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EPO Still Inconsistent On Requiring Supporting Data in the Application in Second Medical Use Cases

The EPO Boards of Appeal continue to be inconsistent on the question of whether a “second/subsequent medical use” (“Swiss”) claim must be supported by test data in the application **as filed**.

Examples of recent Board of Appeal decisions in which lack of supporting data in the application papers was fatal to “second medical use” claims are T210/02, T497/02 and T609/02. In these Decisions, the Boards firmly stated the principle that, although there is no requirement for *in vivo* data, an application claiming a second medical use must include data that makes that use plausible.

In contrast, in Decision T157/03 the patentee was allowed to rely on post-published external evidence. The Board cited with approval the principle from Decision T994/95 that “in the absence of any tangible proof in the patent specification that the claimed concept can be put into practice, post-published documents may be used as evidence [as to] whether the invention was indeed reproducible without undue burden at the relevant filing date” (Decision, paragraph 9). Decision T994/95 was not a “second medical use” case, and concerned the disclosure of a production method rather than a medical use. Therefore, the extension of this principle into the second medical use arena, provided by Decision T157/03, is potentially a valuable tool for the defence of medical patents which contain relatively little supporting data.

To summarise, wherever possible European patent applications should contain test data that makes the new use plausible across the full scope of both the active agent(s) and the diseases/disorders to be treated. However, in the absence of such data, or where there is doubt as to whether the full extent of the claims is supported, Decision T157/03 provides some comfort to applicants and patentees.

- <http://legal.european-patent-office.org/dg3/pdf/t020210eu1.pdf>
- <http://legal.european-patent-office.org/dg3/pdf/t020497eu1.pdf>
- <http://legal.european-patent-office.org/dg3/pdf/t020609eu1.pdf>
- <http://legal.european-patent-office.org/dg3/pdf/t030157eu1.pdf>

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Oncomouse Decision Issued by EPO Board of Appeal 3.3.8

After massive procedural delays, the so-called “Oncomouse” case has now concluded in the EPO. The final appeal decision was recently issued under Decision No. T315/03.

Since practically all of the issues in this case (patentability of transgenic animals and of “immoral” inventions) have been resolved by the introduction of Rules 23b-e EPC in 1999 – which were held to apply to cases, like this one, which were pending at the time – no specific comment is required here.

As would be expected in view of Rules 23b-e EPC, claims to transgenic mice (i.e., at the “species” level rather than the “variety” level) having an introduced gene conferring a susceptibility to cancer were upheld, on the basis that the benefit to mankind from their use in research outweighed any potential suffering of the individual animals.

The European patent is due to expire on 25 June 2005.

- <http://legal.european-patent-office.org/dg3/biblio/t030315ex1.htm>

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Methods of Treatment of the Human or Animal Body by Surgery are Patentable in Some Circumstances

In Decision T383/03, EPO Board of Appeal 3.2.2 recently held that some surgical methods are patentable, despite the wording of Article 52(4) EPC, which reads as follows:

- “Methods of treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body shall not be regarded as inventions which are susceptible of industrial application”.

The decision referred to the preparatory materials recording the deliberations of the drafters of the European Patent Convention, and concluded that the exclusion of surgical methods from patent protection applies only to methods which are “suitable for maintaining or restoring the health, the physical integrity, or the physical well-being of the person or animal” (Decision, paragraph 4.2).

The invention in question related to a surgical method for hair removal. Since the method was not suitable for any of the purposes mentioned above, it could validly be claimed as a method of surgical treatment.

→ <http://legal.european-patent-office.org/dg3/biblio/t030383ep1.htm>

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Supplementary Protection Certificates (SPCs) – The Liechtenstein Question

The European Court of Justice (ECJ) recently decided the joined cases of **Novartis et al v. Comptroller-General and Ministre de l’Economie v. Millennium Pharmaceuticals** (ECJ Cases C-207/03 and C-252/03).

An issue was whether a marketing authorisation for Switzerland (which is not within the European Economic Area (EEA)), granted prior to any marketing authorisation in an EEA country, should be declared in the SPC as the “first marketing authorisation within the EEA” because of the fact that, by virtue of a customs treaty between Switzerland and Liechtenstein, a Swiss marketing authorisation is automatically effective also in Liechtenstein (which since 1 May 1995 has been within the EEA). The court held that such a Swiss marketing authorisation is to be considered as the “first marketing authorisation within the EEA”.

Because some SPC applicants, and some Patent Offices, were following a different understanding of the declaration requirement in this situation, it must now be checked, when reviewing the validity, term and enforceability of any SPC, whether the correct declaration of the first marketing authorisation within the EEA was made.

→ <http://curia.eu.int/jurisp/cgi-bin/form.pl?lang=en>

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