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EUROPEAN PATENT & TRADE MARK ATTORNEYS

Report on Implementation of EC IP Enforcement Directive – “Knowledge” Test Introduced into the Assessment of Damages

The European Council Directive 2004/48/EC on the enforcement of intellectual property rights is in the process of being implemented in Europe.

In the UK, two important aspects of the Directive were implemented on 29 April 2006, by the Intellectual Property (Enforcement, etc.) Regulations 2006, namely: assessment of damages where the infringer knew or had reasonable grounds to know that what he was doing was an infringement; and obtaining information about infringing suppliers.

In UK IP infringement actions where the infringer knew or had reasonable grounds to know of the infringing nature of his acts, the damages must now be “appropriate to the actual prejudice” suffered by the claimant (proprietor or exclusive licensee). Notional royalties are specifically provided for as a possible basis, but if this is not appropriate the court must take all economic and other factors into account (Regulation, Article 3).

This provision provides an additional incentive for prospective claimants to inform infringers in the UK of the existence of the rights. However, senders of such letters must still take care not to issue an actionable threat of infringement proceedings (see the September 2004 and January 2005 issues of this Newsletter).

In addition, the Regulations bring the powers of the Scottish courts to order disclosure of information about infringing suppliers into line with the existing powers of the English courts (the so-called “*Norwich Pharmacal*” order) (Regulation, Article 4).

We will keep you informed of the process of implementation in other countries in future issues of this Newsletter.

→ http://europa.eu/eur-lex/pri/en/oj/dat/2004/l_195/l_19520040602en00160025.pdf

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Interpretation of EPC Rule 23d(c) Referred to Enlarged Board

In its Interlocutory Decision T1374/04 (Wisconsin Alumni Research Foundation), the Galligani Board of Appeal 3.3.08 has referred questions of interpretation of EPC Rule 23d(c) to the Enlarged Board of Appeal.

The Rule provides that, under the “morality” requirements of the EPC, “European patents shall not be granted in respect of biotechnological inventions which concern ... uses of human embryos for industrial or commercial purposes”.

The patent application relates to primate (including human) embryonic stem cells in a cell culture in which certain desirable characteristics are present, but does not cover human embryos as such. Such a human stem cell culture may use stem cells extracted from a human embryo, the normal extraction procedure adhering to legal and ethical standards using an unimplanted IVF embryo (although the use of such an extraction procedure is not currently a limitation of the claims). Alternatively, if a suitable human embryonic stem cell line exists, the culture may be prepared from that (although in that case the cell line itself would previously have been initiated using stem cells extracted – however historically or geographically remotely – from a human embryo).

The central question referred to the Enlarged Board is therefore whether the prohibition of Rule 23d(c) is restricted to **claimed uses** – which would render “product” claims like the present ones patentable - or whether the unpatentability extends also to **claimed products** whose preparation inevitably involves – however historically or geographically remotely – a destructive use of a human embryo.

→ <http://legal.european-patent-office.org/dg3/pdf/t041374eu1.pdf>

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SPCs Not Available for Delayed-Release Formulations of Old Actives

The judgement of the European Court of Justice (ECJ) in Case C-431/04, which was delivered recently, has ruled that Supplementary Protection Certificates (SPCs) are not available for patented delayed-release formulations of an old active.

SPCs for medicines can only be granted for an active ingredient or a **combination of active ingredients** of a medicinal product.

The ECJ stated that an SPC could not be validly granted for a "combination" product where only one of the combination has therapeutic effects of its own, the other(s) merely rendering possible a pharmaceutical form of the medicinal product which is necessary for the therapeutic efficacy of the first.

In such cases, it is therefore critically important whether the co-ingredients or any of them have **therapeutic effects**. A mere **delivery** effect on a primary active ingredient will not be sufficient.

→ <http://www.curia.eu.int/en/content/juris/index.htm>

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Verbatim Incorporation of Full Cross-Referenced Document Adds New Matter

In Decision T960/03, EPO Board of Appeal 3.5.03 recently held that it is not permissible to incorporate verbatim the text of a cross-referenced document into a European patent application, and that to do so would usually add new matter to the application, contrary to Article 123(2) EPC.

This applies even where - as in this case - the cross-referenced document was stated in the original application to be "incorporated by reference as if fully set forth herein".

The Board cited with approval the earlier Board of Appeal Decision T689/90, which set up a prima facie position that nothing from any cross-referenced document is within the content of a European patent application, the prima facie position being displaceable on certain conditions, one of which is that the information in the cross-referenced document "implicitly clearly belongs to" the description of the invention. To the extent that the conditions are fulfilled, the information in the cross-referenced document can then be considered part of the content of the European patent application.

Decision T960/03 reinforces that normally only portions of a cross-referenced document - and then only those of clearest relevance - will be seen as effectively imported into the content of the description in a European patent application.

→ <http://legal.european-patent-office.org/dg3/pdf/t030960eu1.pdf>

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