

Report Q202

in the name of the Belgian Group
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The impact of public health issues on exclusive patent rights

Questions

1) Analysis of current law and case law

- 1) *Is a research or experimental use exception recognised under your patent law? If so, under which conditions? What is the scope of the research exception? Specifically, is research or experimental use permitted for commercial purposes?*

The experimental use exception was provided by article 28 §1 b) of the Belgian Patent Act of 28 March 1984, which stated that *"The rights conferred by the patent shall not extend to acts done for experimental purposes relating to the subject matter of the patented invention"*.

There was some legal uncertainty as to the exact scope of this research exception. Although it was accepted by case law that it would not be an infringement to use the patented invention to *"assess the merits of the invention and to discover its shortcomings and possible improvements"*, this use must not go beyond a *"disinterested purpose"* experimentation¹.

Article 28 §1 b) of the Belgian Patent Act of 28 March 1984 has been modified by the law of 28 April 2005, implementing also the European directive 98/44/CE of 6 July 1998 on the legal protection of biotechnological inventions. The text now provides that *"The rights conferred by the patent shall not extend to acts done for scientific purposes with or on the subject matter of the patented invention"*.

During discussions in Parliament it was stated that the term *"on"* refers to experiments to verify the function, efficiency or working condition of the object of the patent, while the term *"with"* refers to experiments in which the patented invention itself is used for research as a means or an instrument².

The new wording of article 28 §1 b) of the Belgian Patent Act shows an intent of the legislator to guarantee the application of the exception in all cases involving scientific research. The expression *"for scientific purposes"* may therefore be interpreted in a broad sense, so that the research exception can encompass all acts with a purely scientific character, but also so called *"mixed"* acts that are committed for both scientific and commercial purposes. Acts committed and intended for commercial purposes only, without any scientific purpose or intent, are therefore excluded from this exception.

¹ Brussels, 11 May 1995, Ing.-Cons., 1995, p.254 – Fabricom Air Conditioning v. ABB Flakt AB.

² Parl Chambre, 2004-2005, DOC 51 1348/006, p. 58 and 59 (available at <http://www.lachambre.be/FLWB/PDF/51/1348/51K1348006.pdf>)

- 2) *Is a Bolar-type exception recognised under your patent law? If so, under which conditions? What is the scope of the Bolar exception? Specifically, is it limited to drugs or does it also apply to other products, including biological products, research tools, etc.? If your patent law does not provide for a Bolar exception, will using an invention without the patentee's consent for the purpose of obtaining approval of a generic product be covered by the research exception?*

The Bolar provision has been implemented by amending the Belgian Act on Medicinal Products of 25 March 1964, rather than through an amendment of the Belgian Patent Act of 28 March 1984.

Article 6bis, 1, of the Belgian Act on Medicinal Products, amended by the law of 1st May 2006, is almost identical to article 10 of the Directive 2004/27/EC amending Directive 2001/83/EC on the EU code relating to Medicinal Products for Human Use. Article 6bis, 1, of the Belgian Act on Medicinal Products reads as follows: "Conducting the necessary studies, tests and trials with a view to meeting the conditions and modalities referred to in the sections 1 to 8 of this paragraph and the consequential practical requirements shall not be regarded as contrary to patent rights or to supplementary protection certificates (...)". In comparison to article 10 of the Directive, the word "tests" has been added into the Belgian text. Discussions in Parliament have not clarified this difference which appears to be without further consequences.

This exception is meant to exclude from the scope of protection of patents and supplementary protection certificates, studies, tests and bioequivalence tests, performed in order to obtain a marketing authorization of a generic drug. Neither the Belgian Act on Medicinal Products nor the preparatory works give more details about the specific activities that should fall within the exception.

The scope of the Bolar exception may be clarified further by the European Court of Justice whenever a national court refers a question to it on the interpretation of the exemption.

Before the implementation of the Bolar exception in Belgian law, the Brussels Court of appeal had already admitted that the mere fact of filing an administrative request for obtaining a marketing authorization for a generic drug, without such request entailing the submission and hence introduction of any sample on Belgian territory, could not be considered as an infringement of the original patented drug³.

- 3) *Are parallel imports of patented medicines, medical devices or similar permitted? If so, under which conditions? Do the same principles apply if the products originate from markets where they were made available under a compulsory license?*

Parallel importation is permitted under both Belgian law and EC law.

Under the Belgian Patent Act, article 28 §2 provides that the rights conferred by a patent shall not extend to "acts relating to a product covered by that patent which are committed on the Belgian territory after that product has been put on the market in Belgium by the owner of the patent or with his express consent".

Under EC law, the theory of exhaustion of rights will lead to the same result albeit on a Community wide basis: whenever goods are placed on the market of a member state within the Community by a holder of an intellectual property right, or with his consent, the intellectual property right shall be exhausted. Once the product has been put on the market, the right holder is assumed to be rewarded adequately for his intellectual property right.

³ Brussels 10 November 2000, I.R.D.I. 2001, 63. Ely Lilly vs Eurogenerics.

The rule that patent rights shall be exhausted whenever the goods are placed on the market in Belgium or in another member state within the Community by a holder of an intellectual property right, or with his consent, is applicable for any type of patented products, including pharmaceutical products or medical devices.

In case of pharmaceutical products originating from markets where they were made available under a compulsory license, parallel importation shall not be allowed since the patent holder did not give his consent for the production and eventual placing on the market of its patented product⁴.

This rule is confirmed by article 13 §1 of the EC Regulation N° 816/2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export into countries with public health problems, which prohibits the re-importation into the Community of products manufactured under a compulsory license granted pursuant this Regulation.

- 4) *Is an individual prescriptions exception recognised under your patent law? If so, under which conditions?*

The Belgian Patent Act organizes an individual prescriptions exception under article 28 §1 c). This article provides that the rights conferred by the patent shall not extend to *“the extemporaneous preparation for individual cases in a pharmacy of a medicine in accordance with a medical prescription or acts concerning the medicine so prepared”*.

In order to prevent misuse, it is required that the preparation of the medicine is effected upon individual prescription, for immediate use or administration, and in a pharmacy (hence not in an industrial enterprise).

- 5) *Please answer this question only if in your country methods of medical treatment are patentable subject matter: Does your patent law provide for a medical treatment defence or similar exception to the patentee’s exclusive rights?*

Article 7 of the Belgian Patent Act provides that methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body shall not be regarded as patentable inventions.

- 6) *Are compulsory licenses available under your patent law? If so, under which conditions and on which grounds (e.g. to remedy anticompetitive conduct, for cases of emergency, other public interest grounds, etc.)? Are you aware of any compulsory licenses granted in your country for the domestic manufacture and supply of pharmaceutical products? If so, please provide details, including the name of the licensor, the licensee and the product covered.*

Compulsory licences are provided by article 31 and 31bis of the Belgian Patent Act of 28 March 1984.

The main grounds on which a compulsory license can be granted pursuant to article 31 of the Belgian Patent Act of 28 March 1984 are the following⁵:

- 1) When the patentee fails to exploit his invention on Belgian territory, without a valid justification, within either four years from the application or three years from grant, whereby the longest term shall be applied (article 31 §1.1°);
- 2) When a patent cannot be exploited without infringing the rights conferred by a patent granted on an earlier filing, insofar as the dependent patent permits an important technical progress of considerable economic significance in relation to the invention claimed in the dominant patent (article 31 §1.2°);

⁴ ECJ 9 July 1985, Pharmon BV v. Hoechst AG, ECR, 1985, 2281.

⁵ Article 31 provides for two other instances of Compulsory licensing but these seem irrelevant to Question 202.

In both instances, the license can only be granted primarily or predominantly for the supply of the domestic market. In order to be granted a compulsory license, it is up to the applicant to prove that:

- 1) The requirements of Article 31 §1° or 2° apply to the owner of the patent;
- 2) The applicant has applied in vain to the owner of the patent for a voluntary license;
- 3) In case a license is applied for under Article 31 §1.1°, the Applicant has the necessary means to undertake effective and continuous manufacturing in Belgium in accordance with the patented invention.

In relation to public health and pursuant to articles 8 and 30 of the TRIPs Agreement, the Belgian legislator has provided for an additional compulsory licensing mechanism in article 31 bis of the Belgian Patent Act. When deemed in the interest of public health, the Government may grant a license for the exploitation and application of an invention protected by a patent for:

- 1) A medicine, a medical device, a product or medical device used for performing a diagnosis, a derived or combinable therapeutic product;
- 2) The process or product necessary for the manufacture of one or more products indicated under a);
- 3) A diagnostic method applied outside of the human or animal body.

In order to be granted a compulsory license under article 31bis of the Belgian Patent Act, it is up to the applicant to prove that he has the necessary means or bona fide intention to undertake effective and continuous manufacturing in Belgium in accordance with the patented invention.

The request for a compulsory license in the interest of public health must be submitted to the Minister of Public Health with a copy for the Consultative Bioethical Committee. The patentee shall be allowed to make observations and the Consultative Bioethical Committee shall issue a reasoned recommendation. Upon said recommendation, the Minister shall then decide but he must formally justify the decision that is made.

- 7) *Has new Article 31bis TRIPS been ratified in your country? Are you aware of any other legislative amendment in your country with a view to implementing the WTO decision of August 30, 2003? Are you aware of any compulsory licenses granted in your country for the importation or exportation of pharmaceutical products? If so, please provide details, including the name of the licensor, the licensee and the product, if they are publicly available.*

The Belgian legislator has not implemented article 31 bis of the TRIPs agreement in Belgium. As of the present date, no legislative initiative was taken by the Belgian parliament in order to formally implement the WTO decision of 30 August 2003.

However, through the adoption of the European Regulation N° 816/2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems, which aims at addressing public health problems faced by least developed countries and other developing countries by improving access to affordable medicines for these countries, article 31bis TRIPs as well the WTO decision of August 30, 2003 may be considered to have been implemented within the Belgian legal system as well. Within the European Union, regulations are indeed directly enforceable in the Member States.

It should also be noted that a proposition of law dated 27 December 2007 has been recently submitted to the Belgian Senate in order to amend article 28§1 of the Belgian Patent Act of 28 March 1984. The purpose of this proposition of law is to facilitate the exportation of generic

drugs to developing countries which have emitted compulsory licenses in order to deal with the major health problems of these countries. As far as we know, the Government has as yet not supported this proposition of law.

So far, no compulsory license of this type has been granted in Belgium for the import or export of pharmaceutical products.

- 8) *Is the government allowed to make use of a patented invention without previous license and if so, on what basis (e.g. crown use) and under which conditions?*

No such specific provision exists under the Belgian law.

- 9) *Is the government allowed to expropriate a patent and, if so, under which conditions?*

No such specific provision exists under the Belgian law.

- 10) *If your patent law recognises other means of facilitating access to medicines, medical devices, diagnostics and the like, notably in the context of public health crises (including, among others, information tools such as the Orange Book providing timely consumer information on generic drug approvals), which have not been discussed above, please explain.*

There are no other specific means under Belgian patent law.

II) Proposals for adoption of uniform rules

The Belgian Group favours uniform rules and therefore replies as follows:

- 1) *Should patent law provide for*

- *research and experimental use exception;*

Yes.

- *Bolar exception;*

Yes.

- *parallel import of patented medicines;*

Yes.

- *individual prescriptions exception;*

Yes.

- *medical treatment defence;*

Insofar there is a need for a medical treatment defence exception; the Belgian group is of opinion that this issue should also be harmonized taking into account both the interests of the public health and patent holder.

- *compulsory licensing;*

Yes.

- *expropriation;*

The Belgian group is of opinion that compulsory licence mechanisms should be adequate to address public health or any other public interest issues and that the expropriation of a patent holder from its patented product is disproportionate and goes beyond what is necessary.

- *any other limitations of the exclusive patent rights to facilitate access to medicines, diagnostics, medical devices and the like?*

No.

- 2) *Do you see other ways than by limitations of patent rights in which patent law might facilitate access to medicines, diagnostics, medical devices and the like?*

The Belgian Group has no specific proposals to make.

- 3) *Should any of the limitations of patent rights, specifically the research and experimental use exception, Bolar exception, and individual prescriptions exception be harmonised? If so, how? If not, why not?*

The Belgian Group considers that harmonisation is recommended for all three exceptions.

A common interpretation of these exceptions should avoid discrepancies from country to country and allow effective and coherent exploitation of the patent for the rights holder.

A harmonized research and experimental use exception in particular seems to be necessary to encourage the development of both medicine and technology, without putting at risk the incentive to innovation, or creating an arbitrary concentration of research activities in countries which have the broadest interpretation of this exception.

Summary

- In Belgium, Article 28 §1 b) of the Belgian Patent Act provides a research or experimental use exception which can encompass all acts with a purely scientific character, but also acts that are committed for both scientific and commercial purposes.
- Article 6bis, 1, of the Belgian Act on Medicinal Products contains a Bolar provision which is almost identical to article 10 of the Directive 2004/27/EC.
- Article 28 § 2 of the Belgian patent act contains the principle of exhaustion of rights which is similar to the exhaustion of rights in EC law, albeit on a national basis. Therefore parallel imports in Belgium are in principle allowed.
- The Belgian Patent Act organizes an individual prescriptions exception under article 28 §1 c).
- Compulsory licences are provided by article 31 and 31bis of the Belgian Patent Act.
- Article 31 bis of the TRIPs agreement or the WTO decision of August 30, 2003, may be considered to have been implemented within the Belgian legal system by the adoption of European Regulation N° 816/2006 which is directly enforceable in the Member States. A proposition of law dated 27 December 2007 has recently been submitted to the Belgian Senate in order to amend the Belgian Patent Act to facilitate the exportation of generic drugs to developing countries which have emitted compulsory licenses.

Résumé

- En Belgique, l'article 28 §1 b) de la Loi belge sur les brevets d'invention prévoit une exception pour l'usage à des fins expérimentales ou de recherche, qui inclut tous les actes à caractère purement scientifique mais qui peut également s'étendre aux actes qui combinent des fins scientifiques et commerciales.
- L'article 6 bis 1, de la Loi belge sur les Produits Médicinaux contient une disposition Bolar qui est quasiment identique à l'article 10 de la Directive 2004/27/CE.
- L'article 28 §2 de la Loi belge sur les brevets d'invention contient le principe de l'épuisement des droits, qui est similaire à l'épuisement des droits en droit européen, bien qu'il ait une

base nationale. Pour cette raison les importations parallèles en Belgique sont, en principe, autorisées.

- La Loi belge sur les brevets d'invention organise une exception de prescription individuelle à l'article 28 §1 c).
- Des licences obligatoires peuvent être octroyées conformément aux articles 31 et 31 bis de la Loi belge sur les brevets d'invention.
- L'article 31 bis des ADPIC ou la décision de l'OMC du 30 août 2003 peut être considérée comme ayant été transposée dans le système belge par l'adoption du Règlement 816/2006 qui est directement applicable dans les Etats membres. Une proposition de loi datée du 27 décembre 2007 a récemment été soumise au Sénat en vue de modifier la Loi belge sur les brevets d'invention pour faciliter les exportations de médicaments génériques vers les pays en voie de développement qui ont émis des licences obligatoires.