Stem Cell Technology

Questions on patenting of human embryonic stem cells referred to the Enlarged Board of Appeal of the European Patent Office.

The Technical Board of Appeal of the European Patent Office (“EPO”) last month referred four questions on patenting inventions relating to human embryonic stem cell cultures to the Enlarged Board of Appeal. The answers in connection with the Wisconsin Alumni Research Foundation patent application appeal could be central to the future approach of the EPO to patenting stem cells derived from human embryos.

THE EUROPEAN PATENT CONVENTION (“EPC”)

Article 53(a) of the EPC prohibits the grant of patents for inventions which are contrary to ‘ordre public’ or morality. The 1998 Directive on Biotechnological Inventions amended the Implementing Regulations to the EPC introducing a new Rule 23d on interpretation of Article 53(a). Rule 23d(c) provides specifically that under Article 53(a), patents will not be granted for biotechnical inventions concerning uses of human embryos for industrial or commercial purposes except (by Recital 42 of the Directive) where the invention benefits the embryo via therapeutic or diagnostic means.

WISCONSIN ALUMNI RESEARCH FOUNDATION’S APPLICATION

With currently known technology, new human embryonic stem cell lines are derived via a process which inevitably results in destruction of the embryos. The embryos used to establish cell lines are generally sourced from excess embryos created during human fertility treatments, in which the fertility patients consent to research and experimental use of the excess embryos. After a stem cell-line is established, provided it is properly maintained, no further destruction of fresh embryos should be necessary.

In the patent application in issue, filed by the Wisconsin Alumni Research Foundation, the claims were directed towards a cell culture of primate embryonic stem cells maintaining, in culture, their undifferentiated state and the ability to differentiate into each of the major tissue types. Although human cell-lines were not specified in the application, it was clear to the EPO’s Examiner that the teaching of the application enabled generation of such human cultures, including because the application stated that human embryonic stem cell lines had been deposited with the National Institute of Health Human Embryonic Stem Cell Registry. The Examiner therefore refused the majority of the application’s claims for non-compliance with Article 53(a) interpreted under Rule 23d(c) of the EPC as, in respect of generation of the human cultures, the use (and destruction) of human embryos was described in the original application files as being indispensable. The Examiner considered it irrelevant that the application did not claim a method of producing such human cell cultures.

The applicant lodged its appeal from that decision in September 2004, the appeal was heard in November 2005 and the Board made its reference last month based on four questions submitted by the applicant. The issue of sufficiency of disclosure in respect of the human cultures was also considered and the
Board found in the applicant's favour on that issue. The reference to the Enlarged Board of Appeal on the Article 53 morality/ordre public issues was made on the basis of Article 112(a) of the EPC - that an outstanding important question of law arises for decision.

THE QUESTIONS
The Enlarged Board of Appeal are requesting answers to the following:

1. "Does Rule 23d(c) EPC apply to an application filed before the entry into force of the rule?"

2. "If the answer to question 1 is yes, does Rule 23d(c) forbid the patenting of claims directed to products (here: human embryonic stem cell cultures) 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, if the said method is not part of the claims?"

3. "If the answer to question 1 or 2 is no, does Article 53(a) EPC forbid patenting such claims?"

4. "In the context of questions 2 and 3, is it of relevance that after the filing date the same products could be obtained without having to recur to a method necessarily involving the destruction of human embryos (here: e.g. derivation from available human embryonic stem cell lines)?"

It seems from comments made in the decision of the Technical Board of Appeal that it does not find the applicant's arguments attractive and would be inclined to refuse grant of a patent relating to human embryonic stem cell cultures even where, as in this case, the claims do not fall strictly within the exclusions to patentable subject matter laid down in the EPC and the rules governing its interpretation. Some of the applicant’s arguments which received negative comments from the Technical Board include:

(i) the relevant sections of the EPC should be given a narrow interpretation in light of the fact that they are exclusions to patentability;

(ii) the method for producing human embryonic stem cell cultures was known at the time the Biotech Directive was introduced, so if this technology was intended to be excluded, the legislators would have specifically excluded it when drafting the Directive; and

(iii) a balancing exercise should be applied comparing the benefits of exploitation of the technology against any rights of the embryo, a test applied previously in relation to animal patenting.

The Technical Board suggested it found these arguments, and others, unconvincing and gave a fairly clear indication of a disinclination to encourage grant of this type of patent relating to or dependent on the use of human embryos.

We await the Enlarged Board’s decision with interest.

Helen Smith
hsmith@klng.com
011.44.207.360.8148
If you have questions or would like more information about K&LNG’s Stem Cell Technology practice, please contact one of our lawyers listed below:

**BOSTON**
- Michael Brodowski, Ph.D. 617.261.3113 mbrodowski@klng.com
- John Cotter 617.261.3178 jcotter@klng.com
- Eileen Smith Ewing 617.951.9227 eewing@klng.com
- Thomas Turano 617.261.3148 tturano@klng.com
- Christine Vito, Ph.D. 617.261.3150 cvito@klng.com

**LONDON**
- Helen Smith 011.44.207.360.8148 hsmith@klng.com

**PALO ALTO**
- Jake Schwarz 650.798.6710 jschwarz@klng.com

**PITTSBURGH**
- Sandy Ferguson 412.355.6494 sferguson@klng.com

**WASHINGTON**
- Gary Yingling 202.778.9124 gyingling@klng.com