

Newsletter



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Announcement



We are proud to welcome Sven J.R. Bostyn (Lic.Jur. (Gent), LL.M. (Stockholm), PhD (Maastricht)) as Legal Counsel in our office. He is also Associate Professor of Intellectual Property Law, Institute for Information Law (IVIR), University of Amsterdam, and acting professorial lecturer at the WIPO Intellectual Property Law Course in Torino and the post-graduate IP course in Zürich (ETHZ). He was member of a Scientific Advisory Committee at the Dutch Royal Academy of Sciences (Gene Patents Committee), and is also member of and rapporteur at the Expert Group of the European Commission for the evaluation of the Biotech Directive 98/44/EC. He has published extensively in the field of patent law and biotechnological and computer implemented inventions, and is the author of 'Enabling Biotechnological Inventions in Europe and the United States. *A study of the patentability of proteins and DNA sequences with special emphasis on the disclosure requirement*', Eposcript Series, nr. 4, EPO, München, 2001, +/- 340 pp., and of a Study prepared for the European Commission, 'Patenting DNA Sequences (Polynucleotides) and Scope of Protection in the European Union: An Evaluation, European Communities, 2004, +/- 140 pp (forthcoming). He is also co-editor of the Journal of International Biotechnology Law. He is a frequent speaker on international conferences.

His fields of expertise are: biotechnological inventions, plant variety right protection, plant and animal patents, methods of medical treatment, pharmaceutical inventions, computer implemented innovations, and in general (compulsory) licensing in patent and know-how matters. Also the relationship between patent law and health care, clinical trials, biodiversity, access to genetic resources and traditional knowledge and IP. Competition law issues relating to intellectual property rights.

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Featured Article

Europe Gets Its Own Bolar—Type Exception for Generic Drugs

It can come as a surprise, but Europe is since December 17, 2003 very close to having its own Bolar-type infringement exception for generic drugs¹. And no, it is not to be found in the Community Patent Regulation, which would have been its natural habitat. Its fate under the Community Patent regime is unstable, which has first of all to do with the level of stability of the future of the Community Patent saga². But irrespective of the community patent regulation's fate, its place within the regulation is not certain. At some point, this exception was inserted in the list of activities exempted from patent infringement, together with the research exemption and other traditional exceptions. But in one of the latest versions of the text, it has been removed again³. Apparently, there is quite some resistance in some circles against such a provision. But those who lobbied against it now seem to have lost at least part of the battle, since it has survived in a directive which has in general nothing to do with patent law.

What does the text exactly embrace?⁴ Directive 2001/83/EC deals with a great deal of aspects relating to production and distribution of medicinal products for human use, quality, safety and efficacy issues, issues relating to market authorization and clinical trials, mutual recognition of market authorization procedures, particulars relating to market authorization of generics pharmacovigilance, etc. For our purposes, it suffices to deal with the profoundly amended Art. 10, which relates to generics, clinical tests and patent infringement, the latter issue being completely new in this directive.

Article 10

1. By way of derogation from Article 8(3)(i), and without prejudice to the law relating to the protection of industrial and commercial property, the applicant shall not be required to provide the results of pre-clinical tests and of clinical trials if he can demonstrate that the medicinal product is a generic of a reference medicinal product which is or has been authorised under Article 6 for not less than eight years in a Member State or in the Community.

A generic medicinal product authorised pursuant to this provision shall not be placed on the market until ten years have elapsed from the initial authorisation of the reference product.

The first subparagraph shall also apply if the reference medicinal product was not authorised in the Member State in which the application for the generic medicinal product is submitted. In this case, the applicant shall indicate in the application form the name of the Member State in which the reference medicinal product is or has been authorised. At the request of the competent authority of the Member State in which the application is submitted, the competent authority of the other Member State shall transmit within a period of one month, a confirmation that the reference medicinal product is or has been authorised together with the full composition of the reference product and if necessary other relevant documentation.

¹ See, European Parliament Legislative Resolution on the common position adopted by the Council with a view to adopting a European Parliament and Council directive amending Directive 2001/83/EC on the Community code relating to medicinal products for human use (10950/3/2003 – C5-0464/2003 – 2001/0253(COD)), Doc A5-0446/2003. The text has been adopted by the European Parliament and accepted by the Commission. It is now for second reading with the Council.

² We will give an overview of the current situation of this proposal in a forthcoming newsletter.

³ See, Proposal for a Council Regulation on the Community Patent, Council Document 122119/03, de dato 4 September, 2003.

⁴ Text in bold and italics refer to amendments made by the European Parliament in second reading compared to the Council Common Position.



The ten-year period referred to in the second subparagraph shall be extended to a maximum of eleven years if, during the first eight years of those ten years, the marketing authorisation holder obtains an authorisation for one or new therapeutic indications which, during the scientific evaluation prior to their authorisation, are held to bring a significant clinical benefit in comparison with existing therapies.

2. For the purposes of this Article:

(a) 'reference medicinal product' shall mean a medicinal product authorised under Article 6, in accordance with the provisions of Article 8;

(b) ***"generic medicinal product" shall mean a medicinal product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product, and whose bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies. The different salts, esters, ethers, mixtures of isomers, complexes or derivatives of an active substance shall be considered to be the same active substance, unless they differ significantly in properties with regard to safety and/or efficacy. In such cases, additional information providing proof of the safety and efficacy of the various salts, esters or derivatives of an authorised active substance must be supplied by the applicant. The various immediate-release oral pharmaceutical forms shall be considered to be one and the same pharmaceutical form. Bioavailability studies need not be required of the applicant if he can demonstrate that the generic medicinal product meets the relevant criteria as defined in the appropriate detailed guidelines.***

3. In cases where the medicinal product does not fall within the definition of a generic medicinal product as provided in paragraph 2(b) or where the bioequivalence cannot be demonstrated through bioavailability studies or in case of changes in the active substance(s), therapeutic indications, strength, pharmaceutical form or route of administration, vis-à-vis the reference medicinal product, the results of the appropriate pre-clinical tests or clinical trials shall be provided.

4. ***Where a biological medicinal product which is similar to a reference biological product does not meet the conditions in the definition of generic medicinal products, owing to, in particular, raw material related differences or differences in manufacturing processes of the biological medicinal product and the reference biological medicinal product, the results of appropriate pre-clinical tests or clinical trials relating to these conditions must be provided. The type and quantity of supplementary data to be provided must comply with the relevant criteria stated in Annex I. The results of other tests and trials from the reference medicinal product's dossier shall not be provided.***

(a). ***In addition to the provisions laid down in paragraph 1, where an application is made for a new indication for a well-established substance, a non-cumulative period of three years of data exclusivity shall be granted, provided that significant pre-clinical or clinical studies were carried out in relation to the new indication.***

5. ***Conducting the necessary studies and trials with a view to the application of paragraphs 1, 2 and 3 to a generic medicinal product and paragraph 4 to a biosimilar medicinal product and the consequential practical requirements relating to those provisions, as well as for export, shall not be regarded as contrary to patent rights or to supplementary protection certificates for those medicinal products.;***



Important to observe here is that export is included in the text. The use of the wording 'necessary studies and trials' and 'the consequential practical requirements relating to those provisions' probably still leaves some doubt. Will for example import fall under this concept? It is likely that these provisions will lead to similar types of cases as have been witnessed in the US in interpreting 35 USC 271(e)(1) relating to the wording 'solely for uses reasonably related to ...',⁵ even though it must be admitted that the text of the directive is somewhat perfected compared to the US text.

Advantage of such a rule is in any event that generic drugs, which can prove to have sufficient safety and efficacy, can be put on the market earlier than under the current regime, where carrying out this types of procedures for generic manufacturers before the patent term of the proprietary drug has lapsed, is a straightforward patent infringement. In other words, the current system in practice prevents generic manufacturers to enter the market as soon as the patent lapses, since they first have to pursue their studies and trials. The exception as accepted in the amended directive 2001/83/EC changes that situation, while at the same time guaranteeing some effective patent protection for proprietary manufacturers and lead time advantages. The proprietary drug producer in any event obtains effective protection of minimum 10 years, since generic medicinal products of the reference product may not be put on the market before 10 years have lapsed since market authorization of the latter.

We have already observed that this exception has been included in a directive, while at the same time it has been removed (at least for the moment) from the text of the draft Community Patent Regulation. The consequence of this somewhat strange state of events is that in a national infringement action, a generic manufacturer will be exempted from infringement if his activities fall within the ambit of Art. 10(5) of the amended Directive 2001/83/EC, while a similar activity could be considered to be an infringement under the hypothetical situation that the Community patent would be in force. Such a scenario is untenable in the long run. Hence, opponents should be prepared to accept that the Bolar-type infringement exception also finds its way into the Community Patent Regulation. Experience in countries already containing such an exception has shown that it has no devastating effects for proprietary drug



Convention update

A. PCT Reform

On 1 January 2004 extensive changes to the PCT Rules have entered into force.

These changes have come about as part of a process of reforming the PCT. One of the most significant changes now made is that of establishing an Opinion at the time of issuing the ISR.

For definitive information about the rule changes applicants should refer to the Rules themselves - which may be obtained from the WIPO web site.

Text of the Rules: <http://www.wipo.int/pct/en/texts/index.htm>

More info on PCT reform: <http://www.wipo.int/pct/reform/en/index.html>

For any international applications already filed or to be filed before 31 December 2003, the current international search and preliminary examination procedure will still apply.

⁵ See e.g., *Scripps Clinic & Research Found. V. Genentech, Inc.*, 927 F.2d 1565 (CAFC 1991); *Intermedics, Inc. v. Ventitrex, Inc.* 775 F. Supp. 1269 (N.D. Cal. 1991), affirmed without opinion 991 F.2d 808 (CAFC 1993).

For applications filed on or after 1 January 2004, the International Search Report will include an "International Search Opinion". **[Rule 43bis.1(a)]**. The opinion will cover all issues that are covered under Preliminary Examination. **[Rule 43bis.1(b)]**.

Following the establishment of the International Search Report, the applicant will have the following options:

1. *Take no further action.*

The International Search Opinion will be re-issued by the International Bureau, as an "International Preliminary Report on Patentability (Chapter I)" This will occur at 30 months from the priority date. Prior to that date, the opinion will be confidential. **[Rule 44bis.1]**

2. *Provide written comments to the International Bureau*

The rules will not provide any formal mechanism for this. But the applicant may provide written comments *to the IB*, which will be included with the "International Preliminary Report on Patentability (Chapter I)" when the International Bureau issues it. It should be noted that the applicant would bear the responsibility for ensuring that the submissions are translated as required in the national phase.

3. *File a Demand for Preliminary Examination*

The time for filing the Demand will be 22 months from the Priority date, or three months from the date of the ISR - whichever expires later. This is a new time limit. Demands filed after this date will be deemed not filed. **[Rule 54bis.1(b)]**. Important to note is that a demand should still be filed prior to the expiration of 19 months from the priority date if the applicant wishes to postpone entry into the national phase before those elected Offices which have not withdrawn their notifications of incompatibility of the time limit under Art. 22(1) PCT with the applicable national law.

The International Search Opinion is taken to be the first opinion under Preliminary Examination - irrespective of which Authority established that Opinion. While there is a reservation mechanism for this, it is not expected that any Authority will make that reservation. **[Rule 66.1bis]**

The time limit for establishing the international preliminary examination report shall be whichever of the following periods expires last: 28 months, or 6 months from when the International Preliminary Examination is started. It may be expected that the 28 month date will apply generally except for offices with severe backlog problems. **[Rule 69.2, 69.1]**

Following completion of the preliminary examination, the Report will be communicated to elected offices after 30 months. The International Search Opinion will not be published as such, as is the case for opinions under Preliminary Examination. **[Rule 73, 44ter]**

Availability of the Search Opinion

- Unlike the ISR, the Expanded International Search Opinion is not published together with the international application.
- The Expanded International Search Opinion is not publicly available from the IB or the ISA before the end of 30 months **[Rule 44ter]**.
- It will be automatically communicated to Offices after 30 months, after having been converted by the International Bureau into an International Preliminary Report on Patentability (Chapter I of the PCT). However, if Preliminary Examination has occurred the opinion will not be converted into a Report **[Rule 44bis.1]**. Rather the report under Preliminary Examination will be communicated to Offices after 30 months, as an **International Preliminary Report on Patentability (Chapter II of the PCT)**. **[Rule 73.2(a)]**
- If the applicant enters national phase early, those Offices can request a copy of the Expanded International Search Opinion following national phase entry. Public access to the Opinion is governed by the national law of the country;



B. European Patent Office partially lifts the limitation on competence as a PCT authority for US biotechnology patent applications

Paragraphs 1(a) and (b) of the notice dated 26 November 2001 issued pursuant to Article 3(4)(a)(ii) of the Agreement between the EPO and WIPO under the PCT (OJ EPO 1/2002, 52) are amended. The effect of these changes is that the EPO will resume its competence as an International Searching Authority and International Preliminary Examining Authority for international applications filed as from **1 January 2004** by nationals or residents of the United States of America where such applications contain one or more claims relating to the field of biotechnology as defined by the International Patent Classification units indicated in paragraph 3 of the notice dated 26 November 2001. The EPO will continue not to be competent to act as an International Searching Authority or International Preliminary Examining Authority in this respect for the remainder of the term specified in paragraph 2 of the notice. In all other respects the notice remains in full force and effect.

See :

http://www.european-patent-office.org/epo/pubs/oj003/12_03/12_6333.pdf

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