Estonia
Estonie
Estland

Report Q202

in the name of the Estonian Group
by Alla HAMMALOV and Juhan HAMMALOV

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?*

No.

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?*

No.

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?*

No.

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

No.

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?*

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.*

Yes, the compulsory licenses are available under Estonian patent law (§ 47). The conditions and grounds are as follows:

1) the proprietor of the patent has not used the invention in Estonia within three years after publication of the notice concerning the issue of the patent or within four years after filing a patent application, and in such case the term which ends later shall apply;

2) the proprietor of the patent does not use the invention in the extent which would correspond to the needs of the domestic market;

3) the patent hinders the use of another, technically advanced invention significant for the economy of Estonia;

4) national defense, environmental protection, public health and other significant national interests of the Republic of Estonia require the use of the invention, including the need to use the invention in connection with a natural disaster or other emergency;

5) the patent hinders the grant of plant variety rights pursuant to the Plant Variety Rights Act or the use of a plant variety which is granted legal protection.

A compulsory license shall not be granted if the proprietor of a patent imports the product protected by the patent from any state member of the World Trade Organisation in the extent which corresponds to the needs of the domestic market.

We are not aware of recoding of any compulsory license granted in Estonia.

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.

No.

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.

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

No.

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.

II) Proposals for adoption of uniform rules

1) Should patent law provide for

- *research and experimental use exception;*
- *Bolar exception;*
- *parallel import of patented medicines;*
- *individual prescriptions exception;*
- *medical treatment defence;*
- *compulsory licensing;*
- *expropriation;*

– *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?

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?*

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?*

Summary

Answers on the working questions are provided on the bases of the Estonian legislation. No proposals are done.

Résumé

Les réponses aux questions de travail se fondent sur la législation estonienne. Le group national estonian n'a pas des propositions.

Zusammenfassung

Die Antworten auf die Arbeitsfragen sind auf Grund von estnische Gesetzgebung gegeben.