a human body. Although these do not directly relate to the question of whether a patented method is excluded under Article

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http://dx.doi.org/10.1016/j.rbmo.2016.10.012

53(c) EPC, which is a different provision, they do provide support for a human embryo being considered to be a human body.

Is the method diagnostic?

The second question of whether the method claimed in the patent was a diagnostic method finds much less support from the case law of the EPO. Sterckx et al. (2014) pointed to the decision G 1/04 (European Patent Office, 2006) from the Enlarged Board of Appeal, which stated that 'practitioners should be free to take the actions they consider suited to diagnose illnesses by means of investigative methods' (G 1/04, point 4 of the reasons for the decision) as a reason for justifying the exclusion from patentability of methods of diagnosis, therapy and surgery. This reasoning was then extended to justify the exclusion of time-lapse microscopy from patentability, largely on public health considerations. What the authors did not note, however, was that G 1/04 also provided specific guidance on when a claim relating to a diagnostic method was to be excluded, as set out in the following test:

'In order that the subject-matter of a claim relating to a diagnostic method practised on the human or animal body falls under the prohibition of [Article 53(c) EPC], the claim is to include the features relating to:

(i) the diagnosis for curative purposes *stricto sensu* representing the deductive medical or veterinary decision phase as a purely intellectual exercise;
(ii) the preceding steps which are constitutive for making that diagnosis; and
(iii) the specific interactions with the human or animal body which occur when carrying those out among these preceding steps which are of a technical nature.'

In effect, for a method to be excluded under European law, it needs to replicate all the steps leading up to a diagnosis, including the step of identifying the condition being diagnosed that would otherwise be made by a practitioner. This allows methods to be patented that, for example, define automated blood testing for a specific condition but which leave the diagnosis to the practitioner. The deductive step of, for example, associating a specific level of a component in a blood sample with a specific disease condition would therefore not be patentable. The key point of difference between the method claimed in the patent and a method that would be excluded according to this test is that the patented method does not appear to be a diagnosis for curative purposes *stricto sensu* (i.e. in the narrow or strict sense). The Board intended the exclusion to be applied in a narrow sense, in which only those methods that resulted in an actual diagnosis would be excluded, rather than methods that merely related to a diagnosis but did not necessarily result in one. The Board also required the diagnosis to be one for curative purposes, referring to the other exclusions for methods of surgery and therapy, inferring that diagnostic methods must also serve a curative purpose. In the case of an assessment of developmental competence of a human embryo, the diagnosis resulting from such an assessment is one of whether the embryo has a good or poor developmental competence. If the embryo is good, it has a better chance of success after transfer, whereas if it is poor it should not be selected for transfer. In no event can the assessment result in anything other than a selection of which embryo to transfer, given a number of potential embryos to choose from. The diagnosis, such as it is, cannot therefore be for curative purposes because there is no possibility of an embryo that has been assessed as having poor developmental competence being made good. The test laid out in G 1/04 is quite clearly against an interpretation of Article 53(c) EPC that would exclude the claimed method from being patentable.

EPO opposition proceedings

In the opposition, the argument emphasised that a method of diagnosis did not need to depend on whether a curative treatment was available because this was not the point of law being addressed in G 1/04. The patent proprietor argued in response that the exception should be interpreted narrowly and that the patented method was not inherently a diagnosis of any condition, since developmental competence was not a reflection of any disease state.

In their preliminary opinion issued in March 2015, the Opposition Division noted that the exceptions to patentability under Article 53(c) EPC should be interpreted narrowly, and questioned whether the claimed method was a diagnosis for curative purposes as defined by G 1/04, although all the other conditions in the test seemed to be met. Although the Enlarged Board did not provide a definition for the expression 'curative purposes', the expression was used numerous times throughout the decision and the Opposition Division considered itself to be bound to apply that criterion to assess whether the claimed method was excluded. After hearing the arguments from the parties at oral proceedings held in November 2015, the Opposition Division decided that the method was not excluded under Article 53(c), and set out their reasoning in a subsequent written decision issued in February 2016. As the Opposition Division noted, Sterckx et al. (2014) had argued that the term 'diagnosis' would be interpreted broadly by the typical practitioner, covering cases where there was no disease state or no cure was possible. The Opposition Division, however, considered that diagnostic methods in connection with the exceptions of Article 53(c) EPC were interpreted narrowly by the Enlarged Board and did not cover all methods that might be considered to be diagnostic by a practitioner. Diagnosis in connection with Article 53(c) EPC was instead, according to G 1/04, only concerned with identifying or uncovering a pathology, also defined as the attribution of the deviation to a particular clinical picture. The Opposition Division considered that the claimed method did not relate to the attribution of a deviation to a particular clinical picture. The scope of the claimed invention was not to determine a pathology or disease in the embryo, but to determine the capacity of the embryo to continue development to a blastocyst. Embryos having a disease state were likely to exhibit poor developmental competence, but this did not mean that the concept of developmental competence could be equated with a particular condition or pathology. There was also no indication as to a therapeutic action that could be taken in response to an assessment to treat an embryo assessed by the method. The Opposition Division did not consider that a decision not to implant an embryo having poor developmental competence could be viewed as a medical treatment directed at the pathology of the embryo.

What happens next?

The decision to maintain the patent has been appealed by Sterckx *et al.* The appeal process is likely to take at least another 2 years, but the

eventual outcome is, in this author's opinion, likely to be that the decision not to revoke the patent on the Article 53(c) ground will be upheld by the Board of Appeal. The opponents may be hoping for a referral to the higher Enlarged Board of Appeal to make a decision that would overturn or amend the guidance set out in the earlier decision of G 1/04. The possibility of this happening is, however, extremely limited. A Board of Appeal can only refer a question on a point of law of fundamental importance or to ensure uniform application of the law. As no inconsistency in the current case law of the EPO Boards of Appeal has been established on the question of the extent to which methods of diagnosis are to be excluded, the only option open is that the point is one of fundamental importance. This outcome would appear to be unlikely, especially given that referrals to the Enlarged Board are quite rare (only one referral is currently pending at the time of writing, while hundreds of cases are currently pending before the lower Boards of Appeal). The eventual outcome of the case will therefore most likely be that the decision by the Opposition Division not to revoke Stanford University's patent on time-lapse microscopy will be upheld, and the attempt by Sterckx *et al.* to effectively change the law will fail.

ARTICLE INFO

Article history:
Received 12 May 2016
Received in revised form 19 October 2016
Accepted 19 October 2016
Declaration: The author reports no financial or commercial conflicts of interest.

Keywords:
patents
time-lapse microscopy
diagnosis

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