CA/PL 4/00

Orig.: German

Munich, 24.01.2000

SUBJECT: Revision of the EPC: Article 54(5)

DRAWN UP BY: President of the European Patent Office

ADDRESSEES: Committee on Patent Law (for opinion)

SUMMARY

This document answers calls from the interested circles and a number of delegations to provide better patent protection for further medical uses of known substances (the so-called "second medical indication"). The proposed amendment to Article 54(5) EPC will make it quite clear that each new (and inventive) medical use of a substance or composition already known as a medicine is patentable.

A further-reaching proposal to make all medical methods patentable by deleting Article 52(4) EPC did not meet with sufficient approval at the 9th meeting of the Committee on Patent Law from 16 to18 March 1999 (CA/PL 7/99, CA/PL PV 9). This proposal will therefore be abandoned.

I. PATENT PROTECTION FOR THE FIRST AND EACH FURTHER THERAPEUTICAL USE OF KNOWN SUBSTANCES OR COMPOSITIONS

1. According to Article 52(4), first sentence, EPC, methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body are not regarded as inventions which are susceptible of industrial application. According to the case law of the Enlarged Board of Appeal, this exclusion from patentability covers not only "methods for treatment ... by therapy", but also the "**use of a substance or composition** for the treatment of the human or animal body by therapy", such use being identical as regards content to a method excluded from patentability under Article 52(4), first sentence, EPC. The difference lies merely in the wording, not the subject-matter, of the claim (G 5/83, "Second medical indication/EISAI", OJ EPO 1985, 64).

2. By way of "compensation" for this exclusion from patentability, known substances or compositions are deemed under Article 54(5) EPC to be new, provided they are used for the first time in a medical method according to Article 52(4) EPC. The Enlarged Board extended the patentability of the "first medical use", expressly acknowledged in the legislation, to apply to each further (new and inventive) medical use (G 5/83, loc.cit.). According to the Enlarged Board, a claim directed to a **substance or composition "for use"** in the treatment of the human or animal body by therapy is directed to an invention which is susceptible of industrial application in accordance with Article 52(1) EPC. In the Enlarged Board’s view, this is clear from the provision of Article 52(4), second sentence, EPC, according to which products, substances and compositions "for use in a medical method" are in principle patentable.

3. In its decision G 5/83, the Enlarged Board held that the legislative purpose of Article 52(4) EPC is to free from restraint non-commercial and non-industrial medical and veterinary activities. However, in order to prevent the exclusion from going beyond its proper limits, the Board felt it appropriate to take a "special view" of the concept of the "state of the art" defined in Article 54(2) EPC. Since Article 54(5) EPC provides only partial compensation for the restriction on patent rights in the industrial and commercial field resulting from Article 52(4) EPC and the legislator did not intend Article 54(5) EPC to exclude further medical uses from patent protection other than by the exclusion of purpose-limited product claims, the Enlarged Board developed its well-known solution to the problem of patent protection for these uses.

4. In doing so, it made particular reference to the Legal Advice from the Swiss Federal Intellectual Property Office of 30 May 1984 (OJ EPO 1984, 581), according to which the second or subsequent medical use may be protected by a claim directed to the "use of a substance or composition **for the manufacture of** a medicament for a

specified new therapeutic application" ("Swiss form of claim"). The Enlarged Board thus considered it justified to derive novelty solely from the new therapeutic application of a substance already known as a medicament (G 5/83, loc.cit.)

5. In contrast, the *Bundesgerichtshof* (Federal Court of Justice) in Germany has held in general terms that an invention which relates to the "use of a known substance to treat an illness" is patentable, since the subject-matter of such a use claim extends beyond the treatment of the illness to the so-called "*augenfällige Herrichtung*", which includes at least the packaging of the substance with instructions for use in the treatment of the illness (BGH, "Hydropyridine", OJ EPO 1984, 26). The UK patent application, which was identical to the German application, was, however, refused by the United Kingdom Patent Office on the grounds that its subject-matter, a method of treatment of the human body by therapy, was not patentable (UK Patent Office, "Bayer AG's Application", "Hydropyridine", OJ EPO 1984, 234).

6. The national courts and appeal divisions of the patent offices of the contracting states to the EPC have taken issue to varying degrees with the case law of the Enlarged Board of Appeal relating to the "second medical use" in the so-called "Swiss form of claim", although for the sake of uniform interpretation they have mainly followed the Enlarged Board's decision (UK High Court of Justice, "Second medical use/WYETH and SCHERING", OJ EPO 1986, 175; NL *Octrooiraad, Afdeling van Beroep* (Appeal Division of the Patent Office), "Second medical use/NL", OJ EPO 1988, 405; SE *Patentbesvärsrätten* (Court of Patent Appeals), "Hydropyridine/SE", OJ EPO 1988, 198; FR *Cour de cassation*, "Alfuzosine", OJ EPO 1995, 252). In the specific case in question, the *Octrooiraad* did not grant the patent. In a more recent decision of the UK High Court handed down in 1998 (Bristol-Myers Squibb Co. v. Baker Norton Pharmaceuticals Inc., R.P.C. 1999, 253), substantial doubts were expressed as to the novelty of "Swiss claims".

7. This legal uncertainty has to be eliminated, as it is difficult to predict with any certainty whether European patents with so-called “Swiss claims” directed to a "further medical indication" will ultimately be found to be valid by the national courts in the contracting states to the EPC. Moreover, there are considerable doubts as to whether patents of this type will actually guarantee the intended protection sufficiently and whether they can be enforced accordingly.

8. It is therefore proposed that Article 54(5) EPC be amended to unambiguously permit patent protection for the second and each subsequent medical use of a substance or composition known for a medical use, in the same way as for its first medical use, in the form of purpose-related product protection.

II. PROPOSAL

Current version	Proposed version
Article 54 **Novelty**	**Article 54** **Novelty**
(1) - (4)	**unchanged**
(5) The provisions of paragraphs 1 to 4 shall not exclude the patentability of any substance or composition, comprised in the state of the art, for use in a method referred to in Article 52, paragraph 4, provided that its use for any method referred to in that paragraph is not comprised in the state of the art.	(5) The provisions of paragraphs 1 to 4 shall not exclude the patentability of any substance or composition, comprised in the state of the art, for use in a method referred to in Article 52, paragraph 4, provided that **this use [....]** is not comprised in the state of the art.