

The regulation of data exclusivity

Arturo D Reyes of Goodrich Riquelme argues that enforcement of data exclusivity protection is possible in spite of the lack of precedent from the courts and limited provisions regarding its scope of protection in Mexico

One of the newest and least analyzed subjects in Mexican IP law is data exclusivity, despite its growing economic, commercial and political impact. The purpose of data exclusivity is to protect the research data that innovative pharmaceutical and agrochemical companies file with the regulatory authorities to obtain marketing approval for new products that use new chemical entities.

Although Mexico was one of the first developing countries to enact provisions regarding data exclusivity, the fact is that Mexican legislation in this field is extremely poor and has many gaps that make it very difficult to understand and enforce.

Sources of data exclusivity

Articles 1771.5 and 1771.6 of the North America Free Trade Agreement (NAFTA), in force in Mexico since January 1 1994, stated the first provisions regarding data exclusivity in Mexico. Although the Mexican Constitution considers international treaties as national law, the Mexican Congress amended many laws to adjust them to the conditions stated in NAFTA. On August 2 1994, several amendments to the Industrial Property Law were enacted. The amendments included the addition of a provision (section 86 *bis*) expressly referred to data exclusivity.

Later, the TRIPs Agreement came into force in Mexico. Article 39 of TRIPs obliges member states to take measures to protect confidential information in general and data exclusivity in particular. Other sources of provisions concerning data exclusivity are the free trade agreements between Mexico, Colombia and Venezuela (G3), Bolivia (MBA), Nicaragua (MNA) and Costa Rica (MCRA). However, most of the stipulations concerning data exclusivity stated in these free trade agreements are copies of NAFTA or TRIPs.

Regarding national legislation, the only provision that refers to data exclusivity is Section 86 *bis* of the Industrial Property Law, located in the trade secrets article:

Section 86 *bis*. The information required by the special laws to determine the safety and efficacy of pharma-chemical and agro-chemical products that use new chemical compounds shall be protected in the terms provided in the international treaties that Mexico is a member of.

Mexican legislation limits the data exclusivity to new chemical entities, excluding from such benefit new uses of known entities and new formulations, consistent with NAFTA and TRIPs.

However, the national legislation does not explain how the Mexican government will protect research data, the minimum or maximum term of data exclusivity, or when the term starts; it just refers to the provisions of the international treaties. Therefore, the scope of the data exclusivity protection depends on the international treaty that a party benefits from. Unfortunately, there are no published precedents from the Mexican courts about data exclusivity.

Data exclusivity in NAFTA in the context of Mexican law

The provisions regarding data exclusivity in NAFTA are more detailed than those in TRIPs or the Industrial Property Law.

In summary, articles 1711.5 and 1711.6 of NAFTA stipulate that regulatory authorities that receive non-disclosed information that involves considerable effort about the safety and efficacy of a new medicine or agro-chemical product based on a new chemical entity shall: (1) refrain from disclosing such information, unless it is necessary to protect the public, provided that measures are taken to avoid unfair commercial use of such information (*non-disclosure*); and (2) take measures to avoid the unfair use of such information (*non-reliance*).

NAFTA explicitly provides that the authorities must avoid relying on the research data filed by the innovator to approve a third party's marketing authorizations without authorization from the originator of the information, for a minimum term of five years counted from the date the authorities granted the marketing authorization to the originator of the data.

Although the provisions of NAFTA are considered to be part of Mexican national law and any person entitled to benefit from NAFTA is allowed to claim the specific rights that NAFTA may stipulate in his favour, the Mexican government has not fully complied with its responsibilities in connection to data exclusivity, particularly regarding non-reliance.

The 2006 Special 301 Report from the United States Trade Representative states a negative evaluation about Mexico's performance of its responsibilities in connection to data exclusivity: "The United States encourages Mexico to make further efforts to provide protection for patents and against unfair commercial use of undisclosed test and other data submitted by pharmaceutical companies seeking marketing approvals for their products".

Data exclusivity in TRIPs in the context of Mexican law

The content of data exclusivity rights of persons entitled to claim benefit from TRIPs only or from other treaties with similar provisions is far more difficult to determine.

Article 39.3 of TRIPs has several gaps. The most important ones are the lack of definition about what should be understood as unfair use of the efficacy and safety information provided by the innovator, the lack of a term for non-reliance and details of when that term should start. There are also no elements to define what the phrase "considerable efforts" means.

The only responsibility that the Mexican regulatory authorities clearly assume under TRIPs is non-disclosure.

One way to try to define "unfair commercial use" and understand the scope of the responsibility of the Mexican government under the TRIPs provisions would be to assume that it should receive treatment similar to the non-reliance responsibility provided in NAFTA, as explained above.

However, this construction has some obvious problems. Plainly assuming that Article 39 of TRIPs provides the same scope of rights as NAFTA seems to be an extension of the data exclusivity rights stated in TRIPs rather than an explanation of them. Further, there are WTO members that have adopted interpretations about the non-reliance stipulation of TRIPs that are different to what NAFTA states.

Another issue that is difficult to define is the term of the non-reliance aspect of data exclusivity in Mexico under TRIPs, and when that term starts. As stated above, NAFTA provides a minimum five-year term of non-reliance and section 86 *bis* of the Industrial Property Law fails to stipulate any term at all. It would be unacceptable to say that the consequence of a lack of term in TRIPs is that the non-reliance aspect of data exclusivity rights never actually starts, and it would not be reasonable to conclude that the non-reliance is perpetual.

One way to figure out what is the term of non-reliance in the case of persons entitled to claim benefit only from TRIPs could be using the minimum term provided in NAFTA and other similar treaties for the non-reliance obligation, and conclude that under TRIPs the non-reliance term is five years. However, there is an alternative solution without using the term provided in NAFTA, but a general term provided in the Mexican Federal Civil Code for the expiry of obligations.

Unlike patent and trade mark rights, data exclusivity does not provide exclusivity rights; it may not prevent third parties from obtaining their own research data. Data exclusivity provides a right to the performance of very specific conduct by the Mexican regulatory authorities: non-disclosure and non-reliance. Unlike other IP rights, data exclusivity provides *relative* rights, as opposed to *absolute* rights.

Further, the responsibilities of the Mexican government in connection with data exclusivity, and particularly non-reliance, are of a *negative* nature; this means the government must *refrain* from relying on this research data to authorize third parties' products.

Section 1159 of the Federal Civil Code provides a general expiry term applicable to relative obligations (and rights) of 10 years. This term starts on the date the right holder may demand the fulfilment of the obligation.

The non-reliance obligation implies as a previous condition that the regulatory authority received the information, evaluated it and decided that it was enough to approve the marketing authorization the innovator requested; otherwise, there would be nothing to rely on. Therefore, the 10 years expiry term for the non-reliance obligation starts on the date the government issues the marketing authorization of the product that uses the new chemical entity.

There is nothing that would prevent the application of the expiry term stipulated in Section 1159 of the Federal Civil Code to NAFTA too, so it would be possible to conclude that under NAFTA the non-reliance aspect of data exclusivity has a term from five to 10 years.

Again, this is a far from flawless solution. The expiry of an obligation, as provided by the Federal Civil Code, is not only a consequence of the passing of time, but also of the lack of activity from the right holder to demand compliance with the obligation. Furthermore, when the right holder files a legal action with a court to demand the fulfilment of the obligation, the Civil Code provides that this action interrupts the expiry term. However, it would not seem reasonable to conclude that the term for the expiry of the non-reliance aspect of data exclusivity starts every time the innovator files an action against the regulatory authority due a breach of that right.

Enforceability of data exclusivity

Data exclusivity involves two different responsibilities for the Mexican regulatory authorities: non-disclosure and non-reliance.

In the case of non-disclosure, the breach of the obligation does not have an effective remedy. In theory, it would be possible to file criminal charges and an action for damages against the official that illegally disclosed the protected information, and even against the Mexican government. However, such an action cannot remedy the negative consequences that the illegal disclosure could provoke.

Concerning non-reliance, the consequence of a breach of this obligation would be the issuance of marketing approvals to third parties for which the regulatory authority relied on the protected data the innovator filed.

In such a case, there would be a remedy. The Federal Law of Administrative Procedure rules on a large number of administrative proceedings and decisions, including the marketing authorizations that the different Mexican regulatory authorities issue, and provides that these decisions may be invalidated under certain conditions.

Therefore, the right holder of data exclusivity may file an action with the Tribunal Federal de Justicia Fiscal y Administrativa (Federal Court of Tax and Administrative Affairs or FCTAA) to invalidate the marketing approval issued in violation of said data exclusivity rights. The defendant would be the Mexican regulatory agency that approved the generic product and the holder of the challenged approval would be a third interested party, with the right to oppose the action, file evidence and even challenge an invalidation decision.

Filing an invalidation action with the FCTAA involves certain practical problems. The term to file the action is 45 business days counted from the date the innovator had undoubted knowledge of the breach of the non-reliance obligation. There are no data exclusivity registrations so proving that the plaintiff is the right holder may be difficult. Regulatory authorities usually keep authorization files confidential, so it may be hard to categorically state that a regulatory agency breached the non-reliance obligation without having reviewed the authorization file.

As stated above, the Mexican courts have not published any precedent regarding data exclusivity and the substantive and procedural issues it involves. The uncertainty about the substantive rights that the data exclusivity provides in Mexico has discouraged innovators from filing actions with the courts to protect their valuable research data.

Of course the best course of action would be an amendment of the Industrial Property Law to define the scope of rights and terms of data exclusivity rights in Mexico, but that is in the hands of the lawmakers at Congress. Meanwhile, all IP practitioners can and must do is construct and integrate the different provisions stipulated in the applicable treaties and statutes and, when possible, test them vigorously in the courts.

Arturo D Reyes



Arturo D Reyes was born in Mexico City, Mexico, and has a law degree from the Escuela Libre de Derecho, Mexico. Reyes has a specialization in industrial and intellectual property law and in Amparo Law from the Universidad Panamericana, Mexico. Since 2000 he has been a junior partner of the law firm of Goodrich Riquelme & Asociados in Mexico City.

Reyes professional activities are focused mainly on trade mark and patent litigation, domain name disputes, licensing and trade secrets protection. He is a member of the Mexican Bar Association, LES-Mexico, and AIPPI Mexican chapter.

Reyes has written several articles for *International Licensing Law Report*, and has given several lectures about IP litigation in Mexico. In 2003, he published *La Proteccion de la Marca Registrada Mediante Acciones Civiles* (Porrúa, Mexico).