Is Mexico on the verge of compulsory licensing?

The swine flu outbreak has reopened the debate about compulsory licences. So far the government has not issued compulsory licences for antivirals, though the threat has encouraged patent owners to keep prices low, at least for now

By **Héctor E Chagoya C**, Becerril, Coca & Becerril, SC, Mexico City

The epidemics related to the human influenza virus A H1N1, (known as "swine" or "Mexican" flu), which apparently started in Mexico, appear to be under control but continue to spread to more and more countries.

The discovery that sufferers are responsive to antiviral drugs, coupled with the fact that it will take time to develop a vaccine, is making reactive treatment the only viable way of controlling the disease, at least for several months to come. However, the global alert announced by the World Health Organisation (WHO), along with drastic measures taken by the Mexican government, has triggered a revival of discussions about compulsory licensing for patents and, in particular, the debate over the "convenience" and "justification" of patent rights in the international arena.

The Mexican government, unlike the governments of other countries such as India and Brazil, has been reluctant to blame patents for the increased cost of medicines. In fact, Mexico's policy with regard to pharmaceuticals has been to strengthen IP rights, which is evident from the country's enactment of the "linkage" system in 2005. However, the health emergency state driven by the A H1N1 influenza outbreak has forced the government to take certain steps related to compulsory licensing, as described below.

The legal framework for compulsory licensing in Mexico

Compulsory licensing is available in Mexico under the Industrial Property Law (IPL) under two different circumstances, both originally TRIPs compliant.

- Lack of exploitation. Any third party may request a compulsory licence from the Mexican Institute of Industrial Property (IMPI) to exploit a patented invention that has not been exploited after three years as of grant or after four years as of filing, whichever is later. Also, a patented invention is considered exploited through importation of products. In such a case, the patent owner is given the opportunity to exploit the invention within one year of a request for a compulsory licence. This provision makes compulsory licensing for lack of exploitation very difficult and is the reason why no compulsory licences have been granted in Mexico as of yet.
- National emergencies or security. The Law on the Promotion and Protection of Industrial Property of 1991 and amendments to the IPL of 1994 included TRIPs-compliant provisions for compulsory licensing in Mexico addressed at national emergencies or matters of national security. Such compulsory licences are described as "public-use" licences in Article 77 of the IPL.

However, the international pressure that led to the Doha Declaration on Pharmaceuticals has had an impact in

Mexico. In 2003, at the first ordinary legislative period of the Mexican Congress, a bill to amend the IPL on compulsory licensing in relation to national emergencies was passed, based on the principle that World Trade Organisation countries are free to use compulsory licensing and to determine what constitutes a national emergency.

The main aim of the promoters of the amendments (ie, Mexican generic drug manufacturers) was to have certain diseases recognised as the cause of national emergencies. After intense and complex debates, under the 2003 IPL amendments the IMPI may now grant public-use licences under the following circumstances:

- The General Health Council (GHC), a technical body coordinated by the health secretariat, must declare a disease to be of "priority attention". This declaration is the trigger for public-use licences.
- The IMPI can then decide whether certain patented drugs should be subject to exploitation through a public-use licence to address the emergency. However, this applies only if patents are jeopardising access to drugs necessary to treat the disease.
- Third parties may then apply for a public-use licence, which the IMPI is obliged to grant after hearing both the licence applicant and the patent owner.
- The manufacturing specifications, quality and duration of the relevant licence will be determined by the GHC, which will also evaluate the applicant's technical skills.
- The IMPI will determine royalties.
- The licences are not exclusive and are not assignable or otherwise transferable.

Influenza A H1N1 as a trigger for compulsory licensing

After the drastic measures taken by the Mexican government to control the epidemic, many generic companies pushed to have Influenza A H1N1 labelled as a priority attention disease. Various journalists published opinions stating that the Mexican government was about to grant a compulsory licence for Roche's Tamiflu® – the active ingredient for which, oseltamivir, is owned by Gilead Sciences – and GlaxoSmithKline's Relenza®.

In fact, Indian producer Cipla, which manufactures generic drugs, has long been a potential threat to both Roche and GSK. If Cipla were granted a compulsory licence from the Indian government, it would be permitted to export to countries that had a compulsory licence in place under both Indian law and the post-Doha Declaration. Cipla's position was strengthened on 31st March 2009 when the Indian patent controller denied Gilead's patent for oseltamivir in India, based on a pre-grant opposition procedure. Following the decision, Cipla announced that it would provide oseltamivir to potential buyers from Mexico.

Meanwhile, in Mexico rumours that the government was going to grant compulsory licences came a step closer to reality on 2nd May 2009, when an extraordinary edition of the *Official Journal of the Federation* published a declaration from the GHC that Influenza A H1N1 was a priority attention disease for the purposes of Article 77 of the IPL.

Several Mexican laboratories put in requests for compulsory licences for oseltamivir. However, the patent owners hit back, arguing that there was no need for compulsory licensing as access to the drugs was guaranteed under suitable conditions and treatment of the disease was not being jeopardised. This led to a second publication by the GHC in the *Official Journal* on 19th May 2009, which clarified that while Influenza A H1N1 was still considered a priority attention disease for the purposes of Article 77, access to the necessary drugs was not being compromised. Therefore, "for the time being", public-use licences were not necessary. This declaration helped to put pressure on patent owners to keep prices low, at least during the emergency.

TRIPs v Mexican Law and practical barriers

There are a number of provisions and omissions in the current Article 77 of the IPL as amended in 2003, but perhaps the two most important are the following:

- The IMPI is obliged to grant a compulsory licence upon a third party's request if the disease is classed as priority attention disease.
- The licence may include all the rights reserved to the patent owner – namely, to sell, offer for sale, distribute, manufacture and import the patented product.

In addition, TRIPs clearly states in Article 31, among many other conditions for compulsory licensing of this kind, that an instance of appeal for any subject related to the grant or the amount of royalties must be available to all member states using a compulsory licence.

This, along with the fact that the 2003

amendments to the IPL left the corresponding regulations unclear as to their applicability to pharmaceutical cases, is a major barrier to the grant of compulsory licences in Mexico.

There are a number of complex issues that should be addressed urgently by the IMPI and the GHC if the conditions related to the disease change and increase in danger, becoming a health emergency again. Some of the most critical are:

A clear and justified determination of the actual patents to be made available for public-use licensing. So far, vaccines have not been discussed, but they may well become more necessary than antiviral compounds. However, vaccine technologies are so varied that the technical complexity in determining the patents would rise steeply.

- A clear and justified determination of the royalties. The existence of alternative treatment sources and the IMPI's lack of experience in determining royalties will make this difficult to accomplish.
- Compliance with the timetable provided by the law for the grant of the compulsory licence. The IMPI has three months in which to grant the public-use licence as of the date of application from an interested party. However, simply evaluating the potential licensees might well take longer than this. This will be a problem and a burden for the health authorities and the IMPI. In addition to the complex political environment surrounding the subject, many companies are interested in a licence and the work may well pile up.

What to expect

Perhaps the Mexican government has, for the first time in the world, used the compulsory licensing system fairly as a tool for negotiating prices. At the very least it has wisely refrained from rushing into the grant of a compulsory licence just because the law allowed it to do so.

The GHC's declaration that Influenza A H1N1 is a priority attention disease remains in force and the WHO still has a severe alert in place for this disease. However, the aforementioned second publication from the GHC is a clear sign that the Mexican government did not take the easy way out by granting a public-use licence, but rather demonstrated that the full conditions necessary for the grant of such a licence will be met with when necessary under TRIPs or other treaties. Further, under Mexican law, courts must follow what is stated in international treaties; therefore, even if the IMPI did not comply with such provisions, there are remedies available to patent holders in the event that such licences are granted abusively.

The dice are still rolling and the Mexican government and manufacturers of generic drugs are placing their bets. During September 2009, the Mexican health authorities once again raised the alert for Influenza A H1N1 in an attempt to prevent an increase of cases during the winter. At the same time, manufacturers of generic drugs have placed an initiative before the Mexican Congress in order to facilitate the grant of compulsory licensing, given the difficulties they face under the current legal framework. However, the proposal is evidently contrary to TRIPS, which will likely lead to its rejection or comprehensive modification.

Mexico is still without a single grant of a compulsory licence of any kind, but the possibility of a "first time" might be closer than ever. *IAM*

Héctor Chagoya, an associate at Becerril, Coca & Becerril, SC, is currently manager of consulting in technology transfer issues, as well as the business and technical aspects of patent litigation. He is experienced in the substantive aspects of patent prosecution, drafting and litigation, and also in negotiating domestic and international technology transfer contracts. Mr Chagoya's areas of practice include technology transfer and negotiation, technology protection and enforcement, patent searches, documentation and appropriation of trade secrets, intangible asset valuation and technological intelligence.

Héctor E Chagoya C
Associate
+52 55 52638730
hchagoya@bcb.com.mx

Becerril, Coca & Becerril, SC
Mexico
www.bcb.com.mx