Working Guidelines

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Question Q202

The impact of public health issues on exclusive patent rights

Introduction

1) The protection of public health is one of the most pressing issues in today's world. The patent system is designed to promote scientific and technological innovation and, as a result, has contributed to significant improvements in the treatment of health conditions, as evidenced by the many medicines which have been invented and brought to the market. The patent system also contributes to public health and society at large by making available patent information which is freely available to other researchers to further improve existing technologies and products. Despite the public policy objectives inherent in the patent system, the relationship between patents and public health has been the subject of debate. Some consider that the current patent system does not adequately address public health issues. More specifically, there have been concerns about how patents may affect access to medicines, diagnostics, medical devices and medical treatment in view of possible future pandemics such as HIV/AIDS, SARS or Avian flu.

2) Access to patented medicines, diagnostics and the like is a complex issue and may be affected by different factors such as pricing, availability, stock, and speed of manufacturing and supply. The exclusionary nature of patent rights has the effect that third parties are excluded from manufacturing or offering for sale products which are covered by the scope of the patents without the authority of the patent owner. By way of example, this may result in a shortage of adequate supplies of drugs capable of treating pandemic diseases if the patentee lacks sufficient manufacturing capacities or maintains high pricing. For instance, in the recent cases of anthrax attacks in the United States, some voices raised concerns that German pharmaceutical company Bayer would not be able to meet all of the demand of its anthrax drug Ciprobay and moreover would not be willing to provide it at affordable rates.

3) In general, the development of new drugs and medical devices requires substantial investment and long-term research, coupled with expensive clinical trials and regulatory approval procedures. The exclusive right conferred by a patent is one of the incentives for pharmaceutical companies to make the necessary investments into that research. To ensure access by third parties to patented technologies, the patent system is primarily based on a voluntary licensing mechanism. If the patent owner is not willing or able to provide access, this may be problematic. The patent system, therefore, provides for a number of limitations of the exclusive patent rights, such as, for example, provision for compulsory licensing in certain circumstances, recognition by some countries of the legality of parallel imports of patented medicines or – with a view to providing access on a longer term basis – research and Bolar exceptions.

4) The purpose of this question is to examine national and international legislation and case law in respect of limitations which may play a role in providing access to patented medicines and other medical or biological products so as to facilitate health care, notably in the context of public health crises such as those which may occur in any country, also in developed

countries, but also those which are currently afflicting some developing and least developed countries. This question is only concerned with limitations of the exclusive nature of patents. It does not deal with issues of patentability, such as the exclusion of patentable subject matter on public policy or morality grounds. In addition, although certain aspects of trademark law, competition law, and medical and health care law may also be relevant in the context of public health crises, this question only addresses patents. Finally, this question does not specifically single out and refer to the issue of access to medicines in developing countries and least developed countries. While access to **affordable** medicines is undoubtedly a pressing issue and also relevant in the context of this question, this issue is not at the core of this question Q202. This question rather looks at limitations on patent protection applicable to medicines and other medical products at a general level, notably in cases of public health crises, without any particular focus on developing and least developed countries. It is taken into account that in the case of developing and least developed countries, other factors may play an even more important role in preventing medicines to reach those in need thereof, such as inadequacies in health care policy and in health care infrastructure.

Previous Work of AIPPI

5) AIPPI has studied health-sensitive limitations of the patentee's exclusive rights in previous questions.

6) Already at the Congress of Washington in 1956 AIPPI studied restrictions of the rights of the patentee for reasons of public interest in the context of Article 5 (A) Paris Convention. In resolution Q3 AIPPI adopted the principle that measures, other than compulsory licenses, restricting the rights of the patentee should only be permitted if compelling requirements of public interest are not satisfied by the granting of a compulsory license. The Congress further recommended that compulsory licences and similar measures be subject to equitable compensation to the patentee. These principles were confirmed at subsequent meetings noting that any restriction of the exclusive right of the patentee would impair the success of the patent system as a means of encouraging invention and, accordingly, be detrimental to the general interest of the public.

7) In 1966 the Congress of Tokyo adopted resolution Q39 (Reasons for which the rights of the patentee can be restricted) which mentions as reasons for restricting the rights of the patentee: abuse resulting from the exercise of the exclusive patent rights, dependent patents, failure to work or insufficient working (both subject to more stringent provisions). The resolution Q39 further specifies that a compulsory license must not be granted until an agreement has proved to be impossible.

8) In resolution Q101 (Parallel Import of Patented Products) adopted by the Executive Committee in Barcelona in 1990 AIPPI resolved that a patentee should be able to invoke its patent against parallel import of a patented product. This resolution was confirmed in resolution Q156 (International Exhaustion of Industrial Property Rights) adopted at the Melbourne Congress in 2001. The resolution Q156 rejects the notion of international exhaustion and notes that there should in any event be no international or regional exhaustion of an IPR where a product has been put on the market under a compulsory licence.

9) The Executive Committee of Tokyo in 1992 adopted resolution Q105 regarding experimental use as a defence to a claim of patent infringement. The AIPPI resolution favours permitting experimental use of a patented invention for academic purposes, including testing of the invention to evaluate the teaching and validity of the patent, but not for commercial purposes. The resolution Q105 considers use of the invention during the lifetime of the patent for the purpose of obtaining regulatory approval (which uses are today exempted by the Bolar exception, where applicable) not to be experimental use.

10) At the Congress of Montreal in 1995, AIPPI resolved that compulsory licensing provisions should equally apply to patents related to the environment (Q128 - Patents and the Protection of the Environment). Similarly, the resolution Q150 (Patentability requirements and scope of protection of Expressed Sequence Tags (ESTs), Single Nucleotide Polymorphisms (SNPs) and entire genomes) adopted by the Executive Committee of Sorrento in 2000 notes that AIPPI is not in favour of special provisions for experimental use or compulsory licenses in the field of ESTs, SNPs and entire genomes.

11) The summary report Q178 (Scope of Patent Protection) in 2004 notes that medical treatment, pharmaceutical inventions and the patentability of second medical use claims inevitably lead to questions of accessibility to new medicines and how doctors can avoid patent infringement in emergency situations. The report mentions the possibility of issuing compulsory licences for such patents.

12) The summary report Q187 (Limitations on exclusive IP rights by competition law) in 2005 confirms that all reporting countries provide for exceptions to the exclusive rights of the patentee, notably the possibility of issuing compulsory licenses (in the United States only in relation to nuclear energy and the environment). In their group reports some groups had noted the exceptional nature of the compulsory licensing provisions and the fact that in practice they were very rarely implemented, but had emphasised that their mere existence would force patentees to negotiate license agreements under more advantageous conditions for future licensees. The summary report Q187 further notes that some reporting countries provide for exceptions relating to tests and experiments. While the group reports Q187 touch on issues which are also relevant in the context of this question, they cannot be seen as comprehensive analysis of compulsory licensing and experimental use exception.

13) Special Committee Q94 (GATT/WTO) which monitors and advises on developments of the GATT/WTO TRIPS Agreement has reported on public health issues in the context of TRIPS, notably on the decision of August 30, 2003 under paragraph 6 of the Doha declaration on the TRIPS Agreement and Public Health and the new Article 31bis TRIPS allowing generic copies of pharmaceuticals made under compulsory licences to be exported to (developing) countries that lack production capacity in the pharmaceutical sector.

Discussion

14) WTO member states retain a considerable degree of flexibility in addressing public health issues.

15) According to Article 8 (1) TRIPS members may adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their development, provided that such measures are consistent with the provisions of this Agreement. Article 8 (2) TRIPS notes that appropriate measures may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.

16) According to Article 30 TRIPS members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties. Article 30 TRIPS leaves WTO member states with considerable freedom to define the nature and extent of exceptions to the exclusive rights of patent owners. There are different types of exceptions that may be provided for within the scope of Article 30 TRIPS and, at the same time, are relevant in connection with public health issues.

17) For instance, a research and experimental use exception permits use of pharmaceutical inventions without compensation to the owner for research and experimentation purposes. Application of the research exception may contribute to access to medicines on a long term basis to the extent that it may lead to improved products. While the research exception is rather narrow in the United States, many countries (notably in Europe) explicitly authorize research on an invention without the consent of the patent owner, for scientific and to some extent even mixed scientific and commercial purposes.

18) Another exception specifically applicable to pharmaceutical patents is the Bolar exception. This exception relates to using an invention without the patentee's consent for the purpose of obtaining approval of a generic product before the patent expiration date. This procedure may permit the marketing of a generic product promptly after the patent expires. Generic competition may in turn lead to lower prices and, as a result, improved affordability of drugs. Some countries have adopted a Bolar-type exception while simultaneously extending pharmaceutical patent terms by way of supplementary protection certificates (SPC) or the like to account for the long time needed to obtain regulatory approval. The scope of the Bolar exemption, however, differs among various jurisdictions.

19) A further possibility of improving access to pharmaceuticals would be to admit parallel imports of a patented medicine from a country where it is sold by the patentee or with his consent at a lower price. Parallel importing is seen as one of the measures that member countries may take to protect public health under Article 8 (1) TRIPS. For instance, in South Africa the medicines law (The Medicines and Related Substances Act, 1965) and not the patent law provides for a parallel import exception but limited to medicines (and subject to the prior decision of the Ministry of Health). However, the doctrine of international exhaustion - the underlying concept for allowing parallel imports - remains controversial as far as patents are concerned.

20) Some patent laws exempt from the effects of the patentee's exclusive rights, medicines prepared for an individual case in a pharmacy or by a medical professional. This exception may also contribute to access to medicines in case of medical crises.

21) Under the law of most jurisdictions methods of medical treatment are not patentable subject matter. If methods of medical treatment are patentable, issues of access to such medical treatment methods may arise. In other words, if methods of medical treatment are patentable, patent law may provide for a medical treatment defence or similar exception to the patentee's exclusive rights to ensure access to medical treatment, notably in the context of public health crises.

22) Compulsory licensing allows a government to licence to a company or other party the right to use a patented invention without the patent owner's consent. The issuing of compulsory licences is seen by some as a crucial element in promoting access to medicines, diagnostics and the like, notably in developing countries. Most countries make available some form of compulsory licensing. Article 31 TRIPS specifically allows WTO members to grant compulsory licenses on grounds to be determined by each member. Compulsory licences are generally available for lack or insufficiency of working, to remedy anti-competitive practices, for cases of emergency (e.g. when urgent public health needs exist for example as a result of a pandemic) and government use, and for other public interest grounds. In Switzerland, for instance, the patent law was recently amended to include compulsory licensing provisions for research tools and diagnostic methods in addition to the traditional compulsory licensing provisions.

23) According to Article 31 TRIPS, the conditions to be met should a compulsory license be granted include: the requirement that a licence be voluntarily requested before being granted on compulsory term, non-exclusivity, and an adequate remuneration to the patent owner. The requirement that a licence be voluntarily requested before being granted on compulsory term may be waived in the case of a national emergency or other circumstances of extreme urgency.

24) Article 31 (f) TRIPS provides that compulsory licences must be granted predominantly to supply the domestic market. The 2001 Doha Ministerial Conference decided that this should be changed so that countries unable to manufacture the pharmaceuticals could obtain cheaper copies elsewhere if necessary. The 2005 Hong Kong Ministerial Conference adopted new Article 31bis TRIPS making permanent the Doha decision of August 30, 2003 by setting aside Article 31 (f) TRIPS in the pharmaceutical sector. The TRIPS amendment will become effective when two thirds of the WTO's members have ratified the change. In the interim, the decision of August 30, 2003 remains applicable. As per September 2007, ten WTO members have accepted the protocol amending the TRIPS agreement. In July 2007, Rwanda notified its decision to import a generic AIDS/HIV product from the Canadian manufacturer Apotex, Inc. and to renounce from enforcing patent rights that may have been granted within Rwanda's territory with respect to the original product. The Commissioner of Patents in Canada has in the meantime granted a compulsory licence to Apotex, Inc.

25) Despite the provisions for compulsory licences in many national laws, relatively few compulsory licenses have actually been granted. The practical value of the existence of compulsory license provisions is that the threat of it usually induces the grant of contractual licenses on reasonable terms. This is, however, not always the case. The Brazilian and Thailand governments recently issued compulsory licences to patents of Merck & Co., Inc. relating to the anti-retroviral drug Efavirenz for the treatment of HIV/AIDS after negotiations between Merck and the government had failed. In 2006 the Italian Competition Authority granted a compulsory licence to GSK's patents relating to Sumatriptan succinate, used in the production of powerful migraine medicines, to a local chemical company after GSK had refused to grant a voluntary licence.

26) In some countries, such as the UK, crown use is a further exemption from the exclusive rights of patentees. The British government may make or sanction use of a patented invention without previous licence, subject only to an obligation to pay compensation for doing so. The exemption covers for example the supply of scheduled drugs in the Health Service.

27) In some countries, such as South Africa, Competition Authorities have relied on competition law principles to require some patentees of medical products to grant licences to competitors, including to generic manufacturers.

28) Finally, some countries such as Switzerland even allow the government to expropriate a patent – as a whole or in part – for reasons of public interest, subject to an obligation to pay compensation for doing so.

Questions

I) Analysis of current law and case law

The Groups are invited to answer the following questions under their national laws:

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?

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?*

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?*

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

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.*

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.*

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?*

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

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.*

II) Proposals for adoption of uniform rules

The Groups are invited to put forward proposals for adoption of uniform rules regarding health-sensitive limitations of patent rights with a view to protecting public health. More specifically, the Groups are invited to answer the following questions:

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) *Dou 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?*

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.

Note:
It will be helpful and appreciated if the Groups follow the order of the questions in their Reports and use the questions and numbers for each answer.