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Patentability of Administration Protocols Under Review in Europe

In the important EPO Board of Appeal Decision T1020/03, reported in the January 2006 issue of this Newsletter, it was held that the Swiss format could be used to claim a novel and inventive administration protocol. However, since December 2007 the provisions of the European Patent Convention (EPC) have been amended by EPC2000, leaving the position of the Swiss format unclear. Medical uses of active agents can now be more effectively claimed by claiming the "active agent/combination for a specified medical purpose".

In case **G2/08** (referring decision T1319/04), questions have recently been referred to the EPO's Enlarged Board of Appeal (EBA) to obtain clarification of whether patents for novel and inventive administration protocols continue to be available, and if so what claim format is appropriate.

In an interesting twist, the EBA referral caught the English Court of Appeal by surprise in the case of Actavis UK Limited v Merck & Co. Inc. (**Cases A3/2007/1625 and A3/2007/1650**). Having prepared a judgment following T1020/03 and reversing the lower court decision to revoke an administration protocol patent (European Patent (UK) 0724444), but before delivering the judgment, the Court of Appeal became aware of the EBA referral. To avoid possibly inconsistent judgments at appellate level in the EPO and the English courts, the court extended the deadline for Actavis to seek leave to appeal to the House of Lords (English Supreme Court) until after the EBA opinion is issued.

→ <http://www.bailii.org/ew/cases/EWCA/Civ/2008/444.html>

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Sufficiency of Patents to Novel Pharmaceutical Products Considered in the English Court of Appeal; Novel Products are Sufficiently Disclosed by One Way of Making Them

In the recent case of H Lundbeck A/S v Generics (UK) Ltd. *et al* (**Cases A3/2007/1326 and A3/2007/1387**), the English Court of Appeal recently had the opportunity to review the law of sufficiency (enablement) in relation to pharmaceutical patents.

In an unusual move, the Court included Lord Hoffmann from the House of Lords. This gave the Court the opportunity to evaluate the House of Lords decision in Biogen v Medeva ([1997] RPC 1), which had looked at how one should assess the technical contribution that a biotech invention makes to the art.

The Court held that, where the patent claims a product (here a resolved enantiomer of a pharmaceutical), the product is the technical contribution and the technical contribution should not be limited to the process by which it has been prepared (Judgment of Lord Hoffmann, paragraph 36). This is different from the situation in Biogen, where the claim of the patent had process features, so that the technical contribution was to be interpreted with reference to the process by which the product was obtained (Judgment of Lord Hoffmann, paragraph 35).

Lord Hoffmann also stressed that, when assessing whether the patent has sufficiently disclosed the invention, the inventive step underlying the invention is not relevant. The requirements for inventive step and sufficient disclosure are not formally linked. The question is whether the invention as defined in, and as understood from, the claims has been sufficiently disclosed in the specification.

Finally, the Court affirmed in strong terms the right of a person who has invented a new product, and has described one way of producing it, to obtain a patent to the product *per se* and thus monopolise all ways of producing and using it. "Parliament has chosen to allow product claims and the jurisprudence of the EPO ... shows that such claims can be made It is too late to have regrets about the breadth of the monopoly which such claims confer." (Judgment of Lord Hoffmann, paragraph 46).

→ <http://www.bailii.org/ew/cases/EWCA/Civ/2008/311.html>

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EPO To Conduct Prior Art Searches on Italian Patent Applications

As is well known, national Italian patents are normally granted without substantive examination. Soon, however, a prior art search performed by the European Patent Office (EPO) will be included in the procedure.

The change was contained in a Ministerial Decree of 3 October 2007. According to our information, the EPO will start to perform these searches on Italian patent applications filed on or after 1 July 2008. Within 9 months after the filing of the Italian patent application, the EPO will provide a search report and written opinion on patentability. The applicant then has the opportunity to amend his claims to allow for the comments in the opinion. If the Italian application serves as priority for a European patent application, or a PCT patent application for which the EPO is the ISA, a refund of the fee will be provided to the applicant to the extent that the searching work can be reused.

To provide claims in English for the EPO to use, applicants for a national Italian patent will need either to file an English translation of the claims or pay a translation fee of €250. However, it is not envisaged that applicants will have to pay a search fee corresponding to the EPO search fee.

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Strict Requirements Applied to Priority Assignments in the EPO

In the case T62/05, the chemical Board of Appeal of the EPO 3.3.03 has held that strict requirements are to be applied to priority assignments in relation to European patents.

As is well known, normally the EPO conducts no examination into issues of entitlement to file a European patent application and to claim priority. There is no requirement for applicants to file any assignment documentation proving any necessary succession of title in Europe from the inventor(s) and the priority applicant(s). However, the entitlement may of course need to be proved in opposition or other contentious proceedings. If the priority application itself is not assigned with the rights to own the invention and patents in Europe, then it would need to be proved that at least the right to claim priority in Europe had been transferred.

In many cases, for example with US-originating inventions, it is routine for the US priority application and the European (or PCT) application to be filed by different applicants, with assignments to safeguard the applicant's position in Europe. The transfer documentation is typically governed by the relevant overseas law and is often signed only by the assignor(s).

According to T62/05, even these precautions may not be enough. The Board stated in paragraph 3.9 of the Reasons that the requirement of signature by or on behalf of all parties to a priority assignment is to be observed (this is the requirement of Article 72 EPC for assignment of a European patent application after filing). Furthermore, the Board indicated that any necessary priority assignment must actually take place before the filing of the European (or PCT) application or before the end of the priority year (Reasons, paragraph 3.16), implying that a document executed later with retroactive effect may be insufficient.

While these statements were made in relation to an assignment of the right to claim priority, rather than the more usual situation of a complete transfer of an invention and its priority application to the European applicant(s), nevertheless it is not clear that a lesser standard would apply to documentation to establish a complete transfer of all rights.

We recommend that, for complete safety, assignments concerning the right to file a European patent application and to claim priority in it are executed as soon as possible in the priority year and that they are executed by all parties to the transfer.

→ <http://legal.european-patent-office.org/dg3/pdf/t050062eu1.pdf>

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Further Referral to the EPO Enlarged Board of Appeal on Plant Production Inventions

In the June 2007 issue of this Newsletter, we reported that case G2/07 had referred questions to the EPO Enlarged Board of Appeal concerning the patentability of a process for the production of plants which includes both crossing/selection and technical steps. This concerns the interpretation of the provisions of the EPC that "microbiological processes", and the plant products thereof, are patentable, whereas plant varieties (i.e. at that particular taxonomic level) are not patentable (Article 53(b) EPC).

This referral has recently been consolidated with referral G1/08 (referring case: T1242/06), in which the following further questions have been posed:

1. Does a non-microbiological process for the production of plants consisting of steps of crossing and selecting plants fall under the exclusion of Article 53(b) EPC only if these steps reflect and correspond to phenomena which could occur in nature without human intervention?
2. If question 1 is answered in the negative, does a non-microbiological process for the production of plants consisting of steps of crossing and selecting plants escape the exclusion of Article 53(b) EPC merely because it contains, as part of any of the steps of crossing and selection, an additional feature of a technical nature?
3. If question 2 is answered in the negative, what are the relevant criteria for distinguishing non-microbiological plant production processes excluded from patent protection under Article 53(b) EPC from non-excluded ones? In particular, is it relevant where the essence of the claimed invention lies and/or whether the additional feature of a technical nature contributes something to the claimed invention beyond a trivial level?

→ <http://legal.european-patent-office.org/dg3/pdf/t061242ex1.pdf>

<http://www.epo.org/patents/appeals/pending.html>

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