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Progress Report on Implementation of the European-style "Bolar Exemption"

In the September 2004 issue of this Newsletter we reported the publication of European Parliament and Council Directive No. 2004/27/EC, setting the deadline of 30 October 2005 for all EU countries to introduce the European-style "Bolar Exemption" into their national laws.

According to latest information from the European Commission and our continental colleagues, the implementation is not proceeding in a uniform or straightforward way.

The UK has implemented the Directive, by means of the Medicines (Marketing Authorisations etc.) Amendment Regulations 2005. At least one published commentary (Harrison, P.S., CIPA Journal, Nov. 2005, p. 724) suggests, however, that the terms of the UK implementation may provide a safe harbour for more activities than originally appeared to be envisaged in the Directive.

Italy, which anyway had a safe harbour provision before the Directive, limited to the final protection year, is reported to have implemented the Directive, again with possibly a relatively wide safe harbour.

The new provisions anyway do not directly affect the pre-existing general "experimental use" exemption from patent infringement. However, no common standard of interpretation of this exemption in the regulatory trials arena has yet been achieved in Europe. It may be expected that, if anything, courts will now be less likely to see the general "experimental use" exemption as providing a safe harbour for commercial drug trialling in preparation for marketing approval (i.e. long after the initial experimental work to discover the drug), if only because the legislators have signalled by Directive No. 2004/27/EC and its national implementing statutes that a specific safe harbour is needed for such trialling.

→ <http://www.opsi.gov.uk/si/si2005/20052759.htm>

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EPO Board of Appeal 3.3.4 Approves Swiss Claims in "Administration Protocol" Case

In Decision T1020/03, the Kinkeldey Board of Appeal has stated that in principle the "Swiss" claiming format is applicable to inventions based on a new administration protocol, and has issued a robust call to European patenting authorities to standardise their approach to Swiss claims in a way which allows patentability to derive in principle from any aspect of a new therapeutic application.

As is well known, the "Swiss" claiming format is the device used in Europe to patent inventions relating to novel therapeutic applications. The typical Swiss claim form is: "Use of [substance X] for the preparation of a medicament for [novel and inventive therapeutic application Y]", although some minor variations on that format are allowed also.

While the allowability, in principle, of the Swiss format in relation to the treatment of particular disease states using X is generally accepted, there has been reluctance in some quarters to accept the "Swiss" format as a universal alternative to the "method of treatment" format. For example, the UK Court of Appeal, in *Bristol-Myers Squibb v Baker Norton Pharmaceuticals* (2000) (see <http://www.bailii.org/ew/cases/EWCA/Civ/2000/169.html>), held that the Swiss format cannot be used for inventions relating to a new administration protocol.

In the decision, the Board stressed that the Enlarged Board of Appeal Decisions G1/83, G5/83 and G6/83, which approved the Swiss format, appear to apply to any therapeutic application, including administration protocol inventions. The Board felt it unnecessary to refer further questions to the Enlarged Board of Appeal, and robustly declined to follow contrary decisions from other EPO Boards and national authorities.

The application in question related to a repeated on-off administration protocol for IGF-I, and was remitted to the Examining Division for examination of novelty, inventive step and other issues.

→ <http://legal.european-patent-office.org/dg3/pdf/t031020ex1.pdf>

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Divisional Practice to be Reviewed by EPO Enlarged Board of Appeal

In the May 2005 issue of this Newsletter we reported the flurry of Board of Appeal decisions that appeared to signal a move towards stricter requirements for European divisional patent applications.

The issues have now been referred to the EPO Enlarged Board of Appeal for further consideration. The referral is pending before the Enlarged Board as Case G1/05. The referring case is T39/03.

All divisional applications in the EPO are currently being first examined on the question of whether they include new matter (whether in the claims or in the description and drawings), and if new matter is found then further examination is being suspended pending the Enlarged Board decision.

→ <http://legal.european-patent-office.org/dg3/pdf/t030039ex1.pdf>

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UK Patent Office Revises Interpretation of Product-by-Process Claims

Following the observations of Lord Hoffmann in Kirin-Amgen (see the October 2004 issue of this Newsletter) that the UK should interpret "product-by-process" claims in the same way as the European Patent Office, the UK Patent Office has now revised its policy.

The amended practice is set out in paragraphs 14 to 16 of the Examination Guidelines for Biotechnological Patent Applications.

"Product-by-process" claims will now be treated in the UK as product *per se* claims, the process feature limiting the claim only to the extent that a detectable "fingerprint" is left on the product by the process steps.

The form of wording used in the claim seems therefore to be immaterial. Such claims could use the words "obtained by", "when prepared by", "obtainable by" or "preparable by", for example.

→ <http://www.patent.gov.uk/patent/reference/biotechguide/novelty.htm>

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