Norway
Norvège
Norwegen

Report Q202

in the name of the Norwegian 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?*

Under Norwegian law there is an experimental use exception. A prerequisite is that the experiment is set up to investigate or improve the invention itself.

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 Norwegian Patents Act does not currently mention a Bolar-type exception. However, a Bolar-type exception as set out in EU/EEA marketing authorisation regulations for pharmaceutical products will be introduced in Norway. In the meantime, it is not unlikely that the experimental use exception would be construed so as to include a Bolar type exception for drugs.

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 of any type of product are permitted, provided the products were brought to market in the EEA. However, imports of medicines from certain EEAcountries where patent protection for drugs was not available when the Norwegian patent application was submitted, could be refused by the patent holder.

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

An individual prescriptions exception is recognised under Norwegian patent law. The prerequisite is that the prescription is an isolated incidence.

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?*

N/A.

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 on the grounds of non-use, use of the invention being necessary for the use of another patented invention or plant variety right, important public interests, the patent holder significantly limiting competition, and in some instances of prior use or substantial preparation for exploitation of the invention. Compulsory licenses are granted by the court or by the Norwegian Competition Authority. There are a considerable number of prerequisites for the granting of compulsory licenses on the different grounds. The general prerequisites are (i) that effort has been made to obtain a license on normal business terms by agreement without achieving it in reasonable time, and (ii) the party aspiring the compulsory license is presumed to be able to exploit the invention in an acceptable manner. A compulsory licence will not prevent the patent holder from exploiting the invention or granting licences. A compulsory licence is only assignable in conjunction with the enterprise where it is being used or intended to be used, and it should mainly be given with the aim of supplying the domestic market. There is an exception from the latter for the export of medicines to certain developing countries.

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 new article has been adopted by Norway (decision by the Ministry of Foreign Affairs). The rules were implemented effective January 1, 2008. To our knowledge, no such licenses have been granted.

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?*

There are no regulations allowing the government to make use of a patented invention without previous licence, except a provision to the effect that a right to utilize inventions which the government deems to have significance for the national defence may be granted to the authorities or others, when desirable in order that the invention may have the maximum utility for the national defence.

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

According to the Patent Act section 70, when it is necessary because of war or danger of war and situations of crisis connected therewith, the government may expropriate the right to an invention on behalf of the government itself or a third party. Compensation shall be paid.

According to the section 6 of the Act on inventions with significance for the Defence of the Realm, inventions that the government deems to have significance for the defence, be ceded to the authorities or other persons, when this is desirable in order that the invention may have the maximum utility for the defence.

Under the Civil Defense Act, the Ministry of Justice can expropriate any property and rights necessary to prevent or repair harm an to the civilian population from acts of war, but also, subject to governmental decree, to prevent or repair harm that is not caused by acts of war.

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.*

In the context of public health crises, the compulsory licensing system would ensure access to medicines, medical devices, diagnostics and the like; see our answer to question 6.

In relation to the issue of timely consumer information on generic drug approvals, it should be noted that the access to generic drugs is an integral part of the prescription and distribution system for pharmaceuticals.

The system includes a list of the products that are interchangeable; the original product and the different generics in each group.

This list can be found and accessed on the web page of the Medicines Agency.

The maximum price eligible for reimbursement will be reduced step-wise, following the introduction of a product on the list of interchangeable products.

For products included in this system, following the prescription of the physician the pharmacy shall be able to deliver one product within the fixed maximum for reimbursement (in most cases a generic drug) in each group. The patient will only be reimbursed the fixed reimbursement price. If he chooses to buy the more expensive original he must pay the balance amount himself.

However, if the physician makes a specific note on the prescription, stating that the patient shall receive the original product, and setting out medical grounds for this, the patient will be reimbursed accordingly.

II) Proposals for adoption of uniform rules

1) *Should patent law provide for*

- *research and experimental use exception;*
  YES. These means may facilitate new inventions in the medical area. Once the inventions are made, the holder of the original patent will be protected to the normal extent in cases where utilization of the new invention infringes the original patent. In order to not undermine patents on research tools, such exceptions should be limited to instances were the invention is being examined or improved.
- *Bolar exception;*
  There are different views on this issue within the Norwegian group, so the group has no official position.
- *parallel import of patented medicines;*
  NO. A general rule, based on global exhaustion of patent rights, and not limited to regional exhaustion within the EEA, is likely to undermine the economic function of patents.
- *individual prescriptions exception;*
  YES. This could be important in some few instances, and is unlikely to affect the patent holder in any substantial way.

– *medical treatment defence;*
YES To the extent that medical treatments are patentable, the availability of a medical treatment defence appears to be justified.

– *compulsory licensing;*
YES. On the grounds of important public interests.

– *expropriation;*
NO. It is thought that compulsory licensing will be sufficient.

– *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?*

A well-functioning patent system will have this effect.

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?*

Yes, harmonisation of these rules between jurisdiction would bring considerable advantages. The group has no specific suggestions as to what approach one should take to achieve harmonisation.