

## **Report Q202**

in the name of the Finnish Group  
by Marjut SALOKANNEL, Pia HJELT, Riikka HÖYKINPURO,  
Saara LAPIOLAHTI, Jan LINDBERG and Jarkko VUORINEN

### **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?*

Experimental use exception is recognised under the Finnish patent law. According to paragraph 3 of Section 3 of the Finnish Patents Act (550/1967), the exclusive rights conferred by a patent shall not apply to use in experiments relating to the invention as such. In other words, research on the invention is permitted without the permission of the patent holder, but research *with* or *using* the invention requires a license. There is no case law relating to the application of the research exemption and its scope seems to be unclear in certain cases, e.g., research tools, as it may be difficult to make a distinction between “on” or “using” the invention. The research exemption covers also commercial purposes.

- 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?*

In connection with the harmonization of the European medicines law, the so-called Bolar exemption was implemented into the Finnish patent law. According to paragraph 3.3 of Section 3 of the Finnish Patents Act (550/1967), the exclusive rights conferred by a patent shall not apply to studies, trials and the consequential practical requirements, which are needed for an application to obtain a marketing authorisation for a medicinal product, and which relate to the patented medicinal product. Finland chose to implement this exemption in a wide manner to the effect that it covers research, studies and other experiments relating to the patented medicine in order to obtain a marketing approval in Finland or abroad.

- 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 imports only within the European Union are permitted. The same principles do not apply if the products originate from markets where they were made available under a compulsory license.

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

Individual prescriptions exception is recognised under the Finnish patent law. According to Paragraph 3.5 of Section 3 of the Finnish Patents Act (550/1967), exclusive right conferred by a patent shall not apply to preparation in a pharmacy of a medicine prescribed by a physician in individual cases or treatment given with the aid of a medicine so prepared.

- 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?*

Not applicable.

- 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 licenses are available under the Finnish patent law. Compulsory licenses are available under the following five main conditions of the Patents Act (550/1967):

Section 45.1: "Where three years have elapsed since the grant of the patent and four years have elapsed from the filing of the application, and if the invention is not worked or brought into use to a reasonable extent in Finland, any person who wishes to work the invention in Finland may obtain a compulsory licence to do so unless legitimate grounds for failing to work the invention may be shown."

Section 46.1: "The proprietor of a patent for an invention whose exploitation is dependent on a patent held by another person may obtain a compulsory licence to exploit the invention protected by such patent if deemed reasonable in view of the importance of the first-mentioned invention or for other special reasons."

Section 47.1: "In the event of considerable public interest, a person who wishes to exploit commercially an invention for which another person holds a patent may obtain a compulsory licence to do so."

Section 48.1: "Any person who was commercially exploiting in this country an invention which is the subject of a patent application, at the time the application documents were made available under section 22, shall, if the application results in a patent, be entitled to a compulsory licence for such exploitation, provided there are special reasons for this and also provided that he had no knowledge of the application and could not reasonably have obtained such knowledge. Such a right shall also be enjoyed, under corresponding conditions, by any person who has made substantial preparations for commercial exploitation of the invention in this country. Compulsory licences may also relate to the period of time preceding the grant of the patent."

Section 49.1: "A compulsory licence may only be granted to a person deemed to be in a position to exploit the invention in an acceptable manner and in accordance with the terms of the licence who, before filing a claim for a compulsory licence, has made a verifiable effort to obtain, on reasonable commercial terms, a licence to the patented invention. A compulsory licence shall not prevent the proprietor of the patent from exploiting the invention himself or from granting licences under the patent. A compulsory licence may only be transferred to a third party together with the business in which it is exploited or was intended to be exploited."

Compulsory licenses have not been granted in Finland for the domestic manufacture and supply of pharmaceutical products.

- 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.*

Article 31bis TRIPS has been ratified by the European Council on behalf of the European Union and its Member States. No compulsory licenses have been granted in Finland for the importation or exportation 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?*

Except for situations where the country is at war or there is a danger of war, the Finnish patent law does not give the government any right to use a patented invention without previous license.

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

Under the Finnish patent law, the government may if the country is at war or in danger of war, decree, where required by the public interest, that the right to a given invention shall be assigned to the State or to another party designated by the government. According to the Act on Inventions with Significance for National Defence (551/1967), certain patent applications can be expropriated by the government. Reasonable compensation shall be paid for the right to any invention thus assigned.

- 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.*

The Finnish patent law does not recognise other means of facilitating access to medicines, medical devices, diagnostics and the like, even within the context of public health crises.

## **II) Proposals for adoption of uniform rules**

- 1) *Should patent law provide for*

– *research and experimental use exception;*  
Yes.

– *Bolar exception;*  
Yes.

– *parallel import of patented medicines;*  
Within economic regions such as EU, yes.

– *individual prescriptions exception;*  
Yes.

– *medical treatment defence;*  
No.

– *compulsory licensing;*  
In principle compulsory licensing provisions should be harmonized according to the TRIPS standards. However, with regard to certain mid-level developing countries and

small industrialized countries without indigenous manufacturing capacity for medicines, the need for current opt-out provisions as provided in connection with the Decision of the General Council of 30th August 2003 relating to the implementation of paragraph 6 of the Doha Declaration should be re-considered. All countries not having local manufacturing capacity for producing medicines should be able to use the TRIPS addendum for national health purposes.

- *expropriation;*  
Only in very exceptional circumstances.
- *any other limitations of the exclusive patent rights to facilitate access to medicines, diagnostics, medical devices and the like?*  
In case of evident abuse of the patent system and ensuing harm to society, the government should have the possibility to intervene.

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

- 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?*

Where the interests of public health demand, and in the event of medicines being made available to the public in insufficient quantity, patents granted for medicines or for processes for obtaining medicines, for products necessary in obtaining such medicines or for processes for manufacturing such products may be subject to ex-officio licenses, e.g. as specified in French law (Articles L 613-16 and L. 613-17).

- 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?*

Harmonisation of the limitations should be attempted considering the international nature of medical markets and research.

National Groups are invited to comment on any additional issue concerning the impact of public health issues on the patentee's exclusive rights which they find relevant.

Generic substitution and reference pricing

Finland introduced mandatory generic substitution of medicinal products in April 2003. The initial law made no exception for patented drugs. The Medicines Act was amended in February 2006 to exclude from the substitution drugs which were protected by so called analogy process patents and were covered by product patents in other countries. This was done to compensate the pharmaceutical industry for the lack of product patent protection before 1 January 1995 and for the relatively short (6 year) data protection period. The data protection period has since been harmonized within the EU and is 10 years with a possible extension of one year.

The exception based on analogy process patents was not required by national nor by international regulations and the exception is being debated again when Finland is considering adopting a reference pricing system to lower the costs of public health care.

## **Summary**

In Finland the Patent Act provides for both research and Bolar exceptions. Parallel imports from other EU countries are permitted. Compulsory license provisions exist but have never been applied. With regard to international harmonization we propose harmonization of the research and Bolar exceptions as well as introducing an ex officio compulsory license for public health purposes.

## **Résumé**

En Finlande, la loi sur brevets comprend les réglementations sur l'exception de recherche et l'exception Bolar. L'importation parallèle des pays de l'Union européenne est permise. Les réglementations relatives à la licence obligatoire existent mais elles ne sont jamais mises en application. À l'égard de l'harmonisation internationale, nous proposons l'harmonisation de la réglementation sur l'exception de recherche et l'exception Bolar ainsi que l'introduction d'une licence obligatoire d'ex officio pour des raisons de santé publique.

## **Zusammenfassung**

Unter dem finnischen Patentrecht werden Benutzung zu Forschungszwecken und Ausnahmen vom Bolar-Typ anerkannt. Parallelimporte aus anderen EU-Ländern sind zugelassen. Zwangslizenzen sind vorhanden, sind aber nie in der Praxis umgesetzt worden. Bezüglich der internationalen Harmonisierung schlagen wir eine Harmonisierung von den Ausnahmen zu Forschungszwecken sowie Ausnahmen vom Bolar-Typ vor. Auch schlagen wir vor, von Amts wegen Zwangslizenzen zu Gesundheitszwecken einzuführen.