Report Q114

Biotechnology (including plant varieties)

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1. UPOV 1991 adherence (Charles GIELEN)

Since mid 2006 four new member adhered to the UPOV 1991 Treaty, namely the Dominican Republic, Morocco, Ukraine, Vietnam and Spain bringing the total number of members to 39. The number is still growing but a number of countries adhering to the 1978 Act are still not adhering to the 1991 Act of UPOV.

2. Filing of Amicus brief with the Enlarged Board of Appeal of the European Patent Office (Charles Gielen)

Upon the recommendation of our Committee AIPPI filed an amicus brief in the case G2/06 that is pending before the Enlarged Board of Appeal of the European Patent Office. It concerns a referral made by the Technical Board of Appeal (case T1374/04) made in April 2006 to the Enlarged Board of Appeal in a case regarding a patent application by Wisconsin Alumni Research Foundation concerning embryonic stem cells. In its referral decision the Board considered the question of the patentability of human embryonic stem cells and of the conditions therefore as being an outstandingly important point of law within the meaning of Article 112 (a) EPC for which a decision by the Enlarged Board of Appeal is required. The patentability of human embryonic stem cells is a highly critical matter which indeed is passionately debated. AIPPI drew the attention of the Enlarged Board of Appeal to the resolution that was adopted during the executive meeting of AIPPI in Berlin in 2005 in which it was resolved that patents should be available without any discrimination for all kinds of inventions including biotechnology. Furthermore it was resolved that inventions based on isolated human embryonic pluripotent stem cells should be treated like any other invention and should be patentable if the general patentability criteria are met. Finally, it was resolved that exclusions to patentability due to the principles of "ordre public" and morality may be applicable but should be as limited as possible and should be defined very precisely.

AIPPI in its amicus brief to the Enlarged Board of Appeal submitted that in accordance with the resolution inventions insofar as they concern pluripotent human embryonic stem cells should in principle be protected by patents assuming, of course, the normal requirements for patent protection are met. The case is still pending at the Enlarged Board of Appeal.

3. Decision of the German Federal Supreme Court of 5 December 2006 (Thomas SEUSS)

The German Federal Patent Court has invalidated German patent 19756864 (Brüstle, filed: 19 December 1997) after an oral hearing dated 5 December 2006. The patent has been declared invalid as far as it covers embyonic stem cells generated from human embryos. As far as other cells are concerned, including human primordial cells, the patent has been held valid.

The granted patent covers isolated cells with neuronal or glial properties from embryonic stem cells which have been generated according to a process further described in claim 1 of the granted patent. In claim 6 of the patent cells are covered which have been obtained from embryonic cells, according to claim 8 cells are covered stemming from different mammals, especially human beings.

The Federal Patent Court has held the patent invalid as far as it covers human embryonic stem cells and cells generated there from. The court held that the cells covered by the patent are totipotent cells which have the possibility to develop into a complete human organism. In order to obtain such totipotent cell, it is necessary to use embryos in an early stage of development called blastocyst. The Court furthermore held that the use of human blastocysts is an action against "ordre public" as it necessarily destroys a human embryos. Such action has been explicitely described in §2, No. 1, of the German Patent Law which has been amended by the law relating to the legal protection of biotechnological inventions of 21 January 2005. This amendment is a result of the implementation of the European Biotech Patent Directive. However, the Court is of the opinion that the amendments having been made by the implementation of the European Biotech Patent Directive are merely a clarification of the term "ordre public" which had been in the law before and which does not change the scope of the exclusion of patentability. The Court furthermore held that the limitations to patentability as provided in §2, No. 1, of the German Patent Law clarified by way of amendment due to the European Biotech Patent Directive do apply to the patent in suit due to the possibility to utilize the protected invention after grant. The Court points out that although possible utilization (after grant) is generally not an issue in the patent prosecution process, it may nevertheless be considered in exceptional cases when the use of a technical teaching described in a patent may be in conflict with "ordre public". Such an invention may be excluded from patentability by the state and must not be rewarded by the grant of a patent. It is therefore the obligation of the decision-making body (e.g. Patent Office or Patent Court) to avoid any impression that the state would award such utilizations against "ordre public".

This summary of the decision does of course not discuss every single aspect of the Court decision. It does merely summarize the main points. I do not know if this decision is going to be appealed. I would hope that the Federal Supreme Court will have the possibility to re consider the presented arguments and the decision provided by the Federal Patent Court. This seems in my view to be necessary at least for two reasons:

1. The reference to "ordre public" is in my view problematic as this may change over time, even in short terms. It might be a devastating problem if early patents will be rejected or invalidated due to "ordre public" considerations whereas patent applications filed later may be granted or will survive in validation proceedings.
2. Patent protection related to stem cells seem to be generally affected since the Patent Court seems to indicate that the development potential of stem cells limits their patentability. Totipotent cells which are able to develop into a whole organism seem to be excluded from patentability. However, currently there are areas of stem cell research in which an adult stem cell is "reprogrammed" to other types of stem cells. During such transition process there may be a transitional stage which is a totipotent (or at least a pluripotent) stem cell. This possibility generates big hopes in the scientific community as it would open the possibility to start with an adult stem cell of a specific tissue and turn it into a stem cell of another type of tissue. However, the scientific results and their practical application may be excluded from patentability due to the reasons provided in the above described Court decision.

This decision as well as further decisions should therefore be monitored and its implications should be discussed inside of AIPPI and maybe even together with scientists working in this area.

4. Decision of District Court of Paris of February 7, 2007 (Thomas BOUVET)

On 7 February 2007, the *Tribunal de grande instance* of Paris dismissed the action for patent infringement initiated by the French research organization, Institut Pasteur, against the French and Irish subsidiaries of the US company Chiron (now known as Novartis Vaccines and Diagnostics).

In this case Institut Pasteur alleged that certain kits for the *in vitro* detection of HIV in blood samples, marketed by Chiron in France, fell within the scope of its European patent No. 178 978 relating to "cloned DNA sequences, hybridizable with genomic RNA of the LAV" (HIV). Institut Pasteur requested 8'000'000 Euro as an interim payment on account of damages.

Institut Pasteur relied on two claims of its patent:

- claim 8 regarding a method for the *in vitro* detection of viral infection due to HIV;
- claim 11 regarding purified RNA of HIV.

The Court noted that the scope of most of the claims of Institut Pasteur's patent had been limited during EPO proceedings (examination, opposition and appeal) and held that, because of their language and the description, claims 8 and 11 could not be given the broad scope claimed by Institut Pasteur, specifically:

- claim 8 could not cover a general method for detecting HIV, but only a specific method characterized by the use of the probes of claim 7 consisting of the specific cloned DNA sequences of claims 1 to 6, characterized by their restriction sites and the fact that they correspond to the genome contained in a deposited clone;
- claim 11 could not cover any purified RNA of HIV, but only a specific purified RNA corresponding to the complementary DNA contained in the deposited clone. The Court specified that any other construction would lead to the nullity of Institut Pasteur's patent claims, in view of the prior art submitted by the defendant. The Court dismissed the claim for infringement of claim 8 (a method for the in vitro detection of HIV), on the grounds that Institut Pasteur had not demonstrated that the kit would use the specific claimed probes and that it had not even challenged Chiron's argument that the probes used in its kit differed from the patented probes. The Court dismissed the claim for infringement of claim 11 (purified RNA), on the grounds that Institut Pasteur relied on contributory infringement and held that the accused detection kit sold by Chiron did not relate to an essential element of claim 11. This decision may be appealed. This judgment is the first decision ever issued by a French Court regarding infringement of a molecular biology patent. The parties' arguments mainly concentrated on claim construction and the scope of the patent claims. The validity of the patent was not challenged as such but only as a secondary argument (namely, should the patent be given a broad scope it would be invalid). The Court issued a detailed decision and relied on ordinary rules of claim construction, based on the wording of the claims and on the patent description. It used the invalidity argument to strengthen its decision and noted that should the patent be given a broad scope it would be invalid.

5. New Guidelines on research tool patents in the field of life science, published in Japan, 1 March 2007 (Yuusuke HIRAKI)

In Japan a guideline relating to smooth use of research tool patents in the field of life science was published by "IP Strategy Expert Panel, Council for Science and Technology Policy, Cabinet Office" on 1 March 2007. The basic Concept provided in the guideline is as follows:

i) Licensing
When a person requests approval of using a patent of a research tool during the research stage, the patentee should, taking into consideration the smooth use of the research tool, provide a non-exclusive license to the person, except where it interferes with his business strategy.

ii) Licensing Fee and Conditions
Taking into consideration the characteristics of the research using a research tool patent and whether or not the patent was a result of a research development financed by a

governmental resource, and paying attention to the smooth use of the research tool, the license fee for non-exclusive licensing the research tool patent should be a reasonable remuneration.

In order to promote use of research tool patents, a comprehensive database will be set up which publishes data relating to research tool patents available to the public, that are possessed by universities or commercial companies. The database includes data such as type of research tool, patent number, condition of use, license term, license fee, method of payment, contact address, etc.