Patent office practice: how Japan and Europe are responding to new trends in pharma research

Is a new administration regimen of a drug patentable or not? Patent offices must be prepared to answer this question, as the pharma industry focuses less on developing new molecules and more on the new uses of known medicaments. The Japanese Patent Office has already made up its mind; not so the European Patent Office, but a case pending before its Enlarged Board of Appeal is expected to provide decisive guidance soon.

For a long time, pharmaceutical research aimed at coming up with new active principles. When that started to get harder, research moved to another level, investigating possible new therapeutic applications of known active molecules in a different clinical context. Today, research is focusing on the optimisation of the administering regimen of known medicaments, used in the same known clinical context, but according to a new schedule.

So what about intellectual property rights? Are patent offices ready to deal with claims concerning new administration regimes? In most countries it is possible to obtain patent protection both for a new active molecule and for a new therapeutical application of a known substance. But what happens when a new therapeutic application does not relate to a new specific disease or a new dosage form, but "merely" concerns the administration regimen, as in the example below?

Claim: A therapeutic agent for use in the treatment of asthma, comprising a compund A, wherein 30 to 40 micrograms/kg body weight of the compund A is orally administered to a patient every three months.
Prior art: it was well known that the symptom of asthma is alleviated by once a day oral administration of the compound A at a dosage level of 1 microgram/kg body weight and that the once daily oral administration is necessary for alleviating asthma symptoms. It was also known that an adverse event B is observed with the once daily oral administration of the compund A.
Summary of the invention: The invention is based on the findings that the symptom of asthma is alleviated for a long period of time by oral administration of the compound A to a human patient at a dosage level of 30 to 40 micrograms/kg body weight every three months and that the adverse event B is greatly reduced by this new dosage regimen.

Let's take two of the world's most busy patent offices: the Japanese Patent Office has recently amended its examination guidelines on medical inventions to provide protection for pharmaceutical inventions substantially consisting in new administration regimens. The European Patent Office is still debating whether or not they are to be considered inventions at all.

Japanese Patent Office: Revised Guidelines Allow Patenting of Non-Obvious Administrative Regimen

In October 2009, the Japanese Patent Office adopted a revised version of its examination guidelines regarding medical inventions including pharmaceutical products. Under the revised version, the dosage and administration mode of a pharmaceutical product are treated as a medical use that imparts novelty to a claimed medicament. Therefore the claim in the example above has novelty over the prior art, although it would be necessary to show that the claimed invention is not obvious over the prior art, specifically that the new dosage regimen has remarkably advantageous effects and/or that the prior art teaches away from the new dosage regimen.

European Patent Office: Situation Still Uncertain, Decisive Guidance from Enlarged Board of Appeal in 2010

The European Patent Office (EPO) accepts that a second therapeutical application of a known medicine may be protected through a specific type of claim which is directed to inventions in which the active principle and medicament are both known, but the use of the medicament in medical treatment is novel and inventive. The EPO also recognises that a new medical treatment may be characterised not only by a new disease, but also by a new typology of patient, a new administering way or a new action mechanism.

When the kind of claims described above started to be filed in which the only element of novelty was the new administering regimen, objections were raised by both the EPO and national courts. A score of sometimes conflicting decisions have provided no definitive guidance on the matter. Moreover, a new version of the European Patent Convention (EPC), known as EPC 2000, has recently been adopted in which the provisions concerning the second application of medicaments (Art. 54) have been amended.

A case pending before the EPO's Enlarged Board of Appeal (Kos Life Science, T1319/04) is expected to provide decisive guidance on the issue by mid-2010. The questions submitted to the Enlarged Board do not only seek answers on whether a known medicament can be patented where the only novel feature of the treatment is a new and inventive dosage regime, but also on whether the case law on the subject developed under the old version of Art. 54 EPC is still valid for interpreting the new Art. 54 EPC 2000. Hopes are that the decision will allow European patent practice to address the above issues with greater certainty.

This article is based on:

Nobutaka Yokota, Japanese patent attorney with Kyowa Patent and Law Office, Japan: *Patent eligibility expanded* (first published in Life Sciences IP Focus 2009, Managing Intellectual Property).

Claudio Germinario, European patent attorney with SIB Società Italiana Brevetti, Italy: *unpublished material*.