

EPO Enlarged Board of Appeal decides on 2nd and further medical use claims: G 2/08, Dosage regimens

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The present decision of the Enlarged Board of Appeal (EBoA) confirms established case law with regard to second (and further) medical use claims.

In the application underlying the decision, claim 1 reads as follows:

1. "The use of nicotinic acid [...], for the manufacture of a sustained release medicament for **use in the treatment by oral administration once per day prior to sleep, of hyperlipidaemia** characterized in that the medicament does not comprise [...]."

The feature "**once per day prior to sleep**" was the only distinguishing feature with respect to the prior art and was held being a medical activity excluded from patentability by the first instance, which referred the following questions to the Enlarged Board of Appeal:

Q1. Where it is already known to use a particular medicament to treat a particular illness, can this known medicament be patented under the provisions of Articles 53(c) and 54(5) EPC for use in a different, new and inventive treatment by therapy of the same illness?

Q2. If the answer to question 1 is yes, is such patenting also possible where the only novel feature of the treatment is a new and inventive dosage regimen?

Q3. Are any special considerations applicable when interpreting and applying Articles 53(c) and 54(5) EPC 2000?

The EBoA decided as follows:

A1: The answer to Q1 is [yes]: Where it is already known to use a medicament to treat an illness, Article 54(5) EPC does not exclude that this medicament be patented for use in a different treatment by therapy of the same illness.

The Board affirmed that Article 54(5) EPC does not define the nature of the further therapeutic use, instead it expressly refers to "any specific use" and the term "any specific use" should not be interpreted to be limiting in any way.

A2: The answer to Q2 is [yes]: "Such patenting is also not excluded where a dosage regimen is the only feature claimed which is not comprised in the state of the art."

In view of the answer to the first question, the EBoA restated that the "specific use" of Article 54(5) may reside in something else than the treatment of a different illness and that there is no reason to approach a feature relating to a dosing regimen differently as compared with other specific uses acknowledged in the case law (e.g. novel group of subjects treated, new route or mode of administration, new technical effect).

A3: The answer to Q3 is: "Where the subject matter of a claim is rendered novel only by a new therapeutic use of a medicament, such a claim may no longer have the format of a so called Swiss-type claim as instituted by decision G 5/83".

According to the EBoA, the old practice set by G5/83 was a necessary exception to the provisions of the EPC1973, that allowed purpose-limited product claims only for first medical uses. The new provision of Article 54(5) EPC 2000 closes the gap in the provisions of the EPC1973, thus allowing purpose-limited product claims for second and further medical uses.

Hence, the EBoA took the opportunity of question 3 to end the practice of pursuing Swiss-type claims in the future. A time limit of three months after publication of the decision in the Official Journal of the EPO is set in order that future applicants can comply with the new situation, the relevant date being the date of filing of the application or, if priority has been claimed, the priority date.

Until then, we recommend to have both claim formats for second and further medical use claims on file, in particular as to date, Swiss-type claims were held to be the only acceptable claim format in Switzerland.

To summarize: A dosage regimen as the distinguishing feature over the prior art can be used for establishing patentability of a medical use claim.