EPO holds new and inventive dosage regimes patentable and abolishes so-called Swiss-type claims

Last week, the Enlarged Board of Appeal ("EBA") of the European Patent Office ("EPO") announced its decision in *Abbott Respiratory (G 2/08)* relating to the patentability of dosage regimes. In answering the questions referred from the Technical Board of Appeal ("TBA") of the EPO in case T 1319/04, the EBA held that a novel and inventive dosage regime is patentable, even where that dosage regime is the only novel feature of a known drug to treat a known illness. The EBA also held that claims for a new therapeutic use of a known drug may no longer be in the format of a so-called Swiss-type claim.

Business impact

This decision will have a number of effects on UK and European patent practice.

First, a novel and inventive dosage regime for a known drug is now patentable in Europe. This decision is consistent with the UK Court of Appeal decision of 21 May 2008 in *Actavis UK Limited v Merck & Co., Inc.* [2008] EWCA Civ 444, which changed English law to permit such patenting in the UK. Although the Court of Appeal in *Merck* unusually extended the time for leave to appeal to the Supreme Court until 28 days after this *Abbott Respiratory* decision - in case the EBA ruled against the patentability of dosage regimes - the present decision now appears to have settled the position. Note, however, that dosage regimes may lack an inventive step since it is standard research practice to investigate them.

Secondly, the potential monopoly for additional uses of existing drugs has broadened in scope. Patents may be obtained for new medical uses of a known drug, even where the new medical use is in the treatment of a known disease (in the sense of a disease already treated by the claimed drug). Novelty can reside not only in a new dosage regime, but also in features such as the class of patients to be treated or the method of administration for a known disease.

Finally, second and further medical uses of a known drug have traditionally been protected using a Swiss-type claim: "Use of X in the manufacture of a medicament for the treatment of Y". However, the EBA has now held that this Swiss-type format can no longer be used where a claim is rendered novel only by a new therapeutic use of a drug. Although this change does not have retrospective effect, future patent applicants have three months from the publication of this decision in the Official Journal to comply with this new requirement.
Background

In essence, the case concerns the patentability or otherwise of a Swiss-form claim for the use of sustained-release nicotinic acid in the treatment of abnormal levels of lipids in the blood (hyperlipidaemia) where the novel feature was providing the drug "once per day prior to sleep". The key point in dispute was whether the new dosing regime could confer novelty on an otherwise known claim.

The law on patents for medical uses

Methods of treatment are excluded from patent protection for public health policy reasons - physicians should be free to take all appropriate action to prevent or cure a disease without being inhibited by patents. The first medical use of a known product is patentable, even if the product is not new; novelty is conferred by the new medical use (Article 52(4) and 54(5) of the European Patent Convention ("EPC") 1973). Further medical uses of a known product were not explicitly protected under EPC 1973, but have been so protected by Swiss-form claims following the decision of the EBA in *Eisai* (G5/83).

Such Swiss-form claims are construed to cover the manufacture of the compound, rather than being a method of treatment that cannot be patented (Article 52(4) EPC 1973). The novelty requirement for such claims can be satisfied by a "specified new and inventive therapeutic application" of the compound.

The key issue is that the EPC does not define the nature of the therapeutic application for it to deserve protection. One construction is that the "specified new and inventive therapeutic application" is the use of a known drug in a new disease. The alternative construction is that it is use that is "specific" rather than generic, and is not confined to any particular indication, i.e. the use need not necessarily consist in the treatment of a different disease. The EBA in this case phrased this question as: "Is a new use, deserving patent protection, of a per se known medicament, necessarily restricted to a disease not yet treated by said composition?"

The patent application and questions for referral to the EBA

The Swiss-form claim for the use of nicotinic acid is contained in European patent application no. 94 306 847.8, originally filed by Kos Life Sciences, Inc., now Abbott Respiratory LLC ("Abbott"). Having been refused by the EPO Examining Division on the basis that the dosing regime "once per day prior to sleep" reflected a medical activity excluded from patentability under Article 52(4) EPC 1973, Abbott appealed to the TBA. The application was still pending when EPC 2000 came into force on 13 December 2007, and the TBA decided that EPC 2000 (Articles 53(c), 54(4) and (5)) rather than EPC 1973 (Articles 52(4) and 54(5)) applied. The TBA referred to the EBA the following questions:

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?

The decision

**EPC 2000**

The EBA held that Articles 53(c), 54(4) and 54(5) of EPC 2000 were respectively
equivalent to Articles 52(4) EPC 1973, Article 54(5) EPC 1973 and the decision of the EBA in *Eisai* (G5/83) in relation to further medical uses of a known drug.

The EBA agreed that the shifting of the former provisions of Article 52(4) EPC 1973 to new Article 53(c) EPC 2000 "is a purely editorial change" and "does not change the actual legal position". Both provisions prohibit the patenting of methods for treatment of the human body by therapy, but the EBA explained that the legislative motive for moving the provision was "the realisation that such methods were excluded from patentability for reasons of public health and that, consequently, to base the exception on lack of industrial applicability [i.e. Article 52(4) EPC 1973] was no longer justified."

The EBA held that "no fundamental change was intended" in moving Article 54(5) EPC 1973 to new Article 54(4) EPC 2000. Both provisions relate to the patentability of the first (new) medical use of a known substance.

Article 54(5) EPC 2000 expressly allows further patent protection of known drugs provided their use in a method under Article 53(c) is new and specific. This replaces the protection that had been provided by Swiss-form claims following *Eisai* (G5/83), although the central issue of construing "specific use" needed to be resolved.

**EBA answers**

The EBA held that the EPC has to be construed according to the principles set out in the Vienna Convention of 1969, which includes the obligation to interpret treaties (here the EPC) in good faith. The provisions of the EPC must be construed according to the ordinary meaning of the terms in their context and in the light of its object and purpose. Preparatory documents (here the *Travaux Préparatoires*) can be considered to confirm a meaning or to determine a meaning if the first and ordinary meaning of construction would lead to ambiguity or to an absurd result.

Guided by the Vienna Convention and the legislative history in the *Travaux Préparatoires*, the EBA interpreted the provisions of EPC 2000 in the light of *Eisai* (G5/83), subsequent case law, the submissions of the President of the EPO and numerous *amicus curiae* briefs, to give the following answers.

**Question 1:** 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.

**Question 2:** 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.

**Question 3:** 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.

---

**To subscribe or unsubscribe**

To enquire about further publications, or to unsubscribe from this e-bulletin, please email us, or visit the Herbert Smith website here.

The content of this article does not constitute legal advice and should not be relied on as such. Specific advice should be sought about your specific circumstances.

Herbert Smith LLP, Gleiss Lutz and Stibbe are three independent firms which have a formal alliance.