



**FÉDÉRATION INTERNATIONALE DES CONSEILS EN PROPRIÉTÉ INDUSTRIELLE
COMMISSION D'ÉTUDE ET DE TRAVAIL (CET)**

SUBJECT: Article from CET 3 - Patentability of second (or further) medical uses as presented to Buenos Aires ExCo as EXCO/AR10/CET/1307

PURPOSE: Article

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At the ExCo Meeting in Buenos Aires, CET Group 3 presented a paper on the patentability of second (or further) medical uses. This paper, EXCO/AR10/CET/1307, was authored by Andrew Meikle and Martin Bensadon, and discusses topics as follows.

While research into additional medicinal or veterinary uses of currently marketed drugs and previously known substances is a very important part in the R&D activities performed by the pharmaceutical industry, some countries do not provide patent protection for new medical uses of known substances either by express prohibition in the national law or by applying a restrictive interpretation of other provisions in the law. For example, a second medical use of a known substance is deemed in some countries as not being inventive or as constituting an unpatentable therapy method, irrespective as to the form of the claim.

Developing countries have been expressing their desire to safeguard public interest flexibilities within the substantive patent law harmonization process. In the context of WIPO's Development Agenda, one of the proposals states that, "WIPO shall make available advice to developing countries and LDCs, on the implementation and operation of the rights and obligations and the understanding and use of flexibilities contained in the TRIPS Agreement". The debates in some countries suggest that some governments intend to interpret TRIPS so as not to require WTO Members to consider new medical uses as patentable subject matter.

This same issue was also subject of discussions in the EPO. The landmark decision G5/83 rendered in 1985 by the Enlarged Board of Appeals established that while a method of treatment claim in the form "Use of substance Y for the treatment of disease X" was unallowable in view of Article 52(4) EPC, a Swiss type claim in the known format "Use of substance Y for the preparation of a medicament for the treatment of disease X" would not contravene that same article. More recently, EPC 2000 has come into force as of December 13, 2007 and includes a newly worded Article 54(5) which provides that the use of a composition in any "specific" method of treatment is patentable provided that such specific method of use is not comprised in the state of the art. Thus, second and subsequent medical uses of known products can now be claimed in an ordinary format without requiring the Swiss type format.

In the United States and other countries, such as Japan, Australia and New Zealand, second medical uses may be patented, as long as other conditions for patent eligibility, such as novelty, inventive step, industrial applicability, etc. are satisfied.

After reviewing the legal framework in TRIPS, the issues arising with regard to the patenting and barriers to patenting new medical uses are addressed, and a conclusion is suggested to the effect that Patent Offices should not exclude from patentability patent claims directed to second (or further) medical uses, provided that such claims meet all other patent eligibility requirements.