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Dosage regime claims

Derk Visser (EIP) · Thursday, April 29th, 2010

A second medical use claim can be based on a novel dosage regimen. In decision T317/95 a Board of Appeal decided that this type of claim was not allowable. It regarded the activity of administrating a medicine as a therapeutic treatment and, hence, an activity in a field excluded from patentability. Since the patent right must be in the industrial and commercial field, the distinguishing feature of the claim should not relate to non-commercial and non-industrial medical activities. However, closer inspection of the decision showed that the reasoning of the Board was in conflict with decision G5/83 of the Enlarged Board of Appeal. In spite of this, several other decisions refused claims based on dosage regimens.

Decision T1020/03 disagreed with the earlier decisions and allowed claims based on a drug regimen, showing that the earlier decisions did not follow the decision of the Enlarged Board of Appeal. Subsequently, the President of the EPO approved the use of T1020/03 by the examining divisions.

Decision T1319/04 has asked the Enlarged Board of Appeal to decide whether a novel dosage regiment for an otherwise known therapeutic purpose is sufficient to confer patentability on that use under the EPC 2000, since decision T1020/03 was taken under the EPC 1973.

In February 2010 the Enlarged Board of Appeal has pronounced its decision G2/08. It gave the following summary:
“I. 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.
II. Such patenting is also not excluded where a dosage regime is the only feature claimed which is not comprised in the state of the art.
III. Where the subject matter of a claim is rendered novel only by a new therapeutic use of a medicament, such claim may no longer have the format of a so called Swiss-type claim as instituted by decision G 5/83. Future applicants must comply with this new situation three months after publication of the decision in the Official Journal of the EPO.”

The Enlarged Board of Appeal arrived at point I of the summary by giving a broad interpretation to ‘any specific use’ in Article 54(5) EPC; the specific use need not be the treatment of another disease. A dosage regimen is not given another treatment than the one given to any other specific use acknowledged in the case law; hence, patenting is not excluded where a dosage regime is the only new feature claimed.

The Swiss-type claim directed to the use of a substance or composition for the manufacture of a medicament for a specified therapeutic application, as permitted by decision G5/83, was used to fill a gap in the legal provisions of the EPC 1973. Article 54(5) EPC 2000, permitting a purpose-related product protection for any further specific use of a known medicament in a method of therapy, closes the loophole. Since the reason for the Swiss-type claim has ceased to exist, the Swiss-type claim may no longer be used.

The abolishment of the Swiss-type claim has no retroactive effect and applies only to future applications that have a date of filing or, if priority has been claimed, a priority date later than three months after publication of G2/08 in the Official Journal of the EPO. At the time of writing (April 2010), the decision had not yet been published.

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