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Report Q202

in the name of the Bulgarian Group
by Valentina NESHEVA

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?*

The exclusive rights of the Patentees are subject to exceptions in cases of use for experimental purposes or scientific research. The condition is that the experiments and research must relate to the object of the patent used. This condition only defines the scope of the research or experimental use exception. There is no explicit prohibition for commercial use in the research and experimental use exception but eventual interpretation of the legal provision should come to this conclusion because scientific research and experiments by definition are non-commercial activities although their outcome can be used commercially if this commercial use does not violate others' rights such as patent rights.

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?*

Bulgarian legislation provides for Bolar type exception. The producer of generic pharmaceutical product does not need the consent of the Patentee to apply for marketing authorization permit before the expiration date of the patent for the reference product if already 8 years have passed since the first marketing authorization permit issued within EU. In any case the producer of the generic product cannot release it on the market before the expiration of 10 years after the first marketing authorization permit issued to the reference patented product within EU. The exception relates only to pharmaceutical products and such other products that may fall within the scope of the research and experimental use exception.

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?*

The parallel import of patented products is not explicitly regulated as such. However the regulation of exhaustion of rights can be interpreted to make the conclusion that the parallel import on the territory of EU is now allowed. However there is no court practice regarding patents at all and the court practice on this subject with regard to trademarks is not uniform.

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

Individual prescriptions exception is recognized under the Bulgarian patent law. It is allowed only in the case of single immediate preparation of a medicine in a pharmacy according to a medical doctor's prescription.

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?*

Methods of medical treatment are not patentable in Bulgaria.

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 Bulgarian patent law. The conditions and limitations under which the compulsory license is granted are numerous. In the first place the party requesting such a license must have negotiated with the Patentee for a contractual license at fair terms and not only once at that. On the other hand the invention must not have been used for 4 years after the filing date of the patent application or 3 years after the grant of the patent whatever term expires later or the invention must not have been used sufficiently to satisfy the national market and there is no serious reason for this inadequate use. The party requesting the compulsory license must prove that it is able to use the invention within the limits of the requested license and the granted license will be declared void if the preparation for the use of the invention according to the granted compulsory license has not started within one year after the grant of such license. Lastly a compulsory license cannot be exclusive license but only non-exclusive one.

There is another type of compulsory license – it is requested and granted even if no negotiations were conducted with the Patentee but the national interest requires that such a license is granted.

Finally there is another type of compulsory license – the so called cross license which is granted in cases when a patented invention with later priority date falls within the scope of protection of a patent with an earlier priority date and the later invention represents an important technical progress with a significant economic importance in comparison with the earlier invention.

We are not aware of any compulsory licenses granted lately.

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.*

Yes.

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?*

The type of compulsory license described above as granted without previous negotiations with the holder of a patent and in case the national interest requires that such a license is granted, can be granted to government entities.

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

The government is not allowed to expropriate a patent.

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 patent law does not recognize other means for facilitating access to medicines but other laws do – the Law on Medicinal Products for Human Medicine provides for the use of pharmaceutical products without marketing authorization permit in cases of epidemics, spreading of chemical agents or nuclear radiation. Furthermore this Law admits the use of certain products without marketing authorization permit and such is not required at all – e.g. medicines prepared in pharmacies under certain conditions, intermittent products used by a holder of marketing authorization permit, active and auxiliary substances. The Drug Agency provides information to the public about granted marketing authorization permits within 14 days after the grant.

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;*
  All these exceptions are foreseen by the Bulgarian legislation and they seem to us sensible and necessary in order to guarantee the public health and to provide the people with cost-effective medicines.
- *medical treatment defence;*
  Methods for medical treatment are not patentable under the Bulgarian and European patent laws and they should stay so in view of the fact that people across the world are not uniform and therefore the applicability of a method of medical treatment with uniform results is highly questionable.
- *compulsory licensing;*
  The presence of compulsory licensing as a tool for overcoming unreasonable demands on the part of patent holders is useful and necessary especially in cases of inventions with great public importance. However there is no doubt that compulsory licensing cannot be the rule but only a rare exception. Our opinion is that Bulgarian patent law has dealt with this problem quite adequately providing for many limitations and conditions to be fulfilled before the grant of a compulsory license.
- *expropriation;*
  Expropriation of a patent seems to be very severe measure violating basic rights of a person in democratic society. It should not be allowed.
- *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?

Patent rights are anyway additionally limited by the expensive patenting procedures, slow prosecution of patent infringement lawsuits and the lack of specialized patent courts in many countries. There is no need to limit further the rights of patent holders.

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?*

No.

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?*

It would be advisable to harmonize the limitations of patent rights. The limitations of the patent rights in any case should not be used to get round the law and make profit of it, therefore any exceptions should exclude commercial use of a patented invention without the consent of the Patentee.