



Newsletter

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Edgard Gevaertdreef 10a
B-9830 Sint-Martens-Latem
Belgium

Phone: +32 9 280 23 40
Fax: +32 9 280 23 45
E-mail: info@dcbpatent.com

You can visit us at:
www.dcbpatent.com

Best wishes

De Clercq, Brants & Partners first of all convey their best wishes for 2005. We hope it will be a year of peace, inspiration and evidently many inventions.

November 2004 seminar

The pharma and regulatory seminar which was organized by our office and held in the inspiring surroundings of Sint-Martens-Latem on 26 November 2004 was a huge success. We received more than 65 subscriptions, which made the conference room well packed. It turned out to be an interesting day, with excellent contributions from our distinguished speakers, and equally interesting interventions from the participants. Through this channel, we once again would like to thank the speakers of the day, Frank Daelemans (J&J), Bastiaan Bruyndonckx (Linklaters De Bandt), Allen Norris (UCB), David Van Passel (Covington & Burling), Geert Glas (Allen & Overy) and Erik Buntinx (Pharmaneurosciences) for their very informative and inspiring presentations. We also take the opportunity to thank all the participants for their presence and for the added value they have given to this event. We of course hope to see many of you in 2005 on one of our seminar events.

Belgium convicted by ECJ

Belgium has been convicted by the European Court of Justice on 9 September 2004 for not implementing the biotech directive 98/44/EC relating to the patentability of biotechnological inventions (case C-454/03).

The Directive was due to be implemented on 30 June 2000. Hitherto, Belgium has still not implemented the directive, in which it was by no means an exception. Steps have been taken by the European Commission to start proceedings before the ECJ with a view to convict all member states who have not implemented the directive. Other countries who have also been convicted in the mean time are The Netherlands, France and Germany. The Netherlands and France have now implemented the directive. Also Germany succeeded in getting the bill through the Bundestag. In Belgium, a bill is currently under review at the federal Parliament (see next item).

A first conviction by the ECJ for not implementing a directive does not have any direct financial effects for the member state. If a member state does not implement the directive for which it has been convicted once within a time span of six months, a second conviction may follow, which will be subject to payment of a daily penalty, which is calculated on the basis of the gross national product of the member state in question. Such a penalty will in any event amount to several millions of euros.



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Bill implementing biotech directive in Belgian Parliament

The Belgian Chamber of Representatives seems to be in a far-reaching stage of discussion in connection with the proposed bill of 21 September 2004 relating to amendments to the Patent Act of 1984, more in particular regarding the patentability of biotechnological inventions.

The title of the bill may seem somewhat misleading, as the impression is created that it limits itself to implementing the biotech directive 98/44/EC. This is not the case, however. The bill also suggests far-reaching amendments in the field of compulsory licensing and the research exemption.

The proposed bill is a rather literal translation of the wording of the directive. To some extent deviating from the directive, as there is a mere recital and not an article dedicated to it, is the introduction of an obligation to disclose the origin of the biological material on which the invention is based in the patent application. There are no sanctions foreseen for non-compliance, however, in the current proposal.

Going beyond the sphere of the directive, the bill also contains a proposal to dramatically expand the research exemption, to include "research on or with the patented invention for scientific purposes". There is currently a debate which entails the discussion of various amendments which have been proposed to this article, as the text as it reads now might have serious effects for those technological fields which are particularly active in the development of tools.

Another, equally controversial provision in the bill is the introduction of an expanded compulsory licensing scheme. The current compulsory licensing scheme as it exists in Belgium only allows the grant of compulsory licenses in a very limited number of cases, i.e., for non-working after 4 years, and in case of dependency. Belgian law does not contain a compulsory licensing scheme in the general interest, as many other countries have. This new provision is meant to fill this gap, but has created a scheme for a rather limited category of health related cases, in the interest of what has been called "public health". The current text is not satisfactory, and various proposals will probably be made to amend the text. 2005 will guide us to a final text.



Oncomouse case has been decided

The famous Harvard oncomouse case has been decided – once again – by the Technical Board of Appeal of the EPO. After a legal battle which has spread during almost the entire life-span of the patent, it has now been concluded in case T 0315/03 that the patent is to be limited to mice. The reasoning for that conclusion is based on the provision in the EPC dealing with ordre public and morality, Art. 53. It is too early to go into details, as the written decision is yet to be published. Again, 2005 will bring more clarity to this issue.

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Swiss proposal to amend PCT in connection with disclosure of origin of biological material

Switzerland has made a proposal to amend the PCT Rules to take into account growing pressure to disclose the origin of the biological material which is the basis of the patent application. In the Convention on Biodiversity of 1992, the signatory parties agreed to stimulate benefit sharing mechanisms (Art. 15). In the FAO International Treaty on Plant Genetic Resources for Food and Agriculture of 2001 (ITPGRFA), a benefit sharing mechanism has been developed more in detail (see Art. 10). Benefit sharing mechanisms aim at providing a sharing of the benefits collected from the use of genetic resources which have been taken from a particular country/region. It has been felt as unfair by the south that industrialized countries benefit from the genetic wealth present in the poorer south, while that same poorer south does not reap any of the benefits from the use of that material.

The idea has arisen that it would be fair and just if patent applicants and holders would at least help in the development of such benefit sharing systems. One of the means to achieve this goal is to introduce a system of disclosure of the origin of the genetic material used in an invention and patent application. A very developed proposal in this connection has been made by Switzerland. Policy objective of the disclosure requirement proposed by Switzerland is to increase transparency in the context of access to genetic resources and traditional knowledge and the sharing of the benefits arising out of their utilization.

The disclosure requirement referred to above is examined for the purposes of determining if a complete patent application has been filed. The biological source disclosure requirement is in the view of Switzerland linked neither to the search, examination or grant of patents, nor to the evaluation of the claims for patentability. Accordingly, it has to be considered as a formal requirement, not a formal requirement strongly linked to substance or even a substantive requirement.

The proposal leaves it up to member states to decide whether such requirement is introduced in national legislation (see proposed PCT Rule 4.17(v)-(vi) and proposed PCT Rule 51bis.1(g)). As a result, any declaration of the source of genetic resources or traditional knowledge contained in an international patent application would generally become accessible to the public after the expiration of 18 months from the priority date of these applications by being included in the international publication. By being included in the international publication, the declaration of the source would be publicly accessible, and would thus increase transparency in the context of access and benefit sharing at the global level, without it being necessary that it is mandatory for the Contracting Parties of the PCT to require patent applicants to declare the source.

If national law requires disclosure of the source, the Designated Office invites the applicant, at the start of the national phase, to comply with such requirement. If not done, the Office may refuse the application or consider it to be withdrawn (see Rule 51bis.3(a) PCT). The Office may not require further evidence to confirm veracity of the declaration, unless there is reasonable doubt (see new proposed Rule 4.17(vi) PCT). National law may provide for other sanctions, including criminal sanctions.



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The EC computer patent soap continues

The tragic life of the proposed directive on the patentability of computer-implemented inventions has not come to a halt. Resistance by the open source movement is violent of a scale unprecedented. Careful and thoughtful readers will know that by mere letting this ship sink, nothing will change to the current practice that computer-implemented inventions are patentable in Europe, but that is no barrier for the opponents. In view of the fact that politicians have to be "massaged" in this context, the activity has concentrated on that level, not without any success. After that the European Parliament had added numerous amendments to the Commission and Council proposal, even though not all of those amendments can be seen as very consistent, the Council planned to adopt a text which does not take into account many of the aforementioned MEP amendments, very much to the discontent of the opponents of the proposed directive. In a counterattack, the opponents were capable of influencing some member states (in which the new member states in particular were worked on), and on the demand of Poland, the adoption of a Common Position on the directive by the Council (after which the adopted text is sent to the European Parliament for second reading), which was scheduled for 21 December 2004, after already some delays, has been postponed once more. Due to this further delay, and to the apparently possible new situation after the enlargement, it is unclear what the future prospects are of this proposal. 2005 will maybe bring more clarity.

New EPO decision relating to computer-implemented inventions

Despite the developments at the level of the European Union, the EPO continues doing its job and has rendered an interesting decision in the T 0258/03 "Automatic auction method/HITACHI" case. As is known, under European patent law, computer-implemented inventions are patentable if there is a technical character or if they produce a technical effect. An issue which was still not entirely clear is the case where technical means are used to achieve a non-technical effect. In case T 0931/95, "Improved pension benefits system/Pension Benefit Systems Partnership", it was held that "the feature of using technical means for a purely non-technical purpose and/or for processing purely non-technical information does not necessarily confer technical character to any such individual steps of use or to the method as a whole: in fact, any activity in the non-technical branches of human culture involves physical entities and uses, to a greater or lesser extent, technical means. [...] The Board notes that the mere occurrence of technical features in a claim does thus not turn the subject-matter of the claim into an invention within the meaning of Article 52(1). Such an approach would be too formalistic and would not take due account of the term "invention"." In case T 0258/03, the then competent Technical Board of Appeal did away with this ruling, by holding that "there should be no need to further qualify the relevance of technical aspects of a method claim in order to determine the technical character of the method. In fact, it appears to the Board that an assessment of the technical character of a method based on the degree of banality of the technical features of the claim would involve remnants of the contribution approach by implying an evaluation in the light of the available prior art or common general knowledge." One can hardly contest the reasoning of the Board in this case. Problem is that we have clearly two contradictory decisions. 2005 will teach us whether the Enlarged Board of Appeal gets a new controversial case to decide.



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