MR/18/00

Orig.: d,e,f

Munich, 21.11.2000

SUBJECT: Basic Proposal - Explanatory notes
- Article 54(4) and Article 54(5) EPC

DRAWN UP BY: Swiss delegation

ADDRESSEES: Revision Conference (for consideration)

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BASIC PROPOSAL – EXPLANATORY NOTES (Text established by the Swiss Delegation)

ARTICLE 54(4) and ARTICLE 54 (5) EPC

Revised wording

Article 54
Novelty

(1) unchanged

(2) unchanged

(3) unchanged

(4) The provisions of paragraphs **2 and 3** 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 **53(c)** provided that its use for any method referred to in that paragraph is not comprised in the state of the art.

(5) Notwithstanding paragraphs 2 and 3, the provisions of this article shall not exclude the patentability of any substance or composition referred to in paragraph (4) for any specific use in any method referred to in Article 53(c), provided that such use is not comprised in the state of the art.

Explanatory remarks
(Preparatory documents: CA/PL 4/00 + Info 2/PL 12; CA/PL PV 12, points 23-31. Info 2/PL 14; CA/PL PV 14, point 199 – 226; CA/100/00, pages 45 – 48; CA/124/00, point 17; CA/125/00, point 74 - 90)

1. According to Article 54(5) EPC, by way of "compensation" for the exclusion from patentability of medical methods under Article 52(4), first sentence, EPC, known substances or compositions are deemed to be **new**, provided they are used **for the first time** in such a medical method. The amendment to **Article 54(5) EPC (now paragraph 4)** takes account of the deletion of previous Article 54(4) EPC and the incorporation of Article 52(4) EPC into Article 53c) EPC. Apart from this editorial amendment the substance of this article is unchanged. Up till now, the Office, following the case law of the Boards of Appeal, has granted a broad claim for the first medical use, i.e. for a general therapeutical purpose, e.g. as a "pharmaceutical substance", a "therapeutic agent" or a "medicament", even if only one specific application is disclosed in the application (see T 128/82, "Pyrrolidine derivatives/ HOFFMANN-LA ROCHE", OJ EPO 1984, 164; T 36/83, "Thenoyl peroxide/ ROUSSEL-UCLAF" OJ EPO 1986, 295). Based on this practice, the first to invent a use of a substance or composition in a medical method should receive broad protection covering any use in a medical method. This corresponds to the contribution to the art, namely opening the field of medical use for the substance or composition.

2. The Enlarged Board of Appeal was asked to decide whether any **further** medical use could receive patent protection under the EPC in spite of the wording of Article 54(5) EPC which seemed to limit patentability to the first medical use. The Enlarged Board extended the notional novelty provided for in Article 54(5) EPC to apply to **each further** medical use in the so-called "Swiss type claim", ie to a claim "directed to the use of a substance or composition **for the manufacture** of a medicament for a specified new and inventive therapeutic application" (G 5/83, "Second medical indication/EISAI", OJ EPO 1985, 64; Legal Advice from the Swiss Federal Intellectual Property Office of 30 May 1984, OJ EPO 1984, 581).

3. The national courts and appeal divisions of the patent offices of the contracting states have, for the sake of uniform jurisprudence, generally followed this decision (see e.g. UK High Court of Justice, "Second medical use/WYETH and SCHERING", OJ EPO 1986, 175; SE *Patentbesvärsrätten* (Court of Patent Appeals), "Hydropyridine/SE", OJ EPO 1988, 198; FR *Cour de cassation,* "Alfuzosine", OJ EPO 1995, 252; UK High Court in *Bristol-Myers Squibb Co. v. Baker Norton Pharmaceuticals Inc.,* R.P.C. 1999, 253). However, the Dutch Octrooiraad cast doubt on the validity of Swiss type claims in general: *Octrooiraad, Afdeling van Beroep* (Appeal Division of the Patent Office), "Second medical use/NL", OJ EPO 1988, 405.

4. The new **Article 54(5) EPC** eliminates any legal uncertainty on the patentability of further medical uses. It unambiguously permits purpose-related product protection for each further new medical use of a substance or composition already known as a medicine. This protection is equivalent, as far as the further uses are concerned, to that offered by the "Swiss type claim". In contrast to previous Article 54(5), now Article 54(4) EPC, providing broad (generic) protection for use in a medical method for the inventor of such use for the first time, new Article 54(5) is expressly limited to a **specific** use. This limitation is intended to match as closely as possible the scope of protection to the scope provided by a "Swiss type claim".