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Report Q202

in the name of the Mexican 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?*

Article 22.I of the Mexican Industrial Property Law states the right conferred by a patent shall not have any effect against a third party who, in the private or academic sphere and for **non-commercial purposes**, engages in scientific or technological research activities for purely experimental, testing or teaching purposes, and to that end, manufactures or uses a product or a process identical to the one patented.

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 exception is not recognized under the Mexican Industrial Property Law, but is recognized, in the case of pharmaceutical products, by regulations issued under the Health Law. Specifically, Article 167*bis* of the *Reglamento de Insumos para la Salud* (Regulations on Health-Related Consumable Goods) states:

ARTICLE 167 bis. – An applicant for registration [of a patent] covering an allopathic medicine must attach to the application documentation which demonstrates that it is the owner of the patent for the substance or active ingredient or has a license for the same, which in either case must be recorded with the Mexican Institute of Industrial Property.

Alternatively, and in accordance with the list of products contained in Article 47*bis* of the Industrial Property Regulations, [the applicant] may state under oath that it has complied with the applicable provisions of patent law regarding the substance or active ingredient that is the subject of the application. In this case, the Secretary will immediately request the technical assistance of the Mexican Institute of Industrial Property in order to determine, within the scope of its competence, within ten business days of the reception of the request, if any subsisting patent rights are infringed. If the Mexican Institute of Industrial Property concludes that there are subsisting patents covering the substance or active ingredient which are not owned by or licensed to the applicant, it will so inform the Secretary so that the applicant may be notified. The applicant must demonstrate that it is the owner of the patent or has a license to use the same, within such period as may be determined by the Secretary, and which may

not be less than five business days counted from the date on which the notification becomes effective. If the applicant does not respond to the omission, the Secretary shall reject the application, and inform the applicant of the basis for its determination, so that the issue may be resolved [on appeal] by the competent authority. The lack of a response by the Mexican Institute of Industrial Property within the period noted above shall be understood in a manner favorable to the applicant.

Notwithstanding the provisions of the previous paragraphs, it shall be possible to request registration of a generic [substance] with respect to a medication, the substance or active ingredient of which is protected by a patent, for the purpose of undertaking studies, tests, or experimental production of the same, within three years of the expiration of the patent. En such a case, the sanitary registration shall be granted only until the expiration of the patent.

Information referenced in Articles 167 and 167*bis* of this Regulation which is of a confidential or secret nature as provided in international treaties to which Mexico is a party, or other legal provisions, shall be protected from disclosure to other private parties.

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 patented goods are permitted under Mexican law. Article 22.II of the Mexican Industrial Property Law states that the rights conferred by a patent shall have no effect against any person who markets, acquires or uses the patented product or the product obtained by means of the patented process, after the product has been lawfully placed on the market. The patent provisions of the Industrial Property Law (unlike the trademark provisions) do not state whether exhaustion is national or international in scope.

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

The individual prescriptions exception is not recognized under Mexican patent law.

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?*

The Mexican Industrial Property law expressly excludes methods of medical treatment from patentability. Article 19.VII expressly states that "methods of surgical, therapeutic or diagnostic treatment applicable to the human body or to animals" are not "inventions" eligible for patent protection.

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.*

Any person may apply for a compulsory license within three years of the patent grant, or four years from the filing of the application (whichever is later), if the invention has not been exploited, and there are no valid reasons for the lack of exploitation. The license may not be granted if the patent owner or a licensee is importing the patented product.

The applicant for a compulsory license must have the technical ability and economic means to efficiently use the patented invention.

Before the grant of a first compulsory license, the Institute shall allow the patent owner one year to make use of the patent. The license, if granted must state the duration, terms and

scope of the license, and the amount of royalties due. If a compulsory license has previously been granted, the holder of that license shall be notified and heard.

The Institute may declare that the patent has lapsed if the compulsory license does not result in use of the patented invention within two years of the grant of the license, or if the patent owner fails to show use of the patented invention, or justify its lack of use.

The Institute may modify the terms of the compulsory license at the request of the licensor or licensee, if, for example, the patent owner has granted another party a license under more favorable terms.

The compulsory license may be revoked after two years (ex officio or at the licensor's request) if the licensee does not begin using the patent, or justify its lack of use.

The compulsory license shall not be exclusive. The licensee may not assign the license without permission of the institute, and the license may be transferred in connection with that part of the production unit in which the licensed patent is being used.

The payment of royalties under the compulsory license shall terminate when the patent lapses or is terminated.

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.*

On December 2007, Article 31bis of TRIPS was ratified by the Mexican Senate. On January 21st, 2008, the Decree of Implementation was published in the Official Gazette of the Federation. However, no compulsory licenses regarding the import or export of pharmaceutical products have been granted to date.

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 Mexican government is not allowed to make use of a patented invention without a previous license.

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

The Mexican 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.*

Article 77 of the Mexican Industrial Property Law allows licenses to be granted for reasons of national security or emergency, for as long as these conditions continue to exist. The outbreak of a serious disease may constitute an emergency. The outbreak of a serious disease may constitute an emergency if the production, supply or public distribution of staple goods or services or medicines would be prevented, hindered, or made more expensive in the absence of a license.

The General Health Council may issue a Declaration of Priority Attention on its own initiative, or in response to a written request from an accredited organization. Once the Council's declaration has been published in the Official Journal, pharmaceutical firms may request that the Institute grant a license of public utility, and the Institute shall grant the license after

hearing the parties, within 90 days of the request, or such shorter period as may be justified by the circumstances.

The Secretary of Health shall determine the conditions of production and quality, duration and scope of the license, and the classification of the applicant's technical ability. After hearing both parties, the Institute shall establish a reasonable royalty to be paid to the patent owner.

Licenses granted under this provision may not be exclusive or transferable.

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?

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?

Heightened scrutiny of patentability, in order to avoid the grant of incremental patents that unduly extend patent protection.

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?

Harmonization of exceptions to patent rights should be achieved, to permit better responses to health emergencies by the social security regimes of developed and underdeveloped economies.

Summary

Mexican patent law already recognizes some limitations to the exclusive rights conferred by pharmaceutical patents, such as research and experiment exception, Bolar exception, compulsory licenses and licenses of public utility. However there are still grey areas like the parallel imports regime.

It would be desirable to have a more harmonized system which balances all the interests involved in the patent system, in order to achieve a better scenario for public health.

Résumé

Dans la loi mexicaine de propriété industrielle, se reconnaissent déjà quelque les limitations a la exclusivité des droits attribuent aux brevets pharmaceutiques, comment les suivants: l'exception du recherche et expérimentation, l´exception Bolar, les licences obligatoire et les licences de utilité publique. Ceci dit, il y a des zones inconnues comme le régime de l'importation parallèle.

Il serait souhaitable d´ avoir un panorama du système plus harmonieux, dans le quel tous les intérêts en relation avec la protection des brevets, avec l´objectif d´acquérir une meilleure situation pour la santé publique.

Zusammenfassung

Das mexikanische Patentrecht anerkennt bereits gewisse Begrenzungen in den ausschliesslichen Rechten welche die pharmazeutischen Patente gewähren, wie zum Beispiel die Untersuchungs- und Versuchsausnahme, die Bolar Ausnahme, Zwangslizenzen und Lizenzen der öffentlichen Dienste. Es bestehen allerdings immer noch Grauzonen wie die Paralleleinfuhrregelung.

Es wäre wünschenswert über ein harmonischeres System zu verfügen, welches alle Interessen im Zusammenhang mit dem Patentsystem in ein Gleichgewicht bringen würde, um auf diese Weise bessere Bedingungen für das öffentliche Gesundheitswesen zu schaffen.