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# METHODS OF TREATMENT IN EUROPE: PATENT CLAIMS COVERING SECOND OR FURTHER MEDICAL USES AND DOSAGE REGIMENS

The decision G 2/08 of February 19, 2010 (published October 28, 2010) of the Enlarged Board of Appeal (EBA) of the European Patent Office confirms that a substance or composition known as a medicament for treating a certain illness can be patented for use in a different treatment by therapy of the same disease. In particular, patentability is allowable where a dosage regime is the only feature claimed that is not disclosed in the state of the art.

According to Article 54(5) EPC 2000, the patentability of any substance or composition, comprised in the state of the art, for any specific use in a method for treatment of the human or animal body by surgery or therapy and in a diagnostic method practiced on the human or animal body shall not be excluded, provided that such use is not comprised in the state of the art.

The EBA indicates that the wording of Article 54(5) EPC 2000, namely "for any specific use," should not be narrowly interpreted as only referring to the treatment of a different disease. A narrow interpretation would also not be in line with the decision G 5/83 and the established case law under the EPC 1973.

The EBA further takes the position that—because second and further medical uses under Article 54(5) EPC 2000 are not restricted to the treatment of a different disease but are directed to "*any* specific use"—there is no reason why a new dosage regime of a known medicament should be treated differently from any other specific use, such as in the case of a novel group of subjects to be treated or a new route or mode of administration, which is acknowledged by established case law.

Thus, a substance or composition known as a medicament for treating a certain illness could be patented for use in treating the same disease. This includes novel and inventive dosage regimes. For pharmaceutical companies, G 2/08 provides ways to prolong patent protection for their blockbuster products by looking into novel dosage regimes of the drug, given that the dosage regime of course involves an inventive contribution over the art.

Furthermore, important for the patent practitioner, in G 2/08, claims may no longer be the so-called Swiss-type, which have the general format of: "Use of substance X for the manufacture of a medicament for treating disease B." Swiss-type claims were adopted by the EBA in decision G 5/83 of December 5, 1984, to make patent protection for second or further medical uses possible, because the EPC 1973 did not contain any provision that allowed second or further medical uses. However, Article 54(5) EPC 2000 explicitly stipulates that substances known as a medicament for second and further medical uses are not excluded from patentability, and thus it provides a legal basis for purpose-limited product claims having the general format: "Substance X for use in treating disease B." As a result, the loophole existing under the EPC 1973 has been closed by Article 54(5) EPC 2000, and, according to the EBA, the Swiss-type claim has lost its meaning.

For inventions relating to second or further medical uses, the European Patent Office will not grant patents in respect to European or International applications having a filing date or earliest priority date of January 29, 2011 or later if they contain Swiss-type claims. If any such application contains Swiss-type claims, the EPO will invite the applicant to correct this deficiency.

In practice, since the EPC 2000 entered into force, purpose-limited product claims have been the preferred form for drafting first and second medical use claims. With regard to the inhomogeneous requirements on the allowed forms for medical use claims on a national level, Swiss-type claims often have been included in parallel to ensure the maximum scope of protection. It is worth noting that Swiss-type claims have not been considered admissible in all contracting states of the European Patent Convention. In the U.K., for example, Swiss-type claims were allowed in order to achieve conformity with European practice (*see*, for example, Decision of the High Court of Justice, Patents Court relating to applications of John Wyeth & Brother Ltd. and Schering A.G., dated July 4, 1985, OJ EPO 6/1986, pp. 175-192). In the Netherlands, however, Swiss-type claims were objected to by the Appeal Division of the Dutch Patent Office (Decision No. 16673 dated September 30, 1987, OJ EPO 10/1988, pp. 405-415). In France, issues relating to validity and scope of protection in relation to Swiss-type claims have not yet been formally settled.

With the uniform application of the purpose-limited product claim format, one might hope that the claims relating to second or further medical uses will become harmonized throughout Europe. However, further pitfalls will still have to be expected in connection with such claims.

Where the second or further medical use is based on a novel dosage regime, national authorities in the various EPC member states have considered admissible different wordings. In the U.K., for example, the Court of Appeal for England and Wales held that a new dosage regime was enough to confer novelty on a Swiss-type claim (*see Actavis UK Ltd. v. Merck & Co. Inc.* [2008] EWCA Civ 444 of May 21, 2008). Thus, one would expect that in the U.K., purpose-limited product claims drafted in the following format would be considered allowable: "Substance X for use in treating disease A, wherein the substance is administered by dosage regime Q."

In Germany, however, the Federal Court of Justice considered that a Swiss-type claim drafted in the format: "The use of a compound X for the manufacture of a medicament for treating condition B, wherein *the medicament is administered* in a dosage regime Q" does not comply with Article 52(4) EPC and § 5(2) of the German Patent Act (Decision X ZR 236/01–"Carvedilol II," dated December 19, 2006). However, the Court considered the following, slightly modified wording allowable: "The use of a compound X for the

manufacture of a medicament for treating condition B, wherein *the medicament is* ***prepared to be*** *administered* in a dosage regime Q."

Therefore, it is to be expected that despite the harmonization achieved by replacing Swiss-type claims by purpose-limited product claims, the exact wording of the claims might still be decisive when it comes to enforcement and invalidation of European patents relating to second or further medical uses on a national basis in the various EPC member states.

## LAWYER CONTACTS

For further information, please contact your principal Firm representative or one of the lawyers listed below. General email messages may be sent using our "Contact Us" form, which can be found at www.jonesday.com.

**Dr. Martin Weber**
Munich
+49.89.20.60.42.200
mweber@jonesday.com

**Dr. Ping Li**
Munich
+49.89.20.60.42.200
pli@jonesday.com