G 2/08: DOSAGE REGIMES AND THE DEATH OF THE SWISS-TYPE CLAIM

Overview

The European Patent Office (EPO) has published the awaited Enlarged Board of Appeal decision G 2/08. This decision provides clarification on the patentability of dosage regimes in Europe, as well as some more general guidance on what is meant by "any specific use" in Article 54(5) EPC. The decision also spells the end for the Swiss-type claim at the EPO.

Background

Under EPC 1973, while purpose-related product claims were provided for in law for the first medical indication ("X for use in treating Y"), there was a gap in the law concerning claims for second or further medical uses. This gap was filled by Enlarged Board decision G 5/83, which provided a way of claiming further medical uses using the Swiss-type claim ("Use of X for the manufacture of a medicament for a specified new and inventive therapeutic application Y").

In implementing the principles laid down in G 5/83, the Technical Boards of Appeal took the view that G 5/83 did not exclude that the patentability of a second medical application could be derived from distinguishing features other than the treatment of a different disease. By doing so they extended the concept the Enlarged Board had evolved to cases where the same medicament was used in the treatment of the same illness.

One intention of EPC 2000 was to enshrine the case law evolved by the Enlarged Board of Appeal into the European Patent Convention.

Thus, contrary to the law under EPC 1973, purpose-related product claims are provided for under EPC 2000 for both the first medical use (A54(4) EPC) and further medical uses (A54(5) EPC). The wording of A54(5) EPC is that:

> "Paragraphs 2 and 3 [*of Article 54 EPC*] shall also not exclude the patentability of any substance or composition referred to in paragraph 4 [*any substance or composition, comprised in the state of the art*] for **any specific use** in a method referred to in Article 53(c) [*methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body*], provided that such use is not comprised in the state of the art."

Since the introduction of EPC 2000, the difficulty for practitioners has been knowing the meaning of "any specific use". Further, there has been much debate over whether the scope of protection conferred by a purpose-related product claim under A54(5) EPC 2000 really is equivalent to the scope provided by a Swiss-type claim, as was apparently intended by the legislators.

G 2/08

European patent application no. 94306847.8 (Abbott Respiratory LLC) was refused by the EPO Examining Division. This decision was based on a Claim 1 which read as follows:

> "1. The use of nicotinic acid or a compound metabolized to nicotinic acid by the body selected from a group consisting of d-glucitol hexanicotinate, aluminium nicotinate, niceritrol, d,1-alpha-tocopheryl nicotinate and nicotinyl alcohol tartrate, for the manufacture of a sustained release medicament for **use in the treatment by oral administration once per day prior to sleep, of hyperlipidaemia** characterised in that the medicament does not comprise in admixture, 5-30% hydroxypropyl methylcellulose, 2-15% of a water soluble pharmaceutical binder, 2-20% of a hydrophobic component and 30-90% nicotinic acid."

The Examining Division was of the opinion that the subject-matter of Claim 1 was anticipated by the disclosure in earlier documents, which contemplated the use of nicotinic acid for the manufacture of a sustained release medicament for use in the treatment of hyperlipidaemia by oral administration. The Examining Division considered that the feature of Claim 1 relating to a specific drug regime, i.e. once per day prior to sleep, reflected a medical activity excluded from patentability under Article 52(4) EPC 1973, which could not therefore be considered to represent a further medical indication from which novelty could be derived. The applicant filed an appeal against this decision.

Since the application was pending on the date on which EPC 2000 entered into force, the Technical Board of Appeal considered the application under the provisions of EPC 2000. It referred the following questions to the Enlarged Board for decision:

> 1. 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 2000 for use in a different, new and inventive treatment by therapy of the same illness?
>
> 2. 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 regime?
>
> 3. Are any special considerations applicable when interpreting and applying Articles 53(c) and 54(5) EPC 2000?

Conclusions of G 2/08

The new use within the meaning of Article 54(5) EPC need not be the treatment of another disease.

In relation to question 1, the Enlarged Board of Appeal noted that the authors of the revised EPC 2000 expressed their will to have the *status quo* maintained for medical uses. In this regard, it was noted that the Technical Boards of Appeal had established the patentability of second and further therapeutic uses of a known medicament in the broadest sense of the term by allowing claims not only directed to the treatment of another disease, but also claims drawing novelty from a method of administration, a new class of patients, as well as from new dosage regimes (see T 19/86, T 893/90, T 233/94,

all relating to a novel group of subjects treated; T 51/93 and T 138/95, both relating to a new route or mode of administration; and T 290/86 and T 254/93, relating to a different technical effect and leading to a truly new application as set out in T 1020/03).

The Enlarged Board considered whether they should adopt a narrow interpretation of "any specific use" in Article 54(5) EPC to mean treatment of another disease. They found that this would amount to arbitrarily introducing a distinction that the law does not make (see reasons 5.9.1.1).

The Enlarged Board said that to decide to the contrary would unduly reduce scope of the new provision under Article 54(5) EPC, and to that extent would not genuinely reflect the intention of the legislator. Thus, the Enlarged Board came to the conclusion that the new use within the meaning of Article 54(5) need not be the treatment of another disease (see reasons 5.10.3).

A claim in which the only novel and inventive feature is the dosage regime is allowable. However, demonstrating inventive step will nearly always require experimental data to confirm some unexpected technical effect associated with the selected dose.

In relation to the second question, the Enlarged Board of Appeal came to the decision that the "specific use" in the sense of Article 54(5) EPC may reside in something else then the treatment of a different illness, and that there is no reason to give to a feature consisting in a new dosage regime of a known medicament a different treatment than the one given to any other specific use acknowledged in case law (see reasons 6.1).

The Enlarged Board felt it important to stress, however, that for the assessment of novelty and inventive step of a claim in which the only novel feature would be the dosage regime, the whole body of jurisprudence relating to the assessment of novelty and inventive step also applies. Here, it is expected that case law relating to selection inventions will become relevant. As such, whilst it may be relatively easy to achieve novelty for a dosage claim, demonstrating inventive step will nearly always require experimental data to confirm some unexpected technical effect associated with the selected dose.

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.

The Enlarged Board of Appeal acknowledges in paragraph 6.5 of the reasons that it appears that the rights conferred on the patentee by the claim category under Article 54(5) EPC 2000 are likely broader than Swiss-type claims. (Note: There was implicit acknowledgement of this in T 250/05, paragraphs 3.4-3.6 of the reasons for the decision, where the Technical Board of Appeal stated that Article 123(3) EPC would not allow the change of category of a granted use claim into a product claim, even if drafted as a purpose-related product claim.)

Despite this acknowledgement from the Enlarged Board that there is a difference in the scope, the Enlarged Board has decided that the loophole existing in the provisions of EPC 1973 has been closed and therefore the need for the Swiss-type claim no longer exists. Therefore, the Enlarged Board has decided that 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 Swiss-type claim. However, this decision is to have no

retroactive effect and is only set to apply to applications with a priority/filing date more than three months after publication of G 2/08 in the Official Journal of the EPO.

Practice Points

The decision of the Enlarged Board of Appeal concerning dosages is broadly in line with the approach of the UK Courts. The UK Court of Appeal held in 2008 in Actavis v Merck that Swiss-type claims are allowable where the novelty is conferred by a new dosage regime or other method of administration of a known substance. However, claims to a second or further medical indication in the purpose-related product claim format have not been tested yet at all in the UK Courts. While the case law and practice develop, our advice is to continue the existing practice of including both purpose-related product claims and Swiss-type claims in pending patent applications. It is not clear yet whether the UK Intellectual Property Office will continue to allow the Swiss-type format in UK patent applications.