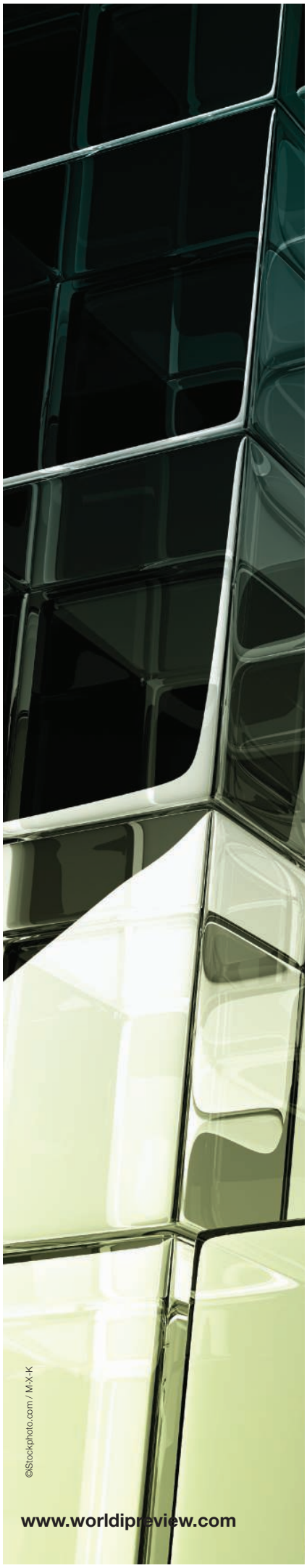
CLARIFYING PATENTABILITY FOR MEDICAL AND SURGICAL DEVELOPMENTS

Two recent Enlarged Board of Appeal decisions provide new guidelines on how to interpret the extent of exceptions to patentability before the European Patent Office, says Annelise Holme.

In decision G2/08 of February 19, 2010, the Enlarged Board of Appeal interpreted the scope of Article 54(5) of the revised European Patent Convention (EPC), which entered into force on December 13, 2007. The board concluded that Article 54(5) does not prevent patenting a medicament when it is used for treating a condition as long as the treatment differs from the existing option by providing a new mode of administration, such as where a dosage regime is the only feature claimed that is not disclosed in the state of the art.

The relevant patent application related to the use of nicotinic acid or a compound metabolised to nicotinic acid for the manufacture of a sustained-release treatment hyperlipidaemia. The treatment was to be orally administered once per day prior to sleep.



The claim was drafted in the form of a so-called Swiss type claim: 'Use of X in the manufacture of a medicament for the treatment of disease Y'. Such claims use the 'fiction' of a novel manufacturing method to get around twin obstacles under Article 54(5) EPC 1973, which only allows claims related to the first medical use of a known compound, and Article 52(4) EPC 1973, which excludes claims related to methods of treatment on the grounds of a lack of industrial applicability.

The prior art disclosed the use of nicotinic acid for the manufacture of a sustained release medicament for use in the treatment of hyperlipidaemia by oral administration. The lack of novelty and inventive step was sought to be overcome by the additional use of the specific dosage regimen: 'once per day prior to sleep'.

The Examining Division stated that the feature reflected a method of treatment of the human body and that the claim therefore was excluded from patentability by the European Patent Convention, specifically Article 52(4) EPC 1973. Accordingly, the feature could not be used in the assessment of novelty.

When the revised European Patent Convention entered into force on December 13, 2007, the amended wording of Article 54(5) EPC made it possible to use the simplified wording 'X for use in the treatment of Y', instead of the original Swiss type claims. When evaluating the application in suit, the Technical Board of Appeal considered that, given the amendments in EPC 2000, the permissibility of so-called 'dosage regimen' claims, and indeed the previously permissible Swiss type claims, it should be reviewed by the Enlarged Board of Appeal with regard to the new articles.

In this respect, the Enlarged Board of Appeal held that the previously allowable Swiss type claims are no longer acceptable. The board reasoned that such claims were inappropriate because they had been allowed under a loophole in the old EPC, which had been closed by the revised Article 54(5) EPC. This part of the decision does not have retrospective effect, so granted patents and applications filed at the EPO, or with a priority date earlier than three months after publication of the decision in the *Official Journal* of the EPO, will not be affected.

The board also concluded that it is possible to obtain a patent for a known medicament even if the same medicament is already known for the treatment of the same condition, when the 'new' treatment differs from the known treatment by providing a new mode of administration.

Even though this decision provides useful clarification on the scope of subsequent therapeutic uses of known medicaments in Europe, the decision is essentially in line with a large part of the corresponding decisions under the previous version of the European Patent Convention. However, it is important that pending applications are reviewed to ensure that second medical use claims are in the correct format.

> "IT IS POSSIBLE TO OBTAIN A PATENT FOR A KNOWN MEDICAMENT EVEN IF THE SAME MEDICAMENT IS ALREADY KNOWN FOR THE TREATMENT OF THE SAME CONDITION, WHEN THE 'NEW' TREATMENT DIFFERS FROM THE KNOWN TREATMENT BY PROVIDING A NEW MODE OF ADMINISTRATION"

In decision G1/07 of February 15, 2010, the Enlarged Board of Appeal reconsidered the 'treatment by surgery' exception to patentability under Article 53(c) EPC, deciding that its earlier conclusion—that such treatments include any physical intervention on the human or animal body—was too broad.

The patent application in question included the step of administering polarised 129Xe to the subject as an imaging agent, either by inhalation or by injection. The technical board of appeal held that the process related to a surgical method that was excluded from patentability pursuant to Article 53(c) EPC.

Rather than creating a new definition of treatment by surgery, the Enlarged Board of Appeal concluded that the claimed imaging method represented a substantial physical intervention on the body. Furthermore, since it entailed a substantial health risk and required professional medical expertise, the claimed method was excluded from patentability as a surgical method.

The Enlarged Board of Appeal indicated that methods involving only a minor intervention or no substantial health risk may not be excluded from patentability. However, the board was reluctant to give any concrete guidelines since medical technology is constantly evolving. In this respect, the board noted that a surgical step could be disclaimed or omitted (e.g. by drafting the claim to the operation of a device) from the claim to enable patentability. The Enlarged Board of Appeal also noted that the possible use of a method by a surgeon to determine a course of action in a surgical intervention does not make a claim unpatentable under Article 53(c) EPC.

This decision will be highly relevant when the European Patent Office is required to evaluate the patentability of methods involving steps that are invasive on the human body. Even though the decision does not give a clear indication as to how to apply the principles in specific circumstances, it is likely that future decisions following G1/07 will provide the necessary guidance in this respect.

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Annelise Holme is a master of science in chemical engineering. Her experience includes the preparation and prosecution of domestic and international patent applications in pharmacology, biotechnological, biochemistry, cell biology, immunology and genetic engineering. She has previously undertaken considerable work in the field of vaccines. Holme is furthermore experienced in litigation practice as well as oppositions and appeals before the European Patent Office. She is a member of FICPI, AIPPI and DDPAF and is a European Patent Attorney.