

August 2007

## Implementation of EU Biotech Directive Now Complete

According to information received recently from UK-IPO, all European Union (EU) member states have now implemented the controversial 1998 Biotechnology Directive (Directive 98/44/EC) into their national laws, Luxembourg and Latvia being the last to comply. The Implementing Regulations of the European Patent Convention, governing the practice of the European Patent Office (EPO), were adapted into conformity with the Directive in 1999.

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## Are SPCs Available for Second/Subsequent Medical Uses?

The European Court of Justice (ECJ) has recently ruled on this question, in the case of **Yissum Research and Development Company v. The Comptroller-General of Patents** (Case C-202/05).

Yissum obtained regulatory authorisation for its Silkis anti-psoriasis ointment, the active agent of which (calcitrol) is a known pharmaceutical for other treatments (although not previously used in ointment form). Yissum holds a European patent for the anti-psoriasis use of calcitrol, and applied for a UK Supplementary Protection Certificate (SPC) for the new use. In its SPC application, Yissum defined the “product” as “calcitrol” or in the alternative “calcitrol with an ointment base”.

European SPCs for medicines are available (on application to each national Patent Office) for a “product” (meaning the active ingredient or combination of active ingredients of a medicinal product), provided that the “product” has not previously been the subject of an SPC in the country concerned, and provided that the SPC is applied for within six months after the first medicinal regulatory authorisation for the “product” in the country concerned and cites that authorisation. The SPC application has to be based on a patent “protecting the product”, and it was not in dispute that the patent for the anti-psoriasis use of calcitrol fulfilled this requirement.

The ECJ ruled last year in Case C-431/04 (see the June 2006 issue of this Newsletter) that any co-ingredient of a combination “product” must have a therapeutic – and not merely delivery – effect. From this it followed that the alternative product definition “calcitrol with an ointment base” was in essentially the same position as the primary product definition “calcitrol”. The sole question to be decided was whether the new use of calcitrol, with which both the authorisation and the basic patent were concerned, could somehow be imputed into the product “calcitrol” as defined in the SPC application, to cause it to be different from “calcitrol the previously-authorized active medicinal ingredient”.

The ECJ followed the strict approach from Case C-431/04, and held that a second/subsequent medicinal use of a previously-authorized active medicinal ingredient does not form an integral part of the definition of the product. From this it follows that an SPC is not available for the second/subsequent medical use of a medicinal active substance, if the “product” as defined in the SPC application does not qualify for SPC protection independently of its proposed use.

→ <http://curia.europa.eu/jurisp/cgi-bin/form.pl?lang=en>

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## Countdown to EPC2000

Continuing our series of alerts about the revision of the European Patent Convention (EPC) to come into effect in December 2007 (see the April and June 2007 issues of this Newsletter), we mention the following:

Under EPC2000, translations of priority documents will not be required to be filed unless relevant to the examination (EPC2000, Rule 53(3)). The question therefore arises: if a European patent application - claiming priority from a priority application that was not in English, French or German - reaches the acceptance stage after early September 2007, so that the four-month deadline routinely set under EPC Rule 38(5) for filing the English, French or German translation of the priority document will expire after the start of EPC2000, will the deadline automatically lapse on the start date of EPC2000?

We have been advised by authoritative sources in the EPO that a Practice Note will soon be published on this matter. The Practice Note will say that, in this situation, the requirement to file the translation or declaration **will** automatically lapse on the start date of EPC2000, so that in that case the translation – even though it has been called for under the current EPC provisions – will **not** need to be filed.

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## Norway to Join the EPC

Norway is set to become the 33<sup>rd</sup> Contracting State to the European Patent Convention (EPC) on 1 January 2008.

Any European patent application having a filing date, or derived from a PCT application having a filing date, on or after 1 January 2008, will be able to designate Norway.

This largely completes the coverage of Europe by the European patent system. Apart from Ukraine, Belarus, Moldova, Andorra, and a few city or small-island states, all European countries up to the Russian border will now be either Contracting or Extension States to the EPC. This is a remarkable achievement for the European patent system in just 30 years.

→ <http://www.epo.org/focus/news/2007/070613.html>

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## EPO to Stop Private Searches

The EPO has announced that it will stop its private searching service (the so-called “standard” and “special” searches) on 1 September 2007, although searches ordered before that date will be completed and reported.

The announcement draws attention to the plans for expansion of the private search functions of the national Patent Offices in Europe in place of the former EPO service. Please contact us for further information on the options.

→ <http://www.epo.org/patents/law/legal-texts/InformationEPO/archiveinfo/20070704.html>

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## Stay Refused in Pharmaceutical Case of Parallel EPO and UK Proceedings

Following the English Court of Appeal decision in **Unilin Beheer** (see the July 2007 issue of this Newsletter), the potential importance of staying UK court proceedings pending the outcome of a parallel EPO opposition is clear.

In the recent patent revocation case of **Glaxo v Genentech and Biogen** (2007 EWHC 1416 (Pat)), the English Patents Court considered in detail the factors to be taken into account, and decided to refuse a stay pending the EPO result.

For the reasons reviewed in the Glaxo case, stays are now typically refused in life sciences cases in the UK courts. Surrounding circumstances such as the desirability of business certainty and the launch of a medicine being delayed by a stay, typically urge *against* a stay unless the EPO opposition/appeal proceedings are nearly completed.

→ <http://www.bailii.org/cgi-bin/markup.cgi?doc=/ew/cases/EWHC/Patents/2007/1416.html>

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