# IP in the life sciences industries 2012

An *IAM* management report

Expert management of IP portfolios has always been crucial in the life sciences industries; in the prevailing economic climate, it has never been more important. From multinational pharmaceutical manufacturers to smaller start-ups and university tech spin-outs, life sciences companies and their counsel need to understand how best to protect, manage and leverage IP rights in order to ensure optimum value.

With *IP in the life sciences industries 2012*, *IAM* offers its readers a selection of practical and commercially focused updates from key jurisdictions, looking at how changes in legislation and case law will affect your IP strategy.

**Jack Ellis**
Reporter, *IAM* magazine

# Maximising IP rights in the life sciences industry

There are various ways in which life sciences companies can create extra value from their IP rights. In some jurisdictions, alternative legal remedies may be available to counter infringement

By **Alejandro Luna,** Olivares & Cia, SC

In jurisdictions such as Mexico, where the process of enforcing patents is extremely slow, certain remedies such as preliminary injunctions can be lifted by paying a counterbond. In order to claim damages for an IP rights infringement, the rights holder must exhaust up to four appeal stages to obtain a final decision declaring that the IP right was violated; only then can it claim damages. However, this claim takes place before the civil courts and there are up to three appeal stages before a damages award will be given. It is thus vital to find alternative ways to prevent the violation of IP rights and to maximise IP protection by enforcing compliance with the applicable regulatory framework — for example, in the case of medicines, the Linkage Regulation and data package exclusivity.

**Linkage Regulation**

The Linkage Regulation was enacted in 2003 and requires the Mexican Patent Office (IMPI) to publish the *Linkage Gazette* every six months, listing the patents in force covering allopathic medicines.

Among other agencies, the Federal Commission for Protection against Health Risks (COFEPRIS) must check the patents which are listed in the gazette, by the generic name of the active ingredient, before granting marketing authorisations to third parties which are not the rights holder.

However, due to an incorrect and limited interpretation of the regulation, the IMPI published only patents covering active ingredients *per se*, excluding from the gazette patents covering pharmaceutical formulations and medical uses. This interpretation was contested through a series of constitutional actions to obtain the publication of patents covering formulations and second uses.

Eight years after the enactment of the regulation, the Supreme Court ruled on the opposing criteria used by three Mexican circuit courts to interpret the regulation, particularly the question of whether the linkage system is limited to compound patents or whether product patents covering pharmaceutical formulations should also be listed. The Supreme Court held that formulation patents should be listed in the gazette; as a result, such patents must be checked by COFEPRIS before granting marketing authorisations.

The inclusion of formulation patents in the gazette prevents COFEPRIS from granting marketing authorisations which may fall within the scope of the listed patents. Publication also has the following benefits:

- It prevents patent infringement.
- The gazette is a valuable source of information for third parties wishing to obtain authorisations for generic drugs in order to clarify the full scope of opposable patents.
- In case COFEPRIS fails to check the gazette, the publication of patents can be used to challenge marketing authorisations for patented formulations granted to third parties without the rights holder's authorisation.
- The gazette can be informative in public acquisition processes to confirm that the product to be acquired is covered by a

patent, particularly when the patent formulation listed in the gazette matches the description of the product in the National Formulary for government purchases of medicines.

The Linkage Regulation has proven to be the best legal mechanism to prevent the violation of patents covering medicines. In addition, the corresponding regulatory requirement for generic approval to prove safety and efficacy through interchangeability tests with the product of reference (sometimes the innovator product) is vital to prove an imminent violation of the Linkage Regulation or the patent in force, as although the generic drug's dossier is confidential, applications for generic medicines are published on the COFEPRIS website and include the name of the applicant, the generic name of the active ingredient and the pharmaceutical form.

Nevertheless, the information about the generic application published online is limited. If the product of reference is the innovator product (ie, a patented product) and the corresponding patents are included in the gazette, there is an assumption that if the generic product is proved to be safe and effective through interchangeability tests, then by law the generic product should be bioequivalent to the innovator product. Therefore, there may be a legal and *prima facie* assumption that the generic product falls within the relevant patents covering the product of reference and listed in the Linkage Gazette.

The legal assumption that the applied-for generic product falls within the scope of the products listed in the gazette provides grounds on which to file a legal action to prevent the grant of generic approval, or to require further information about the generic application to confirm whether the approval may violate the Linkage Regulation or a valid patent.

**Obtaining data package exclusivity**

The regulatory authorities in many countries, including Mexico, require the applicant for a new drug marketing authorisation to provide data concerning the safety and efficacy of that drug. As a result, huge amounts of data on clinical studies are generated, and charts and graphs are necessary to interpret that data. The data package as a whole is submitted to the health authorities. Even when, occasionally and for promotional purposes, the results of these clinical trials are published, the data package and the bulk of the data generally remain confidential.

In this sense, a major part of the costs incurred in obtaining a marketing authorisation for an innovative drug derive from the need to undertake clinical studies of safety and efficacy.

**TRIPs and NAFTA**

Mexico is a signatory to the Agreement on Trade-Related Aspects of IP Rights (TRIPs) and the North America Free Trade Agreement (NAFTA), which require signatory countries to protect undisclosed data on the safety and efficacy of pharmaceutical products that is required by the regulatory authorities in order to obtain marketing authorisations.

On 2nd January 2008 a decree was published in the *Official Gazette* modifying several provisions of the Regulations for Health Consumables of the Health Law to address several aspects relevant to the pharmaceutical market.

Following the reforms, all generic medicines must prove interchangeability with an innovative medication. In relation to data package exclusivity rights, the amendments concerning generic medications removed the specific requirement to prove safety and efficacy and replaced it with the need to prove interchangeability, without making provision for a non-reliance period.

Due to the lack of a legal framework and a recognition of data package exclusivity rights, a request was filed with COFEPRIS asking for data package exclusivity protection to be granted to products that meet the criteria set out by TRIPs and NAFTA.

As COFEPRIS failed to respond, an appeal was filed based on the constitutional hierarchy and administrative proceedings. The court issued a preliminary injunction ordering COFEPRIS to refrain from granting marketing authorisations based on or relating directly or indirectly to the innovator's dossier, and in October 2011 it issued the first two decisions on the merits.

The court rejected of all the grounds for dismissal invoked by COFEPRIS. Furthermore, it agreed with the plaintiff's interpretation of NAFTA and TRIPs, indicating that there is a general right which includes both confidentiality and a prohibition of reliance on information by third parties, and which must last for at least five years. The only point rejected by the court was the plaintiff's claim that the generation of the clinical data in the dossier required considerable effort. The court indicated that it did not have sufficient information concerning the time and financial investments made in this regard.

The court also affirmed that it was required to support a period of protection beyond the five-year minimum, leaving

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open the possibility to grant a longer period of protection.

As a result, the court ordered COFEPRIS to respond to the petition for data package exclusivity protection, taking into consideration the full protection afforded by the international treaties, but only once it had been determined whether a considerable effort was required to generate the clinical data. The court set down no parameters as to what would constitute "considerable" in this regard

COFEPRIS is free to contest the decisions before the circuit court. However, since the decisions constituted orders for COFEPRIS to determine an aspect of the petition, rather than fully granting the petition, it would be more effective for interested parties to file cross-appeals. Rather than requesting any modifications to the legal considerations of the decision, which were positive and favourable, appeals should focus on the argument that the court had a copy of the dossier and so could have determined that a considerable effort had indeed been incurred. It remains to be seen what the circuit court will finally decide.

The existing Mexican regulatory framework tends towards the encouragement of generic competition, providing quick access to markets without taking due care to comply with NAFTA obligations, which are intended to establish proper incentives to bring new drugs to market.

Another possibility for changing this situation is a proposal to reform the Health Law Regulations in order to implement the NAFTA obligations correctly; the proposal has been submitted to the health authorities for consideration. The final option is to exhaust litigation before the courts.

**Obtaining exclusivity by enforcing biologics regulation**

A recently published decree modifies several provisions of the Health Law Regulations, addressing the approval of biologic drugs. The key changes are as follows:

- The provision stating that Mexico will allow for the approval of follow-ons as "biocomparables" now includes more detailed regulation.
- A biocomparable drug will commonly make reference to a previously registered innovator drug. If the innovator drug has not been authorised in Mexico, a previously registered biocomparable drug can serve as reference. The significance of this provision lies in the fact that a biocomparable drug can be the first drug of its kind in Mexico in the event that a developer delays a request for approval.
- The regulations state that prescriptions must contain the international non-proprietary name of the active ingredient. The commercial name is optional.
- Clinical trials for innovator biologics must take place in Mexico in all cases where the drug will be manufactured there.
- For drugs manufactured abroad, the Ministry of Health can request that a clinical trial take place in Mexico if this is considered necessary by the Biologic Products Committee.
- For the approval of biocomparable drugs, pre-clinical and clinical trials may be requested, according to what is determined by the Ministry of Heath in rules to be promulgated in future.
- The regulations provide that the scope of biocomparability clinical trials will be supported by evidence of active ingredient characterisation, and that as such characterisation improves, the number of trials required will decrease.
- An eight-year Bolar-type exemption is included concerning requests for approval of biocomparables when an innovator drug is covered by a patent.
- There is no indication of a data protection period – this was to be expected, as Mexico has not yet implemented data protection for chemical drugs.
- Once a project authorisation request for an innovator or a biocomparable has been approved by the relevant committee and submitted, COFEPRIS has a 180-day period to decide on the application, with the option to issue a single request for additional information, which must be fulfilled within 100 days. Upon the expiration of these periods, the application is assumed to have been rejected.

Although industry participants have welcomed the regulations, specific rules to approve biocomparables are still pending and only the day-to-day application of the regulations will confirm whether they can provide the requisite certainty that biocomparables will pass the safety and efficacy test. Full compliance with the regulatory requirements for biocomparables may guarantee the protection of rights holders' rights. ■

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