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Report Q202

in the name of the Argentine Group

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, an experimental use exception is recognised under the Argentine Patent Law. Section 36 of the Patent Law provides that the right conferred by a patent shall have no effect against any third party who, within the private or academic field and with no commercial purposes, carries out activities of purely experimental scientific or technological research, testing or teaching, and for this purpose manufactures or employs a patented product or uses a patented process. Therefore, according to the Patent Law, experimental use is not 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?*

Although the Patent Law does not contemplate a Bolar-type exception, said exception is recognised by the Confidentiality Law. According to this law, any third party may use a patented product or process before the expiration of the patent, with experimental purposes and to gather the information required for approval of a product or procedure by the pertinent authority, for its sale after the expiration of the patent. The exception is not limited to drugs, and it therefore applies to any other product requiring prior regulatory approval.

Considering that the Confidentiality Law was enacted after the Patent Law, the former would be considered to prevail over the latter. The validity of the Confidentiality Law vis-à-vis the TRIPS Agreement has not been challenged so far at the Argentine Courts.

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?*

Section 36 (c) of the Argentine Patent Law provides:

"The right conferred by a patent shall have no effect against: ... (c) Any person or legal entity that ... imports, or in any other way markets the patented product or obtained by the patented process, once sue product is lawfully placed on the market in the country ..."

Section 36 of the Regulatory Decree provides:

" ... it shall be understood that an imported product has been lawfully placed on the market when the licensee authorized to market it within the country, shows that it has been placed on the market by the patentee in the country where it was acquired, or by a third party authorized to market it."

One possible reading of Section 36 of the Argentine Patent Law is that if the product was lawfully placed on the world market by someone, there would be no further exclusive patent rights in Argentina. For instance, the product could be placed on the market in a country where there is no patent protection at all.

However, we understand that such interpretation is not acceptable because it would contradict the exclusive right conferred by Article 17 of the Argentine Constitution, and more specifically by Section 8 of the Patent Law and Article 28 of the TRIPS Agreement since they both extend the right conferred by a patent to the prohibition of the imports of the concerned product.

For that reason, we estimate that a reasonable interpretation of Section 36 of the Argentine Patent Law would be that "lawfully placed" means with the authorization of the patentee or its licensee or a party authorized by the patentee. In other words, that Section 36 of the Argentine Patent Law would refer to the "exhaustion of rights" situation and that accordingly the exclusive right of the patent holder is exhausted after the product is lawfully placed on the market, in Argentina or abroad.

In addition, to support that interpretation, we would point out that the Supreme Court has accepted the validity of the so-called "parallel imports" in trademark cases as long as these imports are the consequence of an "exhaustion of rights" occurred in another jurisdiction.

In any event, it is worth noting that our patent legislation is not particularly clear on this matter nor is there is any relevant case law.

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

Yes, an individual prescriptions exception is recognised under the Patent Law, which provides that the rights conferred by a patent shall have no effect against: (i) the production of medical products habitually carried out by licensed professionals, and per unit, upon executing a medical prescription, nor (ii) any further acts related to such medical products.

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 non patentable subject matter in Argentina.

In this respect, Section 6.e) of the Argentine Patent Law does not consider methods of chirurgic, therapeutic or diagnostic treatment as inventions.

A related issue is the patentability of second medical uses, which are not explicitly admitted or rejected under the Argentine statute. Few patents were granted that could qualify as focusing on second medical uses. However, afterwards, the Argentine Patent Office started rejecting patent applications for these inventions. Moreover, the Guidelines of the Argentine Patent Offices do not admit Swiss-type claims as main claims in a patent application.

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.*

Yes, compulsory licenses are available under Argentine Patent Law. Patent Law provides that compulsory licenses may be granted due to: (i) lack of working, (ii) anticompetitive practices incurred by the patentee, (iii) sanitary emergency or national security reasons and (iv) dependency. However, no compulsory licenses have been granted in Argentina up to now.

In line with Article 5 of the Paris Convention, the Patent Law provides that mandatory licenses for lack of working may be applied for after three years from grant of the patent, or four years as from application, whichever term is longer and also, if the use of the invention has been interrupted for more than one year after the above terms have expired.

A Patent owner may invoke the following defenses in the case of lack of working:

- that there were effective and serious preparatory measures to work the invention; or
- that the inactivity derived from a force majeure event, including objective difficulties of a technical and legal character to obtain the registration before a public agency for marketing authorization, which made the use of the invention impossible.

To obtain a mandatory license, a third party must also prove that he has the economic capacity to carry out an efficient use of the patented invention, and that he has a plant duly authorized by the competent authority.

The decree regulating the Patent Law provides that importation of the product embodying the invention should be considered to be sufficient working of the patent. Some legal commentators have argued that the decree may not include such type of provision if it is not included in the Patent Law. In any event, Article 27 of the TRIPS Agreement provides that *"patents shall be available and patent rights enjoyable without discrimination as to ... whether the products are imported or locally produced."* That, in the authors' opinion, settles the matter that importation should be deemed as sufficient working, especially considering the higher hierarchy of treaties in Argentina.

Furthermore, to obtain a mandatory license applicant must comply in general with the requirements set forth in Article 31 of the TRIPS Agreement.

The Patent Office determines a reasonable compensation to be paid to the patentee by taking into account the economic value of the authorization being granted and the average royalties being paid within such commercial field of activities when similar license agreements between independent parties are executed. That decision may be appealed to the Federal Courts.

There is a situation in which the patent may be declared to be cancelled as a consequence of lack of working. If a mandatory license is granted to a third party, and that party does not make use of the invention within a term of two years as from the grant of the license for causes attributable to the patentee, the patent may be canceled.

Compulsory licenses may also be granted if patentee incurs in anti-competitive practices, or in cases of sanitary emergency, or for national security reasons.

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.

Argentina has not ratified new Article 31bis TRIPS so far, and we are not aware of any other legislative amendment with a view to implementing the WTO decision of August 30, 2003. We are not aware of any compulsory licenses granted for the importation or exportation of pharmaceutical products either.

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 Patent Law does not allow the government to make use of a patented invention without previous license.

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

Although the Patent Law does not specifically provide for patent expropriations, the government could expropriate a patent on the grounds of the Argentine Constitution and the Expropriation Law. Expropriation is only allowed on the grounds of public interest, which must be declared by a law from the Congress, and the patentee must be previously compensated.

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.*

Law 25.649 obliges doctors to prescribe medicines by their INN, and not by trademark.

If a prescription wants to name the product by its trademark the doctor must state his/her reason. Pharmacists are also compelled to offer alternative medicines to the one prescribed by the doctor, focusing on those being sold at a lower price. However, these provisions are disregarded to a large extent.

Furthermore, in few cases the courts decided that patients should be supplied the product designated by its trademark in the doctor's prescription.

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?

We consider that all the exemptions previously mentioned should be provided for in the patent law, except for: (i) parallel import of patented medicines, and (ii) limitations to patent rights with the aim of facilitating access to medicines since we consider that said goal, unfortunately, can not be achieved by limiting patent rights.

We consider that the *research* and *experimental use exception* should be strictly limited to cases involving non direct commercial purposes.

Moreover, we consider that the *compulsory licensing* and *expropriation* exemptions should be narrowly construed so as to preserve the rights of the patent holder.

On the other hand, we consider that *parallel import of patented medicines* should not be allowed since it produces an economic distortion of markets with the consequent increase of prices. Moreover, *parallel imports* negatively affect local production of medicines since it creates barriers from direct foreign investment.

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?*

There exist indeed other ways than the limitations of patent rights which might facilitate access to medicines, diagnostics, medical devices and the like, particularly in the sense of making less expensive and/or more effective this access to the needy. The government may subsidize the selling prices of the original products still under patent protection and/or give tax benefits to manufacturers and importers of patented medicines and devices.

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 harmonise the limitations of patent rights since it would create certainty for patent holders over different national jurisdictions. In this respect, international organizations such as the WTO could be a suitable means for achieving that result.

Summary

The Group considers that limitations to patent rights should be provided for in the patent law, but not for parallel import of patented medicines nor with the aim of facilitating access to medicines. Research and experimental use exception should be strictly limited to cases involving non direct commercial purposes. Compulsory licensing and expropriation exemptions should be narrowly construed so as to preserve the rights of the patent holder. Parallel import of patented medicines should not be allowed since it produces an economic distortion of markets with the consequent increase of prices and it negatively affects local production of medicines creating barriers from direct foreign investment. There are ways other than limitation of patent rights which might facilitate access to medicines, diagnostics, medical devices and the like. It would be advisable to harmonise the limitations of patent rights since it would create certainty for patent holders over different national jurisdictions.

Résumé

Le Groupe considère que la loi des Brevets devrait spécifier des restrictions au droit des brevets, excepté ce qui concerne l'importation parallèle des médicaments brevetés et ce qui facilite l'accès aux médicaments. L'exemption pour la recherche ainsi que l'usage expérimental devraient être strictement limités pour usages à des fins non commerciales. Les exemptions concernant la licence obligatoire et l'expropriation devraient être rigoureusement étudiées dans le but de préserver les droits du porteur du brevet. L'importation parallèle de médicaments brevetés ne devrait pas être autorisée car elle provoque un déséquilibre économique des marchés ayant comme conséquence une hausse des prix et elle affecte négativement la production locale de médicaments créant des obstacles à l'investissement étranger. Parallèlement aux restrictions au droit des brevets, il existe d'autres moyens de faciliter l'accès aux médicaments, à l'examen médical, aux appareils médicaux et autres. Il serait souhaitable d'harmoniser les restrictions au droit des brevets afin d'offrir sécurité aux porteurs de titres de brevet dans les différentes juridictions nationales.

Zusammenfassung

Die Gruppe betrachtet dass Patentrechtsbeschränkungen sollten in dem Patent Gesetz erstellt werden, aber nicht für Parallelimport von patentierte Arzneimitteln, und auch nicht um die Medizinsbesorgung zu erleichtern. Die Forschung und Versuchsgebrauchausnahme sollte nur zu

keine direkt geschäftliche Anwendungen begrenzt werden. Zwangsmässige Lizenzierung und Zwangsenteignung sollten eingeengt ausgelegt sein damit das Recht von den Patentbesitzern präserviert ist. Parallelimport von patentierte Arzneimitteln sollte nicht erlaubt sein, weil es eine Wirtschaftliche Marktverzerrung vorbringt, der dadurch die Preise steigen und der dadurch die lokale Produktion vom Medizinprodukte betroffen wird, und folglich für die direkt aus dem Ausland herstammte Investierung einen Hindemis schafft. Es gibt andere Arte die nicht Patentrechte beschränken, und mit dem die Besorgung von Medizin, Diagnose, Medizinsapparate, usw., kann erleichtet sein. Es würde sehr ratsam die Patentrechtsbeschränkungen in Übereinstimmung zu bringen weil damit würde Gewissheit für den Patentbesitzern in vielen verschiedene Ländern erschafft.