

Newsletter

Chemical, Pharmaceutical & Biotech

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Each issue of this newsletter is mailed in hard copy to clients, associates and friends of the Chemical, Pharmaceutical and Biotech Group of Haseltine Lake. It is our general policy, where possible, to mail a personal copy to individuals within a particular organisation. If you would like others – whether in your organisation or outside it – to receive their own direct copies, please send us their details by e-mail (dbrown@haseltinelake.com) and we will be happy to include them on our mailing list.

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EPO Approves Claims to an Old Therapeutic Use Defined by a New Mode of Action

As is known, the European Patent Office (EPO) allows novel and inventive therapeutic applications of known medicaments to be claimed via the so-called “Swiss” claiming format (“Use of substance X in the manufacture of (or “for preparing”) a medicament for new/inventive therapeutic application Y”).

Case law of the EPO Boards of Appeal has interpreted the concept of a “new/inventive therapeutic application” broadly, not merely as the treatment of a different disease compared with the prior art, but rather as a new industrial or commercial application. Thus, for example, the mere creation of a distinct group or sub-group of subjects to which a known therapy is to be applied can potentially fulfil the requirement of a “new/inventive therapeutic application” (see Board of Appeal Decision T19/86).

In Decision T836/01, EPO Board of Appeal 3.3.4 has now gone further, and has held Swiss claims of the following form to be novel:

- “Use of human interferon- β 2 for preparing a medicament for influencing tumour cell growth and differentiation”.
- “Use of human interferon- β 2 for preparing a medicament for influencing terminal differentiation of cancer cells”.

This decision is noteworthy because the prior art disclosed the use of human interferon- β 2 for treating cancer via activation of mature lymphoid cells exerting cytolytic T cell activity on cancer cells or via stimulation of the immune system of patients undergoing cancer radiotherapy or chemotherapy (Decision, Paragraph 7).

The Board held that the novel mode of action was clearly distinct from the prior art mode of action, so that each claimed therapeutic application could be seen as “not merely an explanation of how interferon- β 2 heals cancer”, but instead as equivalent to an identification of a new sub-group of subjects (Decision, Paragraph 10).

The Board of Appeal Decision related only to novelty and the application was remitted to the Examining Division for the examination of whether the novel claims involve an inventive step. That examination has not yet concluded.

See <http://legal.european-patent-office.org/dg3/pdf/t010836eu1.pdf>

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Time Limit for Completing EPO Grant Formalities to be Non-Extendible

The EPO has announced that, with effect from 1 April 2005, the four-month period allowed for the grant formalities (payment of the grant fee, filing any desired final amendments and filing translations of the claims into the other two official EPO languages) will be made non-extendible. This will mean that the two-month extension currently available on request will cease to be available. However, the current option of using the “further processing” procedure of Article 121 EPC to obtain approximately three months of further time before completing the formalities will continue to be available.

See http://www.european-patent-office.org/epo/ca/ca_pdf/cad19_04.pdf and http://www.european-patent-office.org/news/info/pdf/not22_12_2004.pdf

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German Federal Court Rules on Claim Construction

The German Federal Court of Justice has issued an important decision relating to patent claim construction (interpretation) in Germany ("Separating Device" – Federal Court of Justice, Germany – X ZR 255/01).

As is well known, Article 69 EPC that the associated Protocol on Interpretation defines a supposedly uniform approach to patent claim construction across Europe. The recent pronouncements of the UK House of Lords on the effect of Article 69 and the Protocol in biotech cases in the UK were reported in the October 2004 issue of this Newsletter.

The German court has now reinforced that Article 69 and the Protocol are the basis for the legal position in Germany, thus building on the earlier decision "Sugar Centrifuge" (X ZR 44/84).

In particular, the court clarified that the examples in a patent can generally not be used for a limiting interpretation of the terms of the claims, even when the examples describe only one type of embodiment or when the stated objects of the invention are otherwise not achieved. Moreover, the court repeated that the terms of the claims do not comprise any implicit disclosure in addition to matters of course. In the decision the judges clarified that the terms of the claims are not to be interpreted by asking the question: "What would an expert have factually thought or understood when reading the claim?" because a patent claim is supposed to have effect for all skilled people doing business in the field, not merely an expert.

From this decision, a welcome trend towards a reasonably uniform approach to claim construction in Europe can be identified, in which equivalents outside the terms of the claim are excluded from protection, whereas the terms of the claim are read so as to balance fair protection for the patentee with a reasonable degree of certainty for third parties.

See <http://juris.bundesgerichtshof.de/cgi-bin/rechtsprechung/document.py?Gericht=bgh&Art=en&sid=f5a64b5c0902fb058b2d81e82b5fbc9d&client=3&nr=30575&pos=0&anz=1>

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EPO to Cease Paper Publication of Patent Applications and Patents

The EPO has announced that, with effect from 1 April 2005, European patent applications, search reports and patents will be published only in electronic form via <https://publications.european-patent-office.org>. The certificate of grant will continue to be issued in paper form. If an applicant so requests during the pre-grant formalities, one paper copy of the patent specification will be provided free of charge with the certificate of grant (or, in the case of multiple applicants, with each certificate of grant).

See http://www.european-patent-office.org/epo/president/pdf/22_12_2004_e.pdf, http://www.european-patent-office.org/epo/president/pdf/22_12_2004b_e.pdf and http://www.european-patent-office.org/news/info/pdf/not22_12_2004.pdf

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