

February 2006

### New Associate

We congratulate Dr. David Rushton of the Chemical, Pharmaceutical and Biotech group on his recent appointment as an Associate of the firm.

→ <http://www.haseltinelake.com/people/profile/djr>

### Update on Implementation of the European Bolar Exemption Provisions

Continuing our reports on the implementation of European Parliament and Council Directive No. 2004/27/EC, which introduces a Bolar Exemption provision into European patent law, we understand that at least Austria, Estonia, Germany, Italy and the United Kingdom now have laws in place which either implement the Directive or provide more extensive safe harbour provisions for third parties seeking to obtain regulatory approval in advance of patent expiry.

All countries seem to have started national procedures for implementing the Directive, and we expect that in the next few months we will be able to report implementation in most or all countries. Some commentators have suggested that national courts may be able to construe the pre-existing "experimental use" exemption from patent infringement so as to give indirect effect to the Directive in the period of delay in national implementation, but we caution that this is not guaranteed, especially where such an interpretation would conflict with earlier case law. As mentioned in the January 2006 issue of this Newsletter, a court may consider that the European legislators have anyway signalled – by the publication of the Directive - that the pre-existing "experimental use" exemption cannot or should not be interpreted in this way.

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### "Diagnostic Methods" Narrowly Interpreted in European Law

The long-awaited Opinion of the European Patent Office's Enlarged Board of Appeal on the meaning of the provisions of Article 52(4) EPC was issued on 16 December 2005 as Opinion No. G1/04.

The relevant portion of Article 52(4) reads as follows: "...diagnostic methods practised on the human or animal body shall not be regarded as inventions which are susceptible of industrial application".

The Enlarged Board gave the words "diagnostic methods practiced on the human or animal body" a very narrow interpretation, and stated that a claimed method is susceptible of industrial application unless it comprises features relating to both **preceding** (constitutive) and **deductive** (intellectual) steps for making a medical/veterinary diagnosis for curative purposes, **as well as** features relating to **specific technical interactions with the human or animal body** which occur when carrying out the constitutive step(s).

It is seen that in most cases it should be possible to claim a diagnostic invention in broad enough terms that the problematic three-way combination of features is not stated in any claim. For example, an invention relating to a method of analysing medical data obtained from a patient should now be considered susceptible of industrial application, if the intellectual deductive step of identifying the patient's disorder is not specified, even if the preceding constitutive steps are specified and clearly involve technical interactions between equipment and the patient.

In view of the strict approach of the EPO to issues of new matter, we recommend that, before a PCT application is filed designating the EPO, our advice is sought if there is any doubt as to whether a proposed claim would comply with Article 52(4), as it may be impossible to correct a defect by amendment during the regional phase.

→ <http://legal.european-patent-office.org/dg3/pdf/g040001e.pdf>

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## Four UK Patent Office Opinions Issued up to 15 February 2006

As of 15 February 2006, the UK Patent Office had issued four Opinions under the new opinion procedure mentioned in the January and September 2005 issues of this Newsletter.

One of the Opinions related to validity (novelty/inventive) step only (Opinion 01/05), one to infringement only (Opinion 04/05) and two to a combination of infringement and validity (Opinions 02/05 and 03/05).

Since none of the Opinions relates to chemical, pharmaceutical or biotech subject-matter, it is too early to draw conclusions as to how the procedure is working in our area. We will keep you informed.

→ <http://www.patent.gov.uk/patent/opinions/withdrawn.htm>

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## EPC 2000 Start Date Established

The date on which the 2000 revisions to the European Patent Convention (EPC 2000) will come into effect has now been established as **13 December 2007**.

It is theoretically possible for EPC 2000 to enter into effect before that date, but it seems unlikely that an earlier start date will be achieved in practice.

In future Newsletters we will explain the changes and how they will impact on chemical, pharmaceutical and biotech patent practice in the European Patent Office.

→ [http://www.european-patent-office.org/news/info/pdf/mitteilung\\_06\\_02\\_2006.pdf](http://www.european-patent-office.org/news/info/pdf/mitteilung_06_02_2006.pdf)

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