Netherlands
Pays–Bas
Niederlande

Report Q202

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

Questions

I) 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?*

Summary:
Yes. Under Article 53(3) Dutch Patent Act 1995, the exclusive rights of the patent owner are curtailed by the experimental use exemption.

Answer:
Therefore, acts solely serving for research on the patented subject matter are permitted, including the product obtained directly as a result of using the patented process. The research or experimental use is not permitted for commercial purposes, but this does not mean that the research may not be performed in a commercial company or further to an assignment by a commercial company (ARS v Organon [1994] NJ 1995, 33).

The exemption, however, has to be interpreted restrictively, meaning that patent infringing activities are allowed only if this is justified by the purpose of the research.

This is only the case if the party undertaking the research can prove that the research is entirely scientific in nature or if the research is aimed at realising a purpose that is in conformity with the intent of the patent law (ICI v Medicopharma [1992] NJ 1993/81).

Such a purpose can be further developing a certain technique. A good example hereof, is the research and manufacturing of pharmaceutical substances and/ or products with the purpose to find a second (or next) medical use (Boehringer v Kirin Amgen [1995] 'NJ 1995/103). However, clinical trials that take place on a very large scale (various research centers) and which are aimed at examining whether a patented invention can be put into practice and can be further developed does not fall under the research exemption. This type of research concerns the application of the patented invention and, therefore, research with the patented invention (ARS v Organon [1995] NJ 1997, 41).

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?*

Summary:
Yes, Article 10 (6) of the EU Directive 2004/27/EC and Article 13 (6) of EU Directive 2004/28 introduced the Bolar exception in the European Community law.

Answer:
These two provisions have been implemented in Dutch law in the Dutch Patent Act 1995, in a new Article 53 (4) which stipulates that conducting the necessary studies and trials with a view to the application of article 10, paragraphs 1, 2, 3 and 4 of EU Directive 2001/83 or article 13, paragraphs 1 to 5 of EU Directive 2001/82 and the consequential practical requirements shall not be regarded as contrary to patent rights or to supplementary protection certificates for medicinal products.

The Bolar exception relates to studies and trials relating to generic human and veterinary (biological) medicinal products, as set forth in the aforementioned paragraphs of the two EU Directives. It can be assumed that the exception does not relate to research tools or medical devices, as these product will – generally – not meet the definition of 'medicinal product'. With respect to the relation between article 53 (3), discussed above under 1, and 53 (4), it is noted that the Bolar exception of article 53 (4) can be seen as a *lex specialis* vis-à-vis the general experimental use exception of article 53 (3). This general experimental use remains in force and also the case law referred to above under 1 is still relevant for the interpretation of this general exception. However, it should be noted that where the case law relates to research that (now) falls within the scope of the new Bolar provision of article 53 (4) – and contains stricter views on when trials are exempted from patent infringement than this new article –, it is no longer valid.

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?*

Summary:
Yes. Under Article 53(5) Dutch Patent Act 1995, once a patented product has been put on the market lawfully in the Netherlands or the Netherlands Antilles, or once it is put on the market lawfully in one of the Member States of the European Union or in another State that is party to the Agreement concerning the European Economic Area by the patentee or with his consent, the person who obtains or later holds the product shall not infringe the patent by parallel import and/or further distribution.

Answer:
This article in the Patent Act does not distinguish in the type of consent. However, in accordance with ECJ 9 July 1985, C-19/84 Pharmon vs Hoechst, the term "consent" does not include consent under a compulsory license.

Furthermore, the 'specific mechanism' (Annex IV(2) of the Act of Accession signed on 16 April 2003) has introduced the requirement that parallel traders in certain circumstances need to provide confirmation to the competent authority that they have informed the patent holder one month in advance of a notification for a parallel distribution. In a recent case, Court of The Hague, 19 March 2008, Fisher Farma vs Z-Index, it was confirmed that only notice by the parallel distributor is required, and not a notice of the relevant health authority confirming that the proposed repackaged medicinal product complies with the terms of the Community Marketing Authorisation and the pharmaceutical legislation.

Although branding issues may play a role in parallel distribution, these are disregarded within the context of Q202.

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

Summary:
No, the current Dutch Patent Act 1995 does not (longer) recognise an individual prescriptions exception.

Answer:
The old Dutch Patent Act used to contain this exception, in article 53(3) DPA (old): "The exclusive right shall likewise not extend to the preparation of medicines in pharmacies for immediate use in individual cases on medical prescription, or to acts related to medicines prepared in this manner." This article was never enacted, and has been removed from the law in November 2004.

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?*

Under Article 3(1)(f) Dutch Patent Act 1995 methods for treatment of the human body or animal body whether through surgery or medical treatment and diagnostic methods practiced on the human or animal body, are excluded from patentability.

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.*

Summary:
Yes, compulsory licenses are available under Dutch law.

Answer:
According to Art. 57 Dutch Patent Act 1995, a compulsory license may be obtained:

- if the public interest warrants it (paragraph 1),
- if neither the patentee, nor a licensee uses the invention in the Netherlands within three years after the grant of the patent (paragraphs 2 and 3),
- for using an invention protected by a later patent, which invention constitutes a technological progress of a significant economic meaning (paragraph 4),
- in case the license is necessary for using a granted plant breeder's right (paragraph 5).

The Minister of Justice of Aruba can, based on the "Arubaanse Octrooiverordening" (AB, 1997, 29) grant a compulsory license in the 'general interest'. For the Netherlands Antilles, the Dutch Patent Act 1995 is applicable and the Dutch Minister of Economic Affairs can grant a compulsory license.

For the public health related scope of Q202, the compulsory licenses that may be obtained in view of the public interest are of primary interest. These compulsory licenses are granted by the Minister of Economic Affairs upon request under certain conditions. These conditions include a specific definition of the scope of the license and of the entity requesting it. The Minister will inquire whether the patentee is willing to grant the license voluntarily. If the patentee refuses, and the Minister is convinced that granting the license is in the public interest he may do so. The Minister may require that the licensee deposits a security. The compulsory license so obtained may be limited in time. Also, a suitable compensation for the limitation of the patentee's rights will be payable by the licensee. In case of a dispute about the height of the compensation, parties may resort to the Court.

The law does not give a definition of when the requirement that the license is in the public interest is met. Case law clarifies that the public interest must be of considerable weight to justify a limitation of the patentee's rights. The sole examples in the Netherlands of granting

a compulsory license in the public interest dates from shortly after World War II, when the financial situation and reconstruction of the country was deemed to justify the grant of a compulsory license to rebuild national industries. Compulsory license for medical or pharmaceutical products in the Netherlands have, to our knowledge, never been granted. High prices are by the Dutch court not considered as a reason to grant a compulsory license in the 'general interest'. In some cases, alleged infringers have invoked a provision from civil law (Art. 6:168 of the Dutch Civil Code) to try to prevent an injunction. This provision stipulates that an injunction of an illegitimate act will not be granted in case this act needs to be condoned on the basis of significant public interest. The case law is not unambiguous in this respect.

In a case where this provision was invoked successfully (District Court of the Hague, November 21, 1989 in Schneider/ACS), the Court held that the interest of patients undergoing treatment could outweigh the financial interests of the patentee to obtain an injunction. It was considered that the financial interests of the patentee could be compensated by way of damages and an injunction was refused.

That condoning of the infringement must serve a significant public interest is clear from another case (District Court of the Hague, May 3, 1995 in C.R. Bard Inc./TD Medical). The Court decided that the evidence merely supported that some cardiologists had a personal preference for the infringing catheter, and not that the infringing product was so unique that there were no real alternatives.

In another case (District Court of the Hague, December 17, 2003 in Medinol/Boston Scientific), the Court was confronted with a defense from the infringer that he was the only one marketing drug coated stents. An injunction would thus be detrimental to the public health. The Court decided that the patentee had to grant a license to the infringer under reasonable conditions, pending the outcome of the appeal and of the (then still pending) oppositions proceedings against the patents involved before the European Patent Office.

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.*

Summary:
Yes, the Dutch Parliament has ratified the Protocol of Geneva (2005), amending the TRIPS agreement in accordance with the Doha declaration, on 31st October 2007, as the sixth country of the 150 Members.

Answer:
Parliament have requested that the same shall be approved by the Netherlands Antilles and Aruba (Kamerstuk 31 272 (R 1838)).

Voting on ratification of the new Article 31 bis of TRIPS was not deemed necessary for The Netherlands as EC regulation No 816/2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems, was already in place, implementing the Doha declaration into Dutch law. This Regulation was issued in May 2006. The Regulation has direct effect in the Netherlands and supersedes the previous rules of policy adopted on 17 December 2004, which have been withdrawn by decision of 7 December 2006 (see Q 94).

The Dutch Group is not aware of any compulsory licenses that have been granted for the importation or exportation of pharmaceutical products granted under these new rules in the Netherlands.

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?*

Summary:
Yes. According to Article 59 of the Dutch Patent Act 1995 the Dutch government can decide (by a Royal Decree) that it can make use of a patented invention without previous license.

Answer:
This can be done under the condition that it is necessary for the defense of the Kingdom. This decision has to be requested collectively by the Minister of Economic Affairs and the Minister responsible for the defense of the country. Subsequent to this decision the Minister responsible for the defense of the country shall negotiate with the patentee about a compensation for such use. If such negotiation does not lead to an agreement, a party can request the judge to decide on the compensation to be paid (Article 58(6) Dutch Patent Act).

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

No mechanism of expropriation of patents by the government is available in the Dutch Patent Act 1995. The principle of expropriation as existing under general Dutch law has never been applied to patent 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.*

No such other tools for facilitating access to medicines and the like are available.

II) Proposals for adoption of uniform rules

1) *Should patent law provide for*

- *research and experimental use exception;*
  Yes, and in particular the Dutch group recommends to clearly define which research and experimental use is exactly exempted.
- *Bolar exception;*
  Yes, although the term Bolar exception may be ambiguous, particularly where it concerns borderline products (part medical device, part medicinal product). They also fall under the definition of 'medical device' provided for in EU Directive 93/42. The new EU Directive 2007/47 which revises the rules on medical devices, provides that the 'medicinal product' part of borderline products must be examined in conformity with the rules on medicinal products, to which the Bolar exception does apply. The Dutch group believes that there is no good reason not to apply the Bolar exception to such borderline products that will be subject to the same regulatory approval as generic medicines.
- *parallel import of patented medicines;*
  No, parallel import should only be possible when patent rights have been exhausted.
- *individual prescriptions exception;*
  No; the Dutch group does not see a need for this provision. There does not seem to exist a clear purpose to include such exception.
- *medical treatment defence;*
  No; as a method of medical treatment is not always considered as a patentable invention (as in The Netherlands), such a defence not be regulated in patent law.

– *compulsory licensing;*
  Yes, as a general principle the government should have means to limit the scope of exclusive rights that have been granted where the interest of the public so requires.

– *expropriation;*
  The Dutch group does not see a need for expropriation of patent rights.

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

If so, under what circumstances? If not, why not?

No. The Dutch group does not expect that limitations to patent rights will facilitate access to medicines etc. in a substantial and sustainable manner. The solution of the problem of public health may also be a political and/or budgetarial problem, which requires social economic restructuring.

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?*

Access to medicines e.g. by export to thrid world countries may be facilitated and so encouraged if inter alia the rights of the patent owner and protection against parallel import are better safeguarded (in conformity with Article 4 of the Annex to the TRIPS Agreement). This requires a pro-active role of the Council for TRIPS.

Also, the Dutch Group recommends the use of (non-violation) complaints against countries who, when applying compulsory licenses in the context of public health, strictly act in accordance with the rules but de facto act against the spirit of the TRIPS Agreement (Articles XXIII:1b GATT 1994).

Also, additional measures might be introduced into patent law in order to limit the disadvantageous consequences of the grant of a compulsory license for a patentee. Examples are: the grant of a limited period of extension of the patent term as a compensation to (periods of) compulsory licensing, subject to certain further requirements that need to be defined; and/or attribution of (more) intellectual or moral recognition to the inventor(s) of a patent subject to a compulsory license.

In order to limit the risk of potential consequent (infringing) parallel trade of exported medicines, pro-active enforcement of rights by customs (also in the country of export) is seen as a relevant means to minimize such risk (article 69 TRIPS). It might be helpful if it would be clarified whether in that context export or transport can be considered as acts of patent infringement.

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 Dutch group is in favour of harmonisation of these provisions on a supra national level. However, as individual prescriptions will generally take place on a small scale and will normally not have a cross border effect, the need for harmonization of the individual prescription exception is not seen as a priority.