Report Q114

Biotechnology (including plant breeders' rights)

Names and Functions of Committee Members

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1) Prejudicial questions on EU Biotech Directive to ECJ (Charles Gielen)

The Hague Court in the case *Monsanto/Cefetra c.s.* decided to refer questions of interpretation of the EU Biotech Directive to the European Court of Justice. The draft questions read as follows (the final questions are expected to be given in the course of September 2008):

1) *Should Article 9 of the Directive be understood such that the protection meant in this Article can also be relied upon in a situation such as in these proceedings whereby the product (the DNA) is present in a materials and does not express its function at the time of the stated breach but has indeed expressed its function or possibly, following the isolation from the material and its incorporation in the cell of an organism, could once again express its function?*

2) *Proceeding from the presence of the DNA sequence as described in claim 6 of the patent in soy meal imported into the European Community by Cefetra and ACTI and assuming that DNA is incorporated in the soy meal as meant in Article 9 of the Directive and that it therein no longer expresses its function:*

   Does the provided protection of a patent for biological material in the Directive, specifically in Article 9, stand in the way for the national patent legislation[1] to (additionally) allow absolute protection for the product (the DNA) as such, whether or not the DNA expresses its function and must the protection provided by Article 9 therefore be considered exhaustive?

3) *Does it make any difference to the answer to the previous question that the patent was applied for and granted (on 19 June 1996) prior to the Directive being adopted? Can you, on answering the previous questions, take into consideration the TRIPS Treaty, specifically the Articles 27 and 30?*

2) Upov 1991 adherence (Charles Gielen)

Since last year only two new member adhered to the Upov 1991 Treaty, namely Turkey on November 18, 2007 and Switzerland on August 1, 2008 bringing the total number of members

[1] In Article 53 ROW95, in so far as relevant this article provides: A patent gives the patent holder (…) the exclusive right: a. to manufacture the patented product in or for his business, to use, bring into circulation or further sell, to rent out, to supply or otherwise trade, or to this end offer , import or have in stock.

to 41. 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.

3) Enlarged Board Referrals at the EPO (Claire Baldock and Charles Gielen)

a) Case G2/06 (on the protection of human embryonic stem cells)

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) in April 2006 to the Enlarged Board of Appeal. The case relates to a patent application by Wisconsin Alumni Research Foundation concerning embryonic stem cells. In its referral decision the Board indicated that the question of the patentability of **human** embryonic stem cells and of the conditions therefor was 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 it 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 but oral proceedings before the Enlarged Board took place in June 2008 and so a final decision is expected shortly.

b) Cases G02/07 and G01/08 (Breadth of "Essentially Biological Processes" Exclusion)

G02/07 and G01/08 are cases pending before the Enlarged Board which have been referred in Technical Board Decisions T0083/05 and T1242/06 respectively. Both Article 4(1)b of EU Directive 98/44EC and Article 53(b) of the European Patent Convention exclude from patentability "essentially biological processes for the production of plants or animals". Both the Directive and the EPC Implementing Regulations provide that *"A process for the production of plants or animals is essentially biological if it consists entirely of natural phenomena such as crossing or selection"*. G02/07 concerns the question of whether any technical step included in the claim is sufficient to avoid the exclusion, even if it is trivial and/or makes no real contribution to inventive step. G01/08 concerns whether for a process to be excluded the crossing and selection steps have to comprise phenomena occurring only in nature.

Specifically, in the G02/07 case the invention involved crossing a wild *Brassica (broccoli)* strain with a double haploid breeding line. The process also involved a step of using molecular markers to select particular hybrids. The proprietor argued that the hybridization between wild strains and breeding line strains of plants, which would not come into contact with one another in nature, could only come about by some form of human intervention, and so should not be subject to the exclusion applied to "essentially biological" processes. They further argued that selection using molecular markers was a technical step which would avoid the exclusion. The Technical Board of Appeal did not accept these arguments, but referred the following questions to the Enlarged Board:

1) *Does a non-microbiological process for the production of plants which contains the steps of crossing and selecting plants escape the exclusion of Article 53(b) EPC merely because it contains, as a further step or as part of any of the steps of crossing and selection, an additional feature of a technical nature?*

2) *If question 1 is answered in the negative, what are the relevant criteria for distinguishing non-microbiological plant production processes excluded from patent protection under Article 53(b) EPC from non-excluded ones? In particular, is it relevant where the essence of the claimed invention lies and/or whether the additional feature of a technical nature contributes something to the claimed invention beyond a trivial level?*

In G01/08 the invention was a process which resulted in the production of tomatoes of reduced water content. The process involved standard methods of crossing and selecting hybrid seed but an additional step of allowing the fruit to remain on the vine past the point of normal ripening and screening for fruit of reduced water content, as indicated by their wrinkly appearance on extended preservation. The proprietor has argued that this step is not a natural phenomena and requires human intervention. Thus, it is not essentially biological as required to be excluded from patentability. In this case the questions referred to the Enlarged Board in G02/07 are reiterated but there is one additional question as follows:

1) *Does a non-microbiological process for the production of plants consisting of steps of crossing and selecting plants fall under the exclusion of Article 53(b) EPC only if these steps reflect and correspond to phenomena which could occur in nature without human intervention?*

In view of the similarity of the subject matter the two cases have been consolidated for the purpose of consideration by the Enlarged Board. As the referral is recent a final decision will be some way off. Should the Enlarged Board interpret the "essentially biological processes" exclusion narrowly, then plant breeders may find themselves more at risk from patent infringement than before.

4) Industrial Applicability of Biological Molcules (Claire Baldock)

a) T0898/05 (Zymogenetics)

According to art. 57 EPC an invention must be industrially applicable in order to be patentable. In several cases the question arises whether the mere fact that, for example, a protein can be biotechnologically made is sufficient for industrial applicability or whether a specific function or utility should be disclosed. It has been defended that the mere possibility of producing a molecule was sufficient. The basis for this would be the text of Article 57 EPC which provides two alternatives for an invention to be susceptible of industrial application, namely that it could be made or used in any kind of industry, including agriculture. Consequently, if the claimed invention could be made, it already met the requirements of the EPC as regards susceptibility of industrial application. Also reference was made to Recital (23) of the EU Directive saying that although the patentability of a mere DNA sequence was denied, immediately afterwards in Recital (24) it was specified that in connection with a gene sequence or partial gene sequence it was necessary to specify which protein or part of a protein was produced or what function it performed. The Board of Appeal decided *inter alia* that a product whose structure is given (e.g. anucleic acid sequence) but whose function is undetermined or obscure or only vaguely indicated might not fulfil the above criteria, in spite of the fact that the structure of the product per se can be reproduced (made). If a patent is granted therefor, it might prevent further research in that area, and/or give the patentee unjustified control over others who are actively investigating in that area and who might eventually find actual ways to exploit it. The Board went on by saying that a product which is definitely described and plausibly shown to be usable, e.g. to cure a rare or orphan disease, might be considered to have a profitable use or concrete benefit, irrespective of whether it is actually intended for the pursuit of any trade at all. Thus, although no particular economic profit might be expected in the development of such products, nevertheless there is no doubt that it might be considered to display immediate concrete benefits which would allow industrial applicability to be recognised.

b) Eli Lilly v Human Genome Sciences, Inc

On 31st July 2008 a decision of the English High Court was handed down by Mr Justice Kitchen in the case of Ely Lilly v Human Genome Sciences Inc (HGS) which addressed issues very similar to those in T0898/05 discussed above. Lilly applied for revocation of HGS Euro(UK)patent EP-B

0939804 which related to a nucleic acid sequence and the protein it encoded which was identified as a novel member of the TNF ligand superfamily of molecules. This new molecule was given the name Neutrokine-a. The nucleic acid and protein were claimed as well as antibodies specifically binding to the protein and pharmaceutical and diagnostic compositions containing the protein or antibodies. HGS had found the new molecule, not by any wet lab technique but purely using bioinformatic tools. The patent attributed to the molecule all the functional properties of other known TNF family members and provided a considerable list of possible pharmaceutical and diagnostic uses on that basis. However, these were mere predictions not supported by any experimental data obtained from *in vitro* or *in vivo* studies. Lilly contended that these predictions were wholly speculative and that HGS did not know the biological activity or function of Neutokine-a, the identity of any diseases with which it might be associated and hence the diseases it might be able to treat, at the time it filed the patent application. No utility existed for the invention claimed at the filing date and hence all the claims were invalid for failing to be capable of an industrial application.

In a very detailed judgement Mr Justice Kitchen agreed with Lilly and found all the claims invalid for lack of industrial applicability. In reaching his decision, great weight was placed on the decisions of the EPO on this point, including T0898/05 discussed above as well as the application of the Utility Requirement in the US. Specifically, the Judge held that the application did not provide any sound or concrete basis for recognising that Neutrokine-a could lead to a practical application in industry. Rather it provided sound and concrete basis only for a research project to find out what the molecule actually did and what it could be used for. It's use as a tool to investigate its own activities did not constitute a relevant industrial application.

This decision is a very important one since it is really the first time an English Court has had to consider what is required for an industrial application to be recognised. Thus the EPO was really the only authority to which the Judge could refer. Interestingly, apart from adopting the EPO position in relation to industrial application of biological molecules, the Judge also found the claims to lack inventive step, not on the basis of prior art, but because no technical problem had been solved. Although not cited in the Judgement, this approach follows T1329/04 (John Hopkins) where it was held that a molecule must be sufficiently characterised to make it plausible that the problem intended to be solved, had indeed been solved.

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