Colombia
Colombie
Kolumbien

Report Q202

in the name of the Colombian 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?*

Our Patent Law does recognize the research and experimental use exceptions when the research and the experimental use are carried out privately and without commercial purposes. This is contemplated in articles 52 and 53 of Decision 486 of the Andean Community, which state:

Article 52 – *A patent shall confer on its owner the right to prevent third parties not having the owner's consent from the acts of:*

a) where the subject matter of a patent is a product:

i) making the product;

ii) offering for sale, selling, or using the product; or importing it for these purposes; and,

b) where the subject matter of a patent is a process:

i) using the process; or

ii) carrying out any of the acts that are specified under paragraph a) above with respect to a product obtained directly by that process.

Article 53 – A patent owner may not exercise the right referred to in the previous article with respect to the following acts:

a) acts carried out in a private circle and for non-commercial purposes;

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;

d) the acts referred to in article 5bis of the Paris Convention for the Protection of Industrial Property;

e) where the patent protects biological material that is capable of being reproduced, except for plants, using that material as a basis for obtaining a viable new material, except where the patented material must be used repeatedly to obtain the new material.

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?*

No, the Bolar exception is not recognized under our patent law, and the use of an invention without the patentee's consent is not covered by the research exception for the purposes of obtaining approval of a generic product.

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 Colombia, parallel imports of patented medicines are permitted, as per article 54 of Decision 486 of the Andean Community, which states:

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.

For the purposes of the preceding paragraph, two persons shall be considered to have economic ties when one of the persons is able to exercise a decisive influence on the other, either directly or indirectly, with respect to the exploitation of the patent or when a third party is able to exert that influence over both persons.

Where the patent protects biological material that is capable of being reproduced, the patent coverage shall not extend to the biological material that is obtained by means of the reproduction, multiplication, or propagation of the material that was introduced into the commerce as described in the first paragraph, provided that it was necessary to reproduce, multiply, or propagate the material in order to fulfill the purposes for which it was introduced into commerce and that the material so obtained is not used for multiplication or propagation purposes.

The same principles do apply if the products originate from markets where they were made available under a compulsory licence.

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

Our patent law does not contemplate the individual prescriptions 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?*

N.A.

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 licences are contemplated in our patent law. Articles 61-69 of Decision 486 of the Andean Community, which state:

Article 61 – *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 the manner specified in articles 59 and 60, in the Member Country in which the license is sought, 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, in accordance with the domestic provisions in effect in each Member Country.

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.

Article 62 – *Decisions to grant a compulsory license, as stipulated in the previous article, shall be taken after the patent owners have been notified to present their arguments as they see fit within the following sixty days.*

The competent national 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.

Opposition to a compulsory license shall not prevent its exploitation or have any effect on any periods that may be running. The filing of an objection shall not prevent the patent owner, in the meantime, from collecting the remuneration specified by the competent national office on the part unaffected by the objection.

Article 63 – *At the request of the owner of the patent or the licensee, the conditions governing the compulsory license may be changed by the competent national office where new circumstances so dictate and, in particular, when the patent holder grants another license on terms that are more favorable than the existing ones.*

Article 64 – *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 competent national office shall revoke the compulsory license.*

Article 65 – *Following the declaration by a Member Country 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 competent national office shall specify the scope or extent of the compulsory license and, in particular, the term for which it is granted, the subject matter of the license, and the amount of remuneration and the conditions for its payment.

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

Article 66 – *The competent national 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 competent national 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.

Article 67 – *The competent national 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, without prejudice to the provisions of article 68, 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.

Article 68 – *In addition to the conditions provided for in the preceding articles, compulsory licenses shall be subject to the following:*

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.

Article 69 – *Compulsory licenses that fail to comply with the provisions of this Chapter shall be devoid of any legal effect whatsoever.*

We have no knowledge of any compulsory licenses filed for or granted in Colombia.

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.

No, Article 31 bis TRIPS has not been ratified and we have no knowledge of other legislative amendments implementing WTO decision of August 30, 2003.

We have no knowledge of any compulsory licenses filed for or granted in Colombia for 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 government cannot make use of a patented invention without previous license.

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

No, the government cannot expropriate a patent under any circumstance.

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.*

No, our law does not recognize other means of facilitating access to medicines, medical devices and the like.

II) Proposals for adoption of uniform rules

1) *Should patent law provide for*

- *research and experimental use exception;*
  Yes, maintaining the restriction to uses with commercial purposes.
- *Bolar exception;*
  No, because it threatens the patent owner's rights and could negatively affect research and development activities.
- *parallel import of patented medicines;*
  Yes, as currently established in our patent law.
- *individual prescriptions exception;*
  N.A.
- *medical treatment defence;*
  Yes, as currently legislated.
- *compulsory licensing;*
  Yes, for public interest, emergencies and to remedy anti competitive conduct.
- *expropriation;*
  No, because it threatens the patent owner's rights and could negatively affect research and development activities as well as foreign investment.
- *any other limitations of the exclusive patent rights to facilitate access to medicines, diagnostics, medical devices and the like?*
  No, we consider the compulsory licenses system sufficient for these purposes.

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?*

No.

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, in order to create an incentive to research and development activities and to economies in general.