Peru
Pérou
Peru

Report Q202

in the name of the Peruvian 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?*

Our patent law recognises as exception patent rights, research and experimentation, so the invention is allowed to be used for those purposes without any compensation for the owner. Our law allows experimentation of an invention without the authorization of the patent owner for acts which only purpose is experimentation.

This recognition is set forth in Article 53, paragraphs b) and c) of Decision 486, Common Intellectual Property Regime, wherein it is stated that a patent owner may not exercise the right referred to in Article 52 with respect to the following acts:

b) acts carried out exclusively to experiment with the subject matter of the patented invention;

c) acts carried out exclusively for the purposes of teaching or scientific or academic research;

Paragraph b) refers to the possibility of manufacturing products with the invention but in a restricted way, that is to say those which are only necessary for experimentation but not for trade.

With regard to scientific research, it is also recognised in paragraph c) as an exception under the condition of teaching, scientific and academic purposes. It is possible to manufacture products with a patented matter in order to achieve a better understanding at the learning level and to develop abilities and skills of scientific research and, for this end, it may be necessary to use certain protected patent.

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 at present recognised under our current law, but a regulation on bolar-type exception will be incorporated, since article 16.9.5. of Trade Promotion Agreement Peru-USA includes the bolar-type exception which allows a third party using a matter

protected by an in force patent in order to produce the necessary information for supporting the approval application for trading a pharmaceutical or chemical-agricultural product. That third party will cause that any good manufactured by virtue of said authorization will not be manufactured, used, sold, offered for sale, or imported in its territory with purposes other than those related to produce information; in order to fulfil the approval requirements for trading that product once the patent has expired and, if the patent allows export the product will only be exported outside the territory of said third party in order to fulfil its approval requirements for trading.

The bolar-type exception is not also covered by the research investigation.

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?*

Article 54 of Decision 486, Common Intellectual Property Regime, allows parallel imports of any product protected by a patent, including medicines, medical devices or similar, under the way of international exhaustion right, which consists in that 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; that is to say, inventor after the first sale loses his exclusive right of resale or distribution since his rights have been exhausted remaining without any control upon the prices.

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

With regard to individual prescriptions, and from a public health point of view, our patent law does not have any exclusion of patent effects to the medicines prepared in an individual case in a drugstore or by a practitioner, that is to say, Article 54 regarding exceptions does not include a regulation related to medicine acts for individual cases.

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?*

They are not patentable.

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, they are. Chapter VII of Decision 486, On the Regime of Compulsory Licensing, sets forth some aspects concerning compulsory licenses by regulating it in nine articles.

Fields:

A compulsory license would be granted in the following fields:

– When on applying for the compulsory license the patent had not been exploited in the member country wherein the license has been applied for, in the terms set forth in Articles 59 and 60 of Decision 486, or if the patent exploitation had been suspended for more than one year, provided that the patent owner does not justify his inactivity with rightful excuses, including force majeure reasons or act of God. In this case, the interested party applying for the compulsory license should have attempted to obtain a contractual

license in reasonable conditions, and there should have elapsed a term of three years counted from the granting date of the patent or four years from its application date, whatever is the oldest.

– Due to reasons of public interest, emergency or national security, after a declaration of a member country of the existence of said reasons, and only during the period these reasons elapse. Granting of compulsory license due to reasons of public interest does not impede the patent owner the right to continuing exploiting it.

– When it is applied for the patent owner, the exploitation of which necessarily requires the use of another one, provided that the owner had not obtained a contractual license under reasonable commercial conditions. This license will be under the following conditions:

  • The invention claimed in the second patent should be an important technical progress of a considerable economic importance with regard to the invention claimed in the first patent;

  • The first patent owner will have right to a cross-license under reasonable conditions for exploiting the invention claimed in the second patent; and

  • License of the first patent cannot be assigned without the assignment of the second one.

Conditions:

Compulsory licenses will be under the following conditions:

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 in accordance with articles 65 and 66;

f) they provide for payment of adequate remuneration according to the circumstances of each case, taking into account the economic value of the license, without prejudice to the stipulations of article 66; and

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

In our country no compulsory licenses have been granted yet, although they are included in our law.

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 has not yet been ratified in our country.

In order to implement the WTO decision, on August 30, 2003, in the Trade Promotion Agreement Peru-USA an Article 13 has been included regarding an understanding with regard to certain measures of public health whereby it is recognised the undertaking of having access to medicines supplied pursuant to Decision of General Counsel of August 30, 2003 on Implementation of Paragraph Six of Doha Declaration, related to TRIPS.

In our country a compulsory license for import or export of pharmaceutical products has not been granted yet.

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 government cannot use a patented invention without a previous compulsory license.

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

Our law does not include any regulation allowing expropriation of 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.*

Our patent law recognises facilitating access to medicines and the like in the context of public health crises, through compulsory licenses in emergency cases, public interest and national security, with a prior declaration of reasons of the member country. Within cases of emergency, public interest and national security it is included to adopt the necessary measures for protecting public health. These cases may be HIV AIDS, tuberculosis, malaria and other epidemics.

II) Proposals for adoption of uniform rules

1) *Should patent law provide for*

- *research and experimental use exception;*
  Yes, provided that the purposes are scientific and teaching which suppose the need of technical progress.
- *Bolar exception;*
  It is allowed that third parties use a matter protected by an in force patent for information of support for approval application in order to trade the product once the patent has expired. This will allow production of generic products before the expiration of the patent in order to guarantee its introduction immediately after the patent has expired but without authorizing its trade.

  Peru has the following proposal:
  "The patent owner will not be able to exercise the right of ius prohibendi, referred to in Article 52 when a third party uses the matter protected by and in force patent in order to produce the necessary information for supporting the approval application for trading a pharmaceutical or chemical-agricultural product."
- *parallel import of patented medicines;*
  Parallel imports are based on the owner exhaustion right principle once the product has been launched into the market. Therefore the countries are at the liberty to purchase medicines in the most convenient market. Parallel imports make possible competition of products of the same manufacturer of different markets and allow fixing different prices for the same product thus the consumer takes advantage thereof. In Peru most of

the population has limited access to medicaments due to economic limitations, which circumstance has lead to take special attention regarding public health.

– *individual prescriptions exception;*
  As an individual prescriptions exception it can mentioned the fact that the patent owner will not be able to exercise the right to avoid third parties without his consent to carry out acts consisting of medical preparations for individual cases of emergency.

– *medical treatment defence;*
  It is not patentable.

– *compulsory licensing;*
  In exceptional cases expressly foreseen by law.

– *expropriation;*
  It will not be accepted in general terms. It only would be accepted in those cases wherein after trying to obtain a compulsory license it has not been granted and exploitation of the patent is necessary for the treatment of an epidemic afflicting the country with a high death rate.

– *any other limitations of the exclusive patent rights to facilitate access to medicines, diagnostics, medical devices and the like?*
  In our case these methods are not patentable.

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?*

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?*

   Yes, they should. In the case of individual prescriptions for emergency cases, in the case of bolar-type exceptions limited to agro-chemical products and drugs and only for obtaining necessary information for trade authorizations. In the case of research and experimental use, when the patent refers to knowledge in the matter of biotechnology, which is necessary to continue with the research and scientific development, and with regard to the experimental use when it is a matter of a patentable matter that is necessary for continuing the experimental use for obtaining a result in the health field.

Résumé

Notre Péruvienne régulation reconnaître comme l'exception droits de patent, l'investigation and l'expérimentation.

En ce qui concerne avec la Médicine, notre régulation aussi reconnaître des parelles d'importation. Il rende possible la compétition de produits des mêmes fabricants du différent marchés et permet d'établir différent prix pour le mêmes produits; alors, les consommateurs bénéficier de cet là.

Notre régulation comprendre les licences obligatoires pour les raisons de publique intérêts, d'urgences ou de sécurité nationale. Nous vous saurions gré d'être au courant que les permis forcés seront dans certaines conditions. Dans notre pays, on n'a accordé encore aucun permis forcé, bien qu'ils soient inclus dans notre loi.

D'ailleurs, nous considérons cela dans le contexte des crises de santé publique, par les permis forcés, dans les cas d'urgence, l'intérêt public et la sécurité nationale qu'il est inclus pour adopter les mesures nécessaires pour protéger la santé publique.

D'une part, notre droit des brevets péruvien ni n'a n'importe quelle exclusion de prescription individuelle ni inclut n'importe quelle expropriation laissant réglementaire d'un brevet. D'ailleurs, rendez-vous compte avec bonté que les méthodes thérapeutiques ne sont pas patentable.

Le groupe péruvien considère également que l'inclusion de l'exception de Bolar dans la législation péruvienne permettra à la production des produits génériques avant que l'expiration du brevet afin de garantir son introduction juste après le pâté.

Zusammenfassung

Unser peruanisches Recht erkennt das Patentrecht, die Forschung und das Experimentieren als Ausnahme an.

Unsere Vorschriften erkennen auch den parallelen Import im Fall der Medizin an.

Dies ermöglicht den Wettbewerb von Produkten der gleichen Hersteller in verschiedenen Märkten und erlaubt die Festlegung von unterschiedlichen Preisen für dasselbe Erzeugnis, so dass der Verbraucher Vorteile erzielt.

Es sind auch Zwangslizenzen aus besonderen Gründen z.B. der Nationalen Sicherheit, der öffentlichen Interessen oder im Notfall zu genehmigen.

Man sollte unterstreichen, dass die Zwangslizenzen unter bestimmten Bedingungen herbeigeführt werden. In unserem Land wurden noch nicht Zwangslizenzen bewilligt, selbst wenn sie in unserem Gesetz einbezogen werden.

Ausserdem sind wir der Meinung, dass im Rahmen der Krise des öffentlichen Gesundheitswesens durch die Zwangslizenzen im Notfall, Nationale Sicherheit und öffentliche Interessen, die richtigen Massnahme zum Schutz des Gesundheitswesens beschlossen werden.

Andererseits hat unser peruanisches Patentrecht weder ausschliessende Ausnahmen für individuelle Rezepte noch Vorschriften zur Enteignung eines Patents.

Allerdings wird darin festgestellt, dass therapeutische Methoden nicht patentierbar sind.

Die peruanische Gruppe ist auch der Meinung, dass die Annahme der Bolar Ausnahme in der peruanischen Gesetzgebung die Produktion von einem pharmazeutischem Generikum vor Ende der Lizenz erlauben wird. Damit wird ihre schnelle Einführung nach dem Ende der Lizenz garantiert, trotz keiner vorhandenen Genehmigung zum Handel.