Managing Intellectual Property - September 2004, Issue 142

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Recent biotech decisions at the EPO

In the past 12 months the two biotech Appeal Boards at the European Patent Office have handed down about 70 appeal cases relating to biotech inventions. This overview of the most relevant of these recent decisions seeks to provide some guidance for the practitioner in examination or opposition proceedings before the EPO and also to provide some hints in evaluating novelty, inventiveness or enablement when drafting applications. This appears to be even more important since experience has shown that referring to case law in proceedings concerning biotech cases is only of benefit if decisions from this technical field are cited, since decisions from other technical fields are generally rejected out of hand as being not relevant in the biotech sector.

Novelty

In T 486/01 the issue was whether the claimed medical uses of IGF-1 indeed extended beyond those already disclosed in the prior art. The Board pointed out that for a medical application to be construed as “further medical use”, this new technical effect would have to lead to a truly new therapeutic application, such as a the healing of a different pathology or the treatment of the same disease with the same compound but carried out on a new group of subjects distinguishable from the previously suggested subjects for such treatment. In the present case, the appellant relied on, as novel features, the target cells to be rescued by IGF-1, namely glial cells and non-cholinergic neuronal cells, in contrast to the medical use disclosed in the prior art document in question based on rescuing neuronal cells in general. However, the Board had no evidence that such CNS injuries that affect only glia or non-cholinergic neurons exist, while leaving other populations of CNS cells unscathed. Also, the different physiological effects highlighted by the appellant did not allow the identification of a new subgroup of patients to be treated. The Board therefore considered that the observed physiological effects could only be regarded as the discovery of additional knowledge about further mechanisms of action underlying the known therapeutic application of IGF-1 in the treatment of CNS insults, but could not in themselves confer novelty over this known therapeutic application.

The Board in T 12/01 had to decide whether to accept evidence from the opponent that oral disclosure at a meeting had occurred. The decisive factor for the Board was that the opponent did not provide an up-to-the-hilt proof of what was actually shown or distributed by the lecturer. Further, the Board held that the mere contention in declarations by the lecturer and another scientist who prepared this speech that the disclosure occurred could not be accepted because both of them were not qualified to provide evidence safely and satisfactorily establishing the information content made publicly available by the lecture and what an ordinary member of the audience at the lecture would have understood. Hence, this decision confirms that Board’s standards of proof for novelty attacks based on prior oral disclosure are very high. In T 1026/02, dealing with the patentability of oilseed, the Board held in connection with the enablement of a prior art document disclosing an oilseed crossing programme that relying on fortuitous events or chance for reproducibility amounts to an undue burden in the absence of evidence that such chance events occur and can be identified frequently enough to guarantee success. Accordingly, the disclosure of the prior art document was not considered to be enabling and its content could not be considered when judging novelty of the claimed subjectmatter. The Board in T 423/01 held that the evaluation of the disclosure of a prior art document always has to be based on its actual content and not on hypothetically possible interpretations of it. In the Board’s opinion the basic principle which expects from the skilled person that when reading a patent claim he will exclude illogical and meaningless interpretations so that he arrives at a technically reasonable understanding of the claim is also to be applied when reading and interpreting a prior art document.

Inventive step

The Board in T 645/02 had to decide on inventive step of a monoclonal antibody that binds specifically to a human stem cell factor receptor. While the Examining Division denied inventive step in view of the general knowledge with respect to the production of monoclonal antibodies, the Board came to the conclusion that the classic fusion technique for the production of monoclonal antibodies does not allow

any assessment of the prospects of success regarding the isolation of a certain monoclonal antibody having precisely defined characteristics. In this case, it is not the theoretical possibility of producing a particular monoclonal antibody using a known method, but the actual provision of an antibody having precisely defined characteristics which are not disclosed in the prior art and which contain surprising elements, which justify the acknowledgement of inventive step.
In T 216/96 dealing with the pioneer patent on PCR technology, the Board was of the opinion that giving new life to a long-abandoned line of research – in this case the various elements underlying the PCR technique – is already an indicator of inventive step.
In T 1127/00 dealing with a patent on ribozyme technology the Board emphasized that in cases where, in the light of the prior art, the suggested approach is obvious for the skilled person to try, then it still has to be assessed whether there is a reasonable expectation of success. In the case in question the Board considered the situation not to be a case of try and see whether the ribozymes in the prior art were active in vivo, but a case which required certain assumptions to be made and, accordingly, the selection of appropriate parameters, none of them referred to in the prior art. The Board thus concluded that the skilled person had no reasonable expectation of success before performing the actual experiments in vivo.

Sufficiency of disclosure

In T 748/00 the Opposition Division had found the disclosure in the patent specification with regard to the method claimed in claim 1 insufficient for fairly general reasons. No written evidence was cited in support of the insufficiency objections, nor were there any experimental data on file to support them. In the Board’s judgment, the Opposition Division’s reasons amounted to no more than mere assumptions that did not meet the standard required in order to prove that the requirement of Article 83 EPC is not fulfilled.
Similarly, in T 36/00 the opponents’ complaint was merely that the wording of the broadest claims would, inter alia, cover the possibility that other methods for which there was no sufficient teaching in the patent itself, nor any guidance in the prior art, could theoretically achieve the same result as the opposed patent. Here, the Board held that if the subjectmatter of a claim can be made to work in numerous ways in the manner described, there is no cause to interpret Article 83 EPC as requiring the claim to be limited to exclude certain only hypothetically conceivable other embodiments which might also fall under the claim. However, the Board emphasized that it would be different if there were some verifiable facts that raised serious doubts about the enabling character of the patent.
The Board in T 397/02 expounded on the case law regarding the relevance of providing a working example of the claimed subjectmatter. It is established case law that sufficiency of disclosure may be acknowledged if at least one way is clearly indicated enabling the skilled person to carry out the invention. While this does not imply that the “at least one way” has to be in the form of a working example, whether or not the example has legal significance for sufficiency of disclosure depends on the specific circumstances of the case. The Board concluded that if, for an invention that is conceptually different from earlier approaches in the prior art, the patentee fails to give even a single reproducible example, sufficiency of disclosure cannot be acknowledged. It would amount to an undue burden for the skilled person to establish how to put the invention into practice on the basis of a sole generic teaching in the patent.

Clarity

T 610/01 touched on the question of clarity of homology features, which is almost always a bone of contention in examination proceedings where DNA sequences are an issue. The competent Board stated that the reference to percentages of homology to a given sequence used to define the claimed DNA and polypeptide made them of a very wide scope. Yet, as the molecules were also defined in terms of their capacity to encode polypeptides with GA 20-oxidase activity and these activities appeared to be readily measurable, the Board was satisfied that the skilled person could identify the claimed molecules in a straightforward manner. The clarity requirements were thus considered to be fulfilled.

Conclusion

One remarkable aspect is that enablement of the claims is being judged more and more critically by the Appeal Boards, so that a lot of effort should be put into drafting the disclosure, especially the embodiment examples. It should sometimes even be considered to postpone the filing of an application until more experimental data becomes available, so as to be able to put the application on a broader footing. Further, when relying on non-sufficiency objections in opposition proceedings it is of paramount importance that experimental data be submitted.

Finally, it is emphasized that one should not be too diffident about appealing the decision of an Examining Division in order to achieve a wider scope of protection than the Examining Division was prepared to concede, since the Appeal Board is frequently more flexible on questions of novelty and inventive step than the Examining Division.

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