

EPO Enlarged Board of Appeal allows claims to dosage regimes

G2/08, handed down by the Enlarged Board on 19th February 2010, confirms that inventions solely distinguished by a dosage regime may be patented in Europe.

This important decision has cleared up long-standing uncertainty in the law and provides new and wide-ranging opportunities for patentees to protect their pharmaceutical inventions.

Dosage regimes are patentable

The decision hinges on the meaning of Article 54(5) EPC 2000, which provides that *any substance or composition... for any specific use* in a method of treatment by surgery or therapy may be patentable, provided the use is not known.

As discussed in a previous practice note, Article 54(5) EPC was introduced by EPC 2000 and provided a statutory basis for the “new-style” further medical use claims of the form: *Product X for use in a method of treating disease Y*.

In G2/08 the Board has clarified the meaning of *any specific use* in Article 54(5) EPC and, being unable to find any intention by the legislator to limit the scope of the phrase, has held (by reference to the word **any**) that the phrase should be given its ordinary, broad meaning which does not introduce any arbitrary limitation to treatment of a new disease.

Accordingly, the Board held that *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*.

Furthermore, finding that there was no reason to give a dosage regime of a known medicament any different treatment from other specific uses (for instance specific patient sub-populations or new routes of administration which, according to established case law, are capable of being recognised as patentable inventions), the Board concluded that **patenting is also not excluded where a dosage regime is the only feature claimed which is not comprised in the state of the art**.

Applicability beyond dosage regimes

The Board’s reliance upon previously established case law relating to other

specific uses (for example patient sub-populations and new routes of administration, as mentioned above) and its emphasis on **any** specific use appears to provide for a wide variety of acceptable specific uses, not limited to dosage regimes.

Interesting *possibilities* now appear available for claiming pharmaceutical inventions using limitations and distinctions which were not previously open to applicants at the EPO.

This new law provides particular opportunities for line-extension inventions, and the Board has been alive to the concerns of “undue” prolongation of patent rights.

The Board's solution has been to emphasise the need for the whole body of EPO case law to be applied to any new specific use, in particular to distinguish those uses which genuinely reflect a different technical teaching (*i.e. provide a new technical effect*) from those which merely differ from the prior art by semantics.



Benefiting from these new possibilities will therefore require care at the drafting stage: a clear description in the original application of the new specific use; a clear indication of the technical effects obtainable which distinguish the invention from the known uses; and evidence that the invention provides the purported effect.

Abolition of “Swiss-style” claims

Finally, the Board has held that the previous so-called “Swiss-style” claim format (*Use of X in the manufacture of a medicament for treatment of a new and inventive therapeutic application Y*) has no future under the terms of Article 54(5) EPC 2000.

Swiss-style claims will not be permissible in European applications that have a priority date of 3 months after publication of G 208 in the Official Journal of the EPO (as of 25th June 2010, publication has not yet occurred). However, Swiss-style claims remain

important in many other patent offices around the world and best practice should be to add new style further medical use claims under Article 54(5) EPC to existing US-style method of treatment claims and Swiss-style claims.

Notwithstanding the decision to abolish Swiss-style claims, there is no retroactive effect on existing Swiss-style claims before the EPO. The Board has, however, recognised the possibility of a subtle broadening of scope in moving from Swiss-style claims to new further medical use claims under Article 54(5) EPC. In normal circumstances, the difference in scope, if any, is unlikely to have a practical impact on effective protection. However, the Board's view appears to raise the possibility of a scope extension objection if converting a Swiss-style claim to a new further medical use claim after grant.

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