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Observations in Case G 2/08 of the Enlarged Board of Appeal of the European Patent Office

The Association of Danish Patent Agents, representative of the profession in private practice in Denmark, hereby respectfully submits the following observations for the case G 2/08 in accordance with Art. 10 of the Rules of Procedure of the Enlarged Board of Appeal.

The Association of Danish Patent Agents (hereinafter "Association") wishes to express its support to the observations filed by FICPI in this case. In this regard, we would, however, like to stress some specific points.

First of all any restriction in the field of patentable subject matter must be interpreted narrowly. The very aim of the patent system is to reward innovation and this can only be achieved by putting the fewest possible limitations to what is considered a patentable invention.

Art. 53c EPC excludes from patent protection "methods for treatment of the human or animal body" but also stipulates that "this provision shall not apply to products, in particular substances or compositions, for use in any of these methods". The term "any of these methods" is not narrowed down neither by law nor by the "Travaux Preparatoires" for the EPC 2000. Thus, no further qualification with regard to the type or nature of "any of these methods" can be found. In Art. 54(5) EPC 2000, it is stipulated that patentability shall not be excluded for any "specific use" provided that such use is not comprised in the state of the art. No detailed criteria as to what qualifies as "specific" appears from the convention text and thus the wording of the provision does not preclude that the application of a dosage regimen is regarded as a "specific use".

The leading decision with regard to the patentability of second medical use claims until now is decision G 5/83.

In decision G 5/83 the Enlarged Board of Appeal stated in point 2 of its order that *"A European patent may be granted with claims directed to the use of a substance or composition for the manufacture of a medicament for a specified new and inventive therapeutic application".*

In the view of the Association, the word "specified" must be understood to be merely in contrast to the unspecified therapeutic application allowable in a claim for a first medical use and thus not to impose any further restrictions or conditions as to the kind or nature of said "specification". Thus, the Enlarged Board of Appeal in said decision did not seem to make any distinction other than between a first and a further medical indication and did not give any guidance as to the specificity with which the therapy for a further medical indication should be formulated.

In the view of the Association, a specific dosage regimen qualifies as a "new and inventive therapeutic application" and is *prima facie* patentable, provided the general requirements of patentability are met, i.e. novelty and inventive step.

The Association also fully agrees with the points of view expressed in decision T 1020/03 and refers generally to the arguments presented therein.

Thus, the Association is of the opinion that someone who finds a regimen of administration which avoids previous disadvantages of a certain drug substance may be the first to provide a really useful therapy and should be able to enjoy the protection for a composition for that use.

The Association is fully aware of the need for striking a fair balance between on the one hand the interests of the patent holder and on the other hand the interests of any third party and not least the need for legal certainty. However, in the present case said interests are served by stipulating that the ordinary patentability requirements must be met.

The Association is also aware of the point of discussion regarding the role of the physician in relation to patents to a specific dosage regimen. However, for the same reasons as put forward in the above-referenced observations from FICPI this seems not to present any problems, since a patent to a specific dosage regimen will exclude only the production and sale of the drug in question in this dosage regimen, but not the medical use *per se*.

Respectfully submitted

Anne Schouboe
President