Ecuador
Equateur
Ecuador

Report Q202

in the name of the Ecuadorian 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, according to Andean Decision 486, a patented product and or/procedure can be used without the patentee's permission if such use is made with research, experimental or teaching purposes. The Ecuadorian Intellectual Property Law further develops such exception when allowing the mentioned uses if and only if they are not done with a lucrative purpose. Therefore, commercial purposes, understood as the exchange of goods aiming to obtain some profit are not allowed under our legislation.

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 not recognized under the Ecuadorian Patent Law. The use of the invention without the patentee's consent for the purpose of obtaining approval of a generic product could, indeed be considered as an experimental use, since the commercial purpose will not exist until the generic has been approved and the original patent has expired.

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?*

According to Art. 54 of the Andean Decision 486 "a patent shall not confer on its owner the right to proceed against a third party making commercial use of a product protected by a patent once that product has been introduced into the commerce of any country by the owner or another person authorized by the right holder or with economic ties to that patent owner."

According to this rule, it would not be a patent infringement for anybody to import a patented product into Ecuador from another country where it has been marketed either by the patent owner, with his authorization or if by someone with economic ties to that patent owner.

The Intellectual Property Law is more specific on the subject and clearly states that the owner of a Patent can not exercise its rights in case of an import of the product put into the market

of any country by the owner of the patent, anyone authorized by the owner or anyone having a license.

Concerning the compulsory license issue, our legislation is not very specific about it. However, the second paragraph of the same article can be interpreted on the matter; it states that two persons are considered to have economic ties when a third party is able to exert influence with respect to the exploitation of the patent over both persons (in the particular case both persons could be the owner of the patent and the grantee of the compulsory license).

Therefore, if a compulsory license is granted by the government of another country to someone to exploit the patent we would understood that the Government is the third party able to exert influence on both the owner of the patent and the licensee. Thus, these two last parties should be considered as having economic ties and therefore the import in Ecuador from such country of the patented product would not be an infringement of the patent right.

On the other hand, as previously mentioned, the intellectual property law allows the import of the patented product into Ecuador if the product was put into the market by anyone having a license. Since it is not specified if such license shall be compulsory or voluntary a broad interpretation including both of them can be done.

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

An individual prescription exception is not specifically recognized under the Ecuadorian patent law.

The Decision 486 provides to the owner the right to prevent anyone from making the product or using the process, or selling it or offering it for sale. However it restricts such rights to be exercised with respect to acts carried out in a private circle and for non-commercial purposes. An interpretation given to this rule in each particular case, could eventually be transform it into an individual prescription exception. However, the moment a physician or pharmacist sells the preparation, even if it is only for one specific case, such act might be considered as a commercial purpose and thus, it would not be an exception.

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.*

Yes, compulsory licenses are available in Ecuador upon fulfillment of one of the following conditions:

At the expiry of a period of three years following a patent grant or of four years following the application for a patent, whichever is longer, the competent national office may grant a compulsory license mainly for the industrial manufacture of the product covered by the patent, or for full use of the patented process, at the request of any interested party, but only if, at the time of the request, the patent had not been exploited in Ecuador, or if the exploitation of the invention had been suspended for more than one year.

Compulsory licenses shall not be granted if patent owners are able to give valid reasons for their failure to act, which may be reasons of force majeure or an act of God.

A compulsory license shall be granted only if, prior to applying for it, the proposed user has made efforts to obtain a contractual license from the patent holder on reasonable commercial terms and conditions and that such efforts were not successful within a reasonable period of time.

The licensee shall exploit the licensed invention within a period of two years following the date the license was granted, unless that licensee is able to give valid reasons for inaction consisting of force majeure or an act of God. Otherwise, at the patent owner's request, the patent office shall revoke the compulsory license.

The patent office shall specify the scope or coverage of the license, and in particular shall specify the period for which it is granted, the subject matter of the license, the amount of the remuneration, and the conditions for the payment thereof. The remuneration shall be set at an adequate level in accordance with the individual circumstances of each case and, in particular, the economic value of the authorization.

Following the declaration of the Government of the existence of public interest, an emergency, or national security considerations, and only for so long as those considerations exist, the patent may be subject to compulsory licensing at any time. In that case, the competent national office shall grant the licenses that are applied for. The owner of the patent so licensed shall be notified as soon as is reasonably possible.

The grant of a compulsory license for reasons of public interest shall not reduce the right of the patent owner to continue exploiting it.

The patent office may, either ex officio or at the request of a party, and after having obtained the consent of the national antitrust authority, grant compulsory licenses where practices are noted that are detrimental to the exercise of free competition, especially where they constitute an abuse by the patent owner of a dominant position in the market.

The need to correct anti-competitive practices shall be taken into account in determining the amount of remuneration to be paid in such cases.

The patent office shall refuse termination of a compulsory license if and when the conditions which led to the granting of the license are likely to recur.

The patent office shall grant a license, upon request by the owner of a patent whose exploitation necessarily requires the use of another patent, and that right holder has been unable to secure a contractual license to the other patent on reasonable commercial terms. That license shall be subject to the following conditions:

a) the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;

b) the owner of the first patent shall be entitled to a cross-license on reasonable terms to use the invention claimed in the second patent; and,

c) the license authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent.

The following conditions for compulsory licenses are applicable to all of the above:

a) they shall be non-exclusive and may not be sublicensed;

b) they shall be non-assignable, except with the part of the business or goodwill which permits its industrial use. This shall be evidenced in writing and registered with the competent national office. Otherwise, those assignments or transfers shall not be legally binding;

c) they shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to them cease to exist and are unlikely to recur;

d) their scope and duration shall be limited to the purposes for which they were authorized;

e) in the case of patents protecting semi-conductor technology, a compulsory license shall be authorized only for public non-commercial use or to remedy a practice declared by the competent national authority to be anti-competitive.

f) they provide for payment of adequate remuneration according to the circumstances of each case, taking into account the economic value of the license, and,

g) they shall be used predominantly for the supply of the domestic market.

No compulsory licenses have been granted in Ecuador.

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.

Article 31bis TRIPS have not been ratified by Ecuador by March 17, 2008. There has been no legislative amendment in our country concerning the exportation or importation of products protected by a compulsory license. There has not been any compulsory license granted in Ecuador for the importation or exportation of pharmaceutical products.

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, the Ecuadorian 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?

According to the Ecuadorian Constitution the Ecuadorian Government is allowed to expropriate all kind of private property, without excluding Intellectual Property rights. However, the Constitution states that the reasons and processes for such expropriations must be determined by the law. Our patent law does not provide the expropriation of patents and accordingly, they should not be expropriated. Nevertheless, in a particular case with special circumstances, covered by the Constitutional principle the government could eventually justify a patent expropriation.

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.

Together with the experimental exception, our patent law has established an exception for academic purposes, such as teaching (without a lucrative intention). Therefore, methods of preparing and using a patented product may be thought during the life of a patent, for example in a medical school. Nevertheless, the students will not be allowed to use such knowledge to prepare the medicines until they have obtained a license or the patent has expired.

II) Proposals for adoption of uniform rules

1) Should patent law provide for

– *research and experimental use exception;*
We believe that a research and experimental use exception is essential in the patent system. The whole idea of making a patent application public at some time during the prosecution of patent application is to facilitate the research on the same area and allow a fair competition for the benefit of the collectivity.

– *Bolar exception;*
We believe that the Bolar exception should be provided by the patent law, as long as the companies making generics have certain limitations concerning the marketing of the product or process before the patent has expired.

– *parallel import of patented medicines;*
In developing countries such as Ecuador, the parallel import of medicines is a very important tool to permit a fair access to medicines. If the owner of patent has already introduced in the market the patented medicine and is selling it at a lower price in another country, there exists a price discrimination against Ecuadorians. As a developing country we have the right to be able to access medicines at the best possible price. Thus, if someone is able to legally import the same medicine at a lower price it means that the owner of the patent could also do it. Therefore, such exception, in our case should be provided by the law.

– *individual prescriptions exception;*
We believe the individual prescription exception is more controversial. While a pharmacist or doctor could prepare a medicine for its own use, when preparing it for someone else, according to an individual prescription, he/she is already profiting from such preparation. Doctors and pharmacists could begin exercising such right at a larger scale and the rights of the owner of the patent would be at risk. Therefore, if this exception is allowed certain limits and controls should be done. First of all, each preparation should be done by a pharmacist or doctor for one individual case; and the number of preparations in a certain period of time (like monthly) should be reported to determine whether the preparations are not being done at a larger scale. Finally, there should be a determination of which medicines or medical devices might need of individual prescriptions.

– *medical treatment defence;*
In Ecuador, as methods of medical treatment are not allowed such exception is not applicable.

– *compulsory licensing;*
This exception should be allowed internationally for certain cases determined by each country such as national health crises or in cases of acts which are detrimental to the exercise of free competition. Compulsory licenses should be granted with a fair compensation to the owner of the patent and the owner should be able to continue exploiting it. Their scope and duration should be limited to the purposes for which they were authorized. The exportation of a product with a compulsory license should be done only under special circumstances, such as to other developing or less developed countries with a national health crisis or similar problems. The importation of products under a compulsory license should be allowed when required to supply a sufficient amount for the needs of the Country.

– *expropriation;*
With the existence of a compulsory licensing system, we believe that expropriation is not necessary, because as long as people have the access to medicines guaranteed trough the granting of a compulsory license, there is no need to impede the owner of the patent

to continue exploiting the medicine. Of course, the owner of the patent will have to take certain measures (like lowering the price) if he wants to continue being competitive under such circumstances.

– *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?*

Besides limiting the patent rights there are certain ways which might facilitate the access to medicines but they should not be available through a patent law but through other laws as methods for controlling the price of medicines. However, we understand that such measures should not be discussed in the present document.

Concerning the patent law, we believe that methods for pharmaceutical treatment should not be patentable. On the other hand patent laws should establish a maximum amount of time (maybe 5 years) for the prosecution of patent application. This way both the owner of the application as well as the generic companies can have a certainty as to when they can start exploiting the product. Even when the owner of the invention has the right to its exclusive upon filing of the application it is imperative that they can know for certain as soon as possible if they will be able to exploit it for a 20 year timer period or not. That way they can look for or acquire all the machinery, personal and raw material needed. It is also important that the generic companies can know before long, when they can start researching and performing trials for the marketing of the product.

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?*

Limitation to patent rights should be harmonized up to a certain point. We believe that, for example the compulsory licensing conditions should be dependant to the needs of each country. Nevertheless certain conditions for the exportation and importation of products being produced under a compulsory licensing should be harmonized so that there exists a certainty concerning which countries can be exporters, which countries can be importers, the compensation to be paid, etc.

Other limitations such us the research and experimental use and the Bolar exception should be harmonized in order for companies to be able to invest with security in less developed or developing countries. If, for example, generic companies know that they can research with a patented product in a developing country, they might choose such countries for researching, considering that they will probably have to spend less in raw materials or employees. The same conditions for all countries will facilitate such investment decisions. What kind of use is considered as experimental use should also be harmonized.

Should there be specific requirements for the applications of the research and experimental use and the Bolar exception, such as maybe the time prior to the expiration of a patented product, allowed for generics to start seeking approval for commercialization, they should be dependant to each country's rules.

Concerning the individual prescriptions exception it should be harmonized to allow the exception and specify which persons are allowed to prepare such medicines. However other requirements such as maybe, the need to inform the owner of the patent, or the determination of in which cases individual prescriptions is needed should be for each country to decide.