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Report Q202

in the name of the Hungarian 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?*

According to Art. 19(6)(a) of the Hungarian Patent Act (Act No. XXXIII of 1995, hereinafter referred to as "Patent Act") "the exclusive right of exploitation shall not extend to acts performed for the purpose of private use, or being outside the sphere of economic activities". Therefore, any acts which are performed either for private purpose or outside the sphere of economic activities are stipulated as an exemption from the scope of patent protection. So, pursuant to this provision any activity, thus also the research activity is allowed if it is for non-commercial purposes.

A specific research exception is provided for as a Bolar-type exception. See our answer to the question No. 2.

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 Bolar-type exception with a specific reference to pharmaceutical products was introduced into the Hungarian patent law as the present Patent Act was codified in 1995. According to the original (1995) wording of Art. 19(6)(b) of the Patent Act: "The exclusive right of exploitation shall not extend to […] acts for experimental purposes relating to the subject matter of the invention, including experiments and tests necessary for the authorization of the marketing of pharmaceuticals"

After the ratification of the TRIPS-Agreement this provision of the Patent Act had been made product neutral by an amendment of the Patent Act in 2001. Since then Art. 19(6)(b) reads as follows: "The exclusive right of exploitation shall not extend to […] acts for experimental purposes relating to the subject matter of the invention, including experiments and tests necessary for the authorization of the marketing of a product being the subject matter of the invention or a product that is produced by the process being the subject matter of the invention".

A drug-specific form of the same provision exists in connection with the registration of generic medicines in Art. 7(9) of the Decree of the Health Minister No. 52/2005 (XI. 18.) on the Registration of Medicinal Products for Human Use.

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 import of patented medicines, etc. is not allowed unless they originate from the territory of the European Economic Area. According to Art. 20 of the Patent Act "the exclusive right of exploitation pursuant to the patent protection shall not cover further acts related to a product marketed within the European Economic Area by the holder of the patent or with his express consent, unless the holder of the patent has rightful interest in opposing the further marketing of the product."

Thus, parallel imports are only allowed from within the European Economic Area if within this territory the product had been marketed by the patent owner or with his explicit consent. Even this general permission is limited by the last part of Art. 20.

The Decree of the Minister for Health, Social and Family Affairs No. 53/2004 (VI. 2.) on the Wholesale and Parallel Import of Pharmaceutical Products provides for the regulatory requirements for parallel import.

According to Art. 33(2) of the Patent Act the compulsory license – in accordance with Art. 31(f) of the TRIPS-Agreement – the scope of the compulsory license shall be limited predominantly for satisfaction of the domestic need, which constitutes a territorial limit to the license. Since no precedent exists in Hungary, according to the authors of the present report, in view of the ECJ judgement in the case Pharmon v. Hoechst this would mean that products made under a compulsory license do not exhaust the rights of a patent holder, because the patent holder has not given his consent, thus within the European Economic Area no parallel import is possible for a product which was manufactured under a compulsory license.

Since Hungary is a Member State of the European Union in cases of compulsory licenses of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems, the relevant EC Regulation No. 816/2006/EC states "that the import into the Community of products manufactured under a compulsory licence […] shall be prohibited" [Art. 13(1)].

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

Individual prescriptions are recognized among the exceptions from the exclusive right granted by a patent. According to Art. 19(6)(c) of the Patent Act the exclusive right of exploitation shall not extend to "the preparation for individual cases, in a pharmacy, of a medicine in accordance with a medical prescription, or acts concerning the 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?*

Does not apply.

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.*

According to the Hungarian Patent Act there are three grounds upon which a compulsory license can be granted: for lack of exploitation, in case of dependent patents and for export to countries with public health problems.

Lack of exploitation: Art. 31 of the Patent Act: "If within four years from the date of filing of the patent application or within three years from the grant of the patent, whichever period expires last, the patentee has not exploited the invention in the territory of the country to satisfy the domestic demand or if he has not undertaken serious preparations for such purpose, or has not granted a license to others, a compulsory license shall be granted to the applicant for the license, unless the patentee justifies its failure to act."

It has to be remarked that according to Art. 19(2)(a) of the Patent Act importation is regarded as one of the forms of exploitation of patent rights.

Dependent patents: Art. 32(1) of the Patent Act: „If the patented invention cannot be exploited without infringing another patent (hereinafter referred to as "the dominant patent"), a compulsory license for the exploitation of the dominant patent shall be granted, on request and to the extent necessary, to the holder of the dependent patent, provided that the invention according to the dependent patent involves an important technical advance of considerable economic significance in relation to the invention according to the dominant patent."

Compulsory licenses for lack of exploitation and in case of dependent patents are in the competence of the Metropolitan Court of Budapest.

Export to countries with public health problems: according to Regulation (EC) No. 816/2006 of the Parliament and of the Council of 17 May 2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems and in accordance with Art. 33/A of the Patent Act providing for the necessary execution rules, the Hungarian Patent Office may grant a compulsory license in such cases.

In the last ten years no case has been known where a compulsory license was granted.

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 answer to all of these questions is no. As stated above, Regulation (EC) No. 816/2006 referred to by Art. 33/A(1) of the Patent Act, is directly applicable.

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?

Art. 53(5) of the Patent Act stipulates as follows: „The President of the Hungarian Patent Office may order, at the request of the competent Minister and in the interest of national defense or on the basis of an international treaty, that a patent application be dealt with as a State secret. In such case, publication of the application and printing of the specification shall be waived." This provision was introduced into the Patent Act as a consequence of the accession to the Agreement for the mutual safeguarding of secrecy of inventions relating to defense and for which applications for patents have been made. Nevertheless, this provision does not make it possible for the government to use a patented invention without any license.

Theoretically, the state or the government as an entity with legal personality is not excluded from applying for a compulsory license under Art. 31 of the Patent Act referred to above. We are not aware of any case with this issue.

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

Regarding patents, there is no specific provision in the Hungarian law that would permit expropriation.

The Decision No. 1338/B/1992 of the Hungarian Constitutional Court has extended the rights to property as set forth in Art. 13 of the Constitution of the Republic of Hungary (Act No. XX of 1949 as amended) to patent rights as well. According to Art. 13(2) of the Constitution expropriation of property shall only be permitted in exceptional cases, when such action is in the public interest, and only in such cases and in the manner stipulated by law, with the provision of a full, unconditional and immediate compensation.

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 question does not apply in Hungary.

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?

The Hungarian Group is of the opinion that the provisions of the present Hungarian law regarding the above issues are appropriate.

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?*

The Hungarian Group any other ways for facilitating the access to the subject matters protected by patent law.

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?*

We think that this question should only be considered in merits as part of a full harmonisation of substantive patent law.

Summary

Hungarian patent law provides for a right balance between the interest of public access to medicines and the patent owner's exclusive rights. Thus the main exceptions allowing under certain circumstances easier access to medicine – such as the research and experimental exception, the Bolar-exception, the parallel import, the individual prescription exception, the compulsory licensing

– are part of Hungarian patent law, either historically, or as a consequence of Hungary's accession to the TRIPS-Agreement or as a consequence of being one the Member States of the European Union. At the same time, however, credit is also given to the patent owners' interests: thus patent right was recognised as a property right by the Hungarian Constitutional Court giving it the constitutional protection of property. In the opinion of the Hungarian Group the introduction of further exceptions could harm this balance and is therefore unnecessary.

Résumé

Le droit de brevet en Hongrie prévoit un équilibre correct entre l'intérêt de l'accès public aux médicaments et les droits exclusifs du propriétaire de brevet. Par conséquent, les exceptions principales – comme l'exception expérimentale et l'exception de recherche, l'exception Bolar, l'importation parallèle, l'exception de la prescription individuelle, la licence obligatoire – qui, dans certaines conditions, permettent un accès facilité aux médicaments, font partie du droit de brevet hongrois, soit pour des raisons historiques, soit à la suite de l'adhésion de la Hongrie à l'accord TRIPS, ou parce que la Hongrie est membre de l'Union européenne. D'autre part, l'intérêt du propriétaire de brevet est également pris en compte: ainsi, le droit au brevet a été reconnu par la Cour constitutionnelle hongroise comme droit de propriété, lui accordant la protection constitutionnelle de la propriété. Selon l'équipe hongroise, l'introduction d'exceptions supplémentaires pourrait nuire à cet équilibre, et pour cette raison, elle est inutile.

Zusammenfassung

Ungarisches Patentrecht sorgt für eine richtige Balance zwischen den Interessen von öffentlichem Zugang zu Medikamenten und den ausschliesslichen Rechten der Patentinhaber. So sind die wichtigsten Ausnahmen, die unter bestimmten Umständen leichteren Zugang zu Medikamenten sichern – wie die Ausnahme zur Benutzung zu Forschungs- und Versuchszwecken, die Bolar-Ausnahme, Parallelimport, die Ausnahme für individuelle Verschreibungen und die Zwangslizensierung – teil des ungarischen Patentrechts entweder historisch, oder als Folge des Beitritts Ungarns zum TRIPS-Übereinkommen oder weil Ungarn ein Mitgliedstaat der Europäischen Union ist. Gleichzeitig aber wird auch den Interessen der Patentinhaber Rechnung getragen: das ungarische Verfassungsgericht hat den Begriff des verfassungsrechtlichen Eigentumsrecht auf das Patentrecht erweitert, wodurch Patenten der verfassungsrechtliche Schutz des Eigentums zukommt. Nach Meinung der ungarischen Landesgruppe könnte die Einführung weiterer Ausnahmen diesem Gleichgewicht schaden und ist daher nicht von Nöten.