Brazil
Brésil
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Report Q202

in the name of the Brazilian 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?*

Yes. Acts practiced by unauthorized third parties for experimental purposes, related to studies or to scientific or technological research are expressly determined not to characterize infringement of a patent. There is not an established understanding of what would be the scope of this research exception, and no case law has been affirmed in this connection. Unauthorized third parties cannot use the patented invention for a commercial purpose.

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?*

A Bolar-type exception is recognized under the Brazilian Industrial Property Law (Law n. 9,279/96, hereinafter "BIPL"). The exception encompasses acts carried out to produce information, data and test results to seek market approval in Brazil or abroad in order to exploit or commercialize the patented product after the patent in question has expired. Brazilian legislation does not narrow this provision only to drugs. It literally refers to "products" and hence it can be inferred that biological products and research tools are comprehended within this 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?*

In principle, parallel importation is not permitted in Brazil. The unauthorized importation of a product protected by a patent is considered as patent infringement, but not a criminal offense, and, therefore, is subject only to civil sanctions. Importation can be admitted in situations in which a compulsory license has been granted in Brazil due to abuse of the economic power perpetuated by the patent owner for the period of one year, this permission applying to the licensee proposing to manufacture locally, provided it is placed on the market directly by the patentee or with his consent. The importation by third parties of a product manufactured according to a process or product patent is also allowed in our country in the case wherein

the patentee itself exploits the subject-matter of its patent in Brazil by importation due to economic inviability for manufacturing same.

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

Such an exception is recognized under BIPL. It must refer to the preparation of a medicine according to a medical prescription for individual cases, prepared by a qualified professional and it covers the medicine thus 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?*

In Brazil, methods of treatment, as well as operating or surgical techniques are not considered to be inventions and thus are not patentable subject-matter.

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 may be granted under BIPL, and applicable conditions are:

- use of rights in an abusive manner;
- abuse of economic power by applying the rights conferred, proven by an administrative or court decision;
- non-exploitation of the subject matter of the patent in Brazil by lack of manufacture or incomplete manufacture of the product, except due to economic inviability;
- lack of complete use of a patented process, except due to economic inviability;
- when commercialization does not meet the needs of the market;
- when, cumulatively, a situation of dependency of one patent on another is characterized, the subject matter of the dependent patent constitutes a substantial technical advance in relation to the earlier patent, and the patentee does not come an agreement with the patentee of the dependent patent for the exploitation of the earlier patent;
- in cases of national emergency or public interest, declared by an act of the Federal Executive Authorities.

In 2007, compulsory licenses of two patents were determined by the Brazilian Government based on arguments of public interest regarding invention of anti-HIV drug. The compulsory licenses were concluded with the importation, by the government, of the products from an Indian company, instead of starting the local production, following the determinations established in the Governmental Act that formalized the granting of such licenses. The licensor is Merck & Co. Inc., the licensee is the Brazilian Health Ministry and the drug is *efavirenz*.

Further to the above case, the Brazilian Patent Office had previously granted four further compulsory licenses under the previous Industrial Property Law (Law n. 5772/71) which was replaced in 1996 by the current Law (Law n. 9,279/96, BIPL).

Three compulsory licenses were granted regarding Brazilian Patent No. PI 76.767, referring to a process for a viral culture, used for the production of vaccine against aftosa, property of National Research Development Corporation and one for Brazilian Patent No. 7.107.076

obtained by Nortox Agro-Química S/A in 1984, the patent being property of Monsanto Company.

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.*

New article 31 bis of the TRIPS has not been ratified by Brazil.

Two patents were compulsorily licensed in 2007 based on Article 31 of the TRIPS and Article 71 of the BIPL. The Governmental Act formalizing the granting of the licenses comprehended the possibility of importing the drug object of the patents in order to attend the internal needs. The licensor is Merck & Co. Inc., the licensee is the Brazilian Health Ministry and the drug is *efavirenz*.

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, BIPL does not allow government to use a patented invention without previous license, although in case of officially declared national emergency or public interest, a compulsory license can be declared *ex officio*, without prejudice to the rights of the respective patentee.

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

BIPL does not establish such possibility. Please note that, according to article 5, XXIV of the Brazilian Federal Constitution, the State can expropriate any particular goods, in case of public need or utility or social interest, paying a previous monetary indemnification. However, no cases of expropriation of patents were registered in Brazil.

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 granting of patents for pharmaceutical products or processes depends on prior consent from the National Sanitary Surveillance Agency – ANVISA (equivalent to the US FDA). In practical terms, this has meant that patent applications for such subject matter undergo a double examination on the merits, one performed by the Brazilian Patent Office and another by ANVISA. In many instances, ANVISA's examination is quite technical, consisting of another examination on patentability requirements. However, in some cases, broadly definable arguments, such as public interest or national health interests, are used as a basis for denial on the needed prior consent for the granting of the patents, thus halting the administrative processes at the Brazilian Patent Office, preventing this autarchy from pronouncing their final decision, either granting our rejecting the application. An example of ANVISA's position is the objection to the granting of patents for second application of an already known substance. There is a clear political bias in ANVISA's decisions since, although not in large numbers, there have been denials on consenting on the granting of patents regarding inventions for particular drugs, namely anti-HIV related inventions. ANVISA's stand seeks to protect the public health by assuring access to the medicines.

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?

Yes. Patent law should provide for the exemptions to patent holders' rights, as long as their enforcement is directly aimed at achieving a perfect balance between innovation and access to drugs, i.e., in order not to harm either development of new drugs or the public health.

All of the exemptions mentioned in the question are set forth in the BIPL.

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. There are many other means to facilitate access using governmental and non-governamental aid, however they are not liked with the 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?*

The limitations of patent rights, specifically the research and experimental use exception, Bolar exception, and individual prescriptions exception, should not be harmonized, since it should be taken into account the flexibilities in international IP agreements and the different levels of development of the countries.

Summary

In Brazil, the 1996 Industrial Property Law (BIPL), recognized protection for pharmaceuticals, but expressly forbade patent protection for methods of medical treatment. Acts practiced by unauthorized third parties for experimental purposes in connection with scientific, technological studies or research, may not be considered a patent infringement. Bolar type exception and preparation of a medicine according to a medical prescription for individual cases are accepted by BIPL and parallel importation is permitted in some very specific cases. The National Government shall not explore a patent without a license, however expropriation is possible, since its proceedings obey the due process of law and the IPR owner is duly compensated. BIPL guarantees the possibility of compulsory license under determined conditions. Since there were compulsory licenses determined ex officio by the Government in 2007, the Brazilian Group understands that the Government interpretation of this provision is not adequate. Another issue considered by the Group is the necessary consent of the National Sanitary Surveillance Agency – ANVISA (equivalent to the US FDA) for granting patents of pharmaceutical products.

Résumé

Au Brésil, la Loi de Propriété Industrielle (LPI) de 1996, a reconnue la protection des produits pharmaceutiques, mais a interdit de forme explicite la protection par brevet des méthodes de traitement médical. Des actes pratiqués pour des tiers non autorisés dans un but expérimental, liés à des études scientifiques, technologiques ou à des recherches, ne serait probablement considéré

une infraction de brevet. L'exception du type Bolar et la préparation de médicaments en accord avec la prescription médicale pour les cas individuels sont admis par la LPI et l'importation parallèle est permit dans quelques cas bien spécifiés. Le Gouvernement national n'est pas autorisé a explorer un brevet sans licence, de toute façon l'expropriation est possible, pourvu que le procès légale soit observé et le titulaire soit dûment compensé. La LPI garantie la possibilité de licence obligatoire sous de conditions déterminés. Aussitôt qu'il y a eu des licences obligatoires déterminées *ex officio* par le Gouvernement en 2007, le Groupe brésilien comprend que l'interprétation gouvernementale de ce dispositif légale n'est pas adéquat. Une autre question considéré par le Groupe était la nécessité de l'assentiment de l'Agente National de Surveillance Sanitaire – ANVISA (équivalent de la nord américaine FDA) pour la concession de brevets de produits pharmaceutiques.

Zusammenfassung

In Brasilien anerkannte das 1996 Gesetz zum gewerblichen Eigentum (BIPL) den Schutz für Arzneimittel, aber verbat ausdrücklich den Patentschutz für Methoden der medizinischen Behandlung. Die von unerlaubten Dritten praktizierten Handlungen, die für experimentelle Zwecke in Verbindung mit wissenschaftlichen, technologischen Studien oder Forschungen geübt werden, dürfen nicht als Patentverletzung angenommen werden. Die Bolar Ausnahme und die Vorbereitung eines Medikaments nach einer ärztlichen Verschreibung für gegebene Fälle werden von BIPL zugelassen, und parallele Einfuhr ist in einigen ganz spezifischen Fällen erlaubt. Die Nationale Regierung darf nicht ein Patent ohne Lizenz nutzen; dennoch ist die Nutzung möglich, wenn das rechtliche Verfahren beobachtet wird und der Rechtsinhaber die entsprechende Entschädigung bekommt. BIPL gewährt die Möglichkeit der Zwangslizenz unter gegebenen Voraussetzungen. Da 2007 die Regierung Zwangslizenzen von Amts angeordnet hat, versteht die brasilianische Gruppe, dass die Auslegung der Regierung auf dieser Bestimmung nicht angemessen ist. Ein weiteres Problem, das von der Gruppe beobachtet wurde, ist die notwendige Zustimmung der Nationalen Sanitären Agentur – ANVISA (gleichbedeutend mit der US FDA) für die Gewährung von Patenten in Bezug auf pharmazeutische Produkte.