

# Newsletter

## Chemical, Pharmaceutical & Biotech

September 2004

### UK Patent Law Revision

The UK Patents Act 2004 received royal assent on 22 July 2004, and will, when implemented, introduce a number of new features into UK patent law.

Of particular interest are the following:

Employees will become entitled to compensation from their employers where their inventions are of outstanding benefit to the employer. Experience in other countries shows that substantial compensation awards may be achievable, particularly in pharmaceutical cases. Previously it was necessary for employees to show that the patent was the cause of the success, which no claimant has been able to do.

The rules by which patentees and exclusive licensees can warn infringers about the risk of litigation will be relaxed somewhat, so that a stronger letter before action can be sent without potentially constituting an actionable threat.

The UK Patent Office can be asked by the patentee or any other person to provide a non-binding opinion on infringement or validity of a granted patent.

The date of implementation of the substantive portions of the new law is not yet announced.

- (<http://www.legislation.hmso.gov.uk/acts/acts2004/20040016.htm>)

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### European-style “Bolar Exemption” to be introduced

A limited form of the well-known “Bolar Exemption” is set to become a feature of European patent law, following the publication of European Parliament and Council Directive No. 2004/27/EC on 31 March 2004.

Generic pharmaceuticals companies will not infringe patent or supplementary protection certificate rights by conducting “necessary” studies and trials with a view to obtaining regulatory approval for sale within the EU via an abridged application (i.e. an application for regulatory approval filed without full test data and relying on a previous approval). Directive, Article 10.6.

Such a generic product cannot anyway be marketed via the abridged approval procedure before ten years after the previous approval, whatever the patent position. Directive, Article 10.1.

However, an exemption in relation to obtaining approval for non-identical patented actives is not envisaged. Nor is it envisaged to exempt the collection of data for use with other forms of application for regulatory approval.

Member States have until **30 October 2005**, to implement the Directive.

- ([http://europa.eu.int/eur-lex/pr/en/oj/dat/2004/l\\_136/l\\_13620040430en00340057.pdf](http://europa.eu.int/eur-lex/pr/en/oj/dat/2004/l_136/l_13620040430en00340057.pdf))

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## EPO Board of Appeal develops novelty test in disclaimer case

On 30 March 2004 EPO Technical Board of Appeal 3.3.1 issued a Decision in the case T594/01, which related to a process for preparing ethylene glycols.

The process comprised reacting an alkylene oxide with a suitably defined solid material. The claim contained a proviso requiring that with a particular type of solid material the process must be performed with "less than 0.1wt% carbon dioxide" present.

The prior art disclosed the process performed in the presence of 0.1wt% carbon dioxide. The proviso was intended as a disclaimer of this item of prior art. The proviso was based on matter present in the application as filed, so no issue of new matter arose.

While the Board agreed with the applicant that novelty is strictly tested in the EPO, so that only an unambiguous disclosure can be cited to destroy novelty (Decision, paragraph 4.1.5), nevertheless the Board introduced into the procedure a prior publication which showed that it was part of common general knowledge that "every experimental measurement in quantitative analytical chemistry as well as any result of any physical measurement cannot be dissociated from the margin of uncertainty attached to the measurement".

As a result, the Board rejected the claim by reason of lack of novelty over the prior art. It apparently considered that it was not necessary to quantify the margin of uncertainty in this case; any uncertainty would lead to the prior art making available a process within the claim.

This decision was issued at about the same time as the recent Enlarged Board of Appeal Decisions G1/03 and G2/03, which have confirmed the rules and limitations of the EPO's disclaimer practice. In essence, disclaimers can be introduced by amendment in EPO examination or opposition proceedings, provided that they serve only to recover novelty in the face of Article 54(3) (co-pending EP application, unpublished but of earlier priority date) or "accidental" prior art, and provided that the terms of the disclaimer reflect exactly the terms of the novelty-destroying disclosure. If – as seems likely – the substance of Decision T594/01 is followed by other Boards, it may present a particularly difficult challenge to applicants seeking to define the extent of the prior art disclosure, where a disclaimer is based on a physical or experimental measurement disclosed in the prior art.

Similarly, where a proviso or disclaimer is being prepared **before the filing** of the EP or PCT application, and makes use of a physical or experimental measurement disclosed in the prior art, the draftsman must take care to "position" the boundary of the disclaimer so that the lack of novelty is genuinely cured.

- ([http://legal.european-patent-office.org/dg3/search\\_dg3.htm/T\\_0594/01](http://legal.european-patent-office.org/dg3/search_dg3.htm/T_0594/01))

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