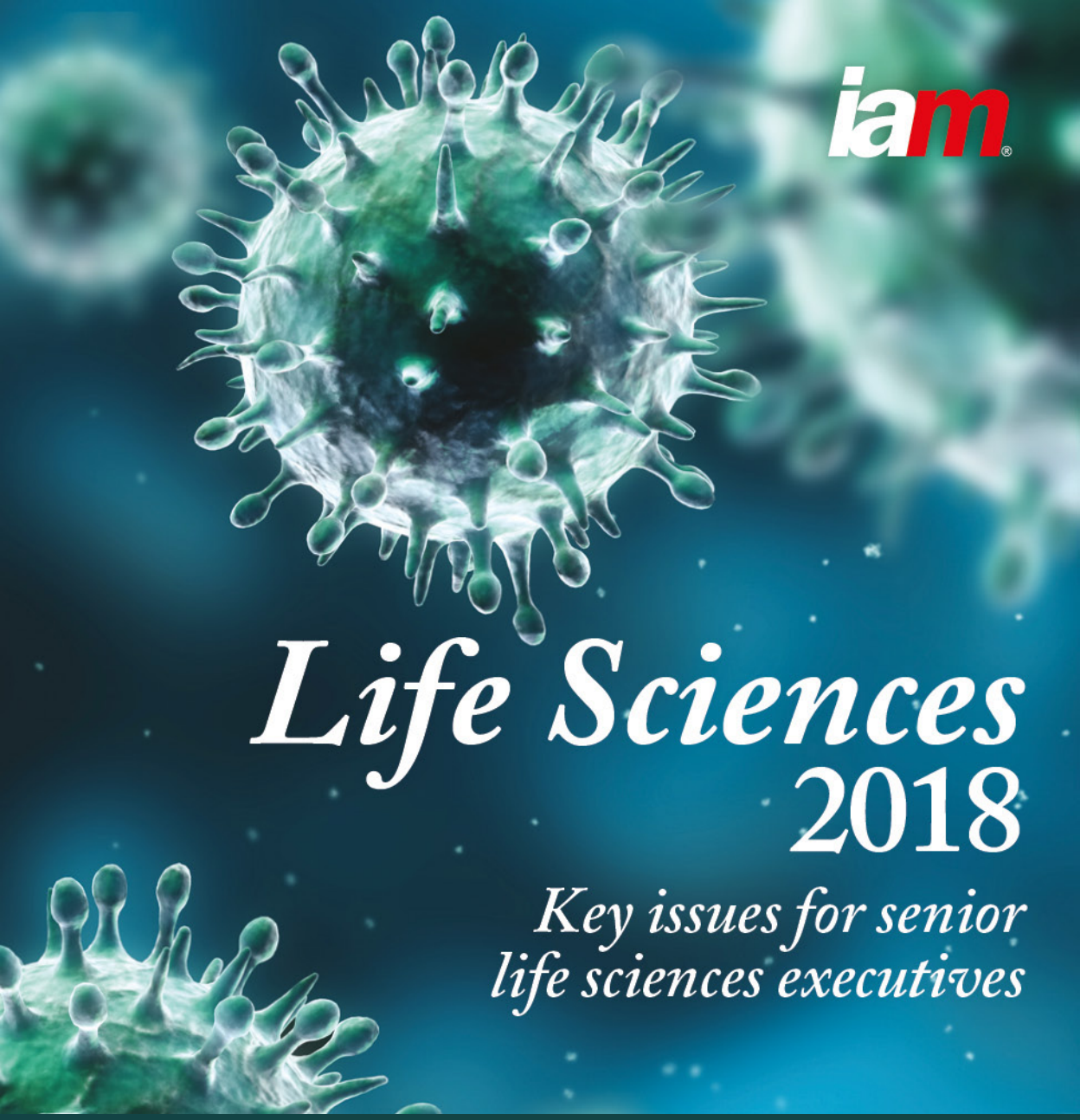

Life Sciences 2018

Key issues for senior life sciences executives

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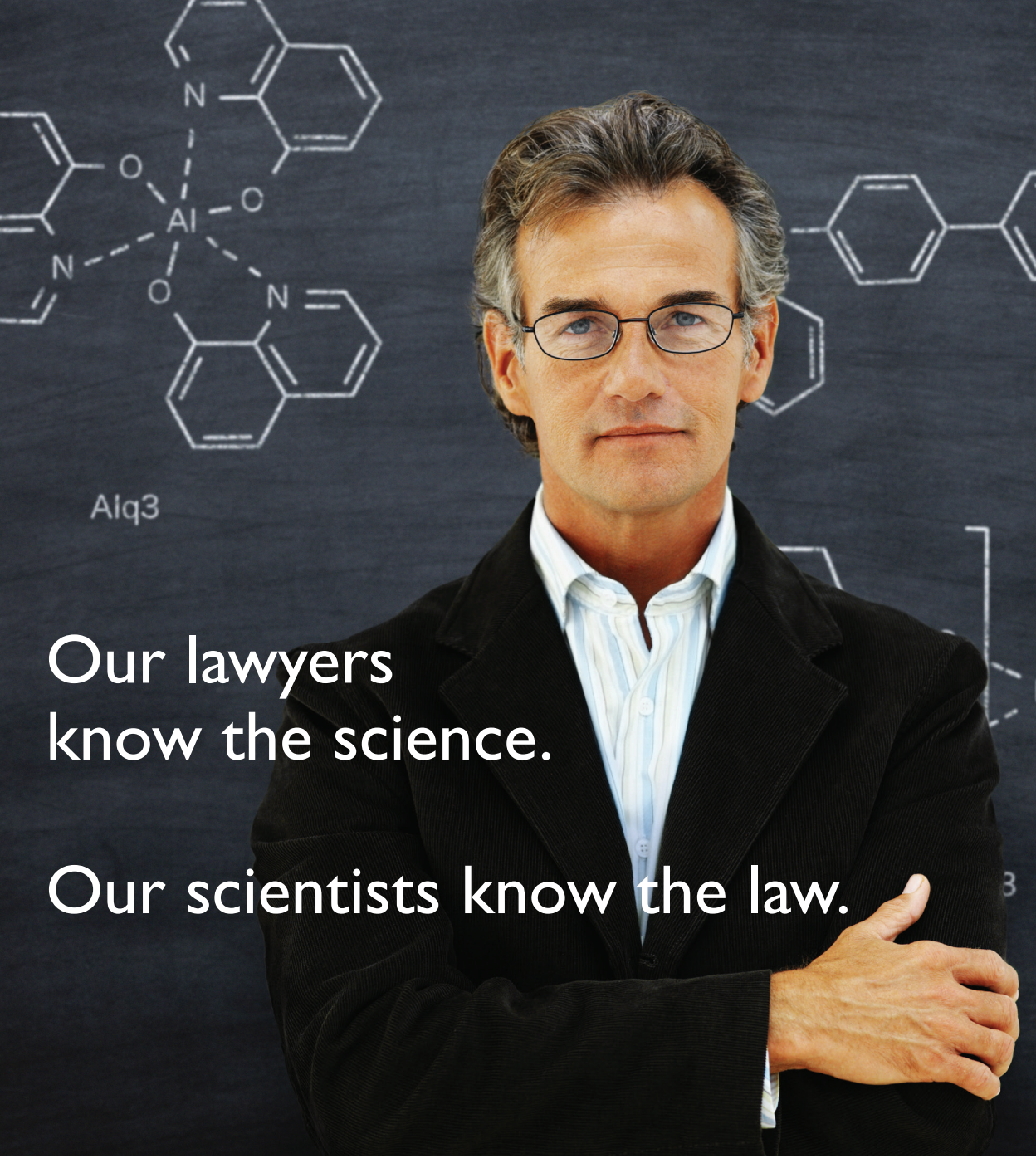
Olivares



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Modernisation of international treaties – impact on life sciences

By **Alejandro Luna F**, **Erwin Cruz** and **Rommy Morales**, Olivares

Mexico's statutory IP law, the Industrial Property Law (enacted in 1991 and modified in 1994), resulted from the North American Free Trade Agreement (NAFTA) negotiations with the United States and Canada and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs).

A degree of uncertainty followed the first round of NAFTA negotiations, and during the seventh round, which took place in Mexico City in February 2018, a meeting between Presidents Peña and Trump was cancelled, possibly due to the border wall dispute.

US negotiators in the automotive sector travelled back to Washington DC to meet with the corresponding sector. Close to the end of the negotiations, according to Trump's tweets, the United States announced its general import tariffs for steel and aluminum and proposed that it would exempt Mexico from the tariffs if better and fair conditions were achieved with NAFTA. Strategy and pressure by all parties involved has been commonly reported in the media and it is no secret that negotiations are being held in a 'David and Goliath' scenario. Fortunately, the Mexican negotiating team is made up of experienced public officers in international negotiations who are well-versed in the topics and issues under discussion. The Mexican negotiators also have the collaboration of the private sector and access to essential information with which to negotiate in Mexico's best interests. However, the expertise and position of the Mexican negotiators have not reduced the tense nature of negotiations.

Mexico is playing its role in international trade by renegotiating free trade agreements with the European Union (TLCUEM), the European Free Trade Association (EFTA) and the Trans-Pacific Partnership Free Trade Agreement (TPP 11) without US participation.

Intellectual property is playing a key role in the high-level discussion and debate.

Comprehensive and Progressive Agreement for Trans-Pacific Partnership

On June 18 2012 during the G20 summit in Los Cabos, Mexico, the countries participating in the TPP decided to invite Mexico to participate. The TPP countries originally included Brunei, Chile, New Zealand and Singapore. Since 2009 negotiations have opened up to include Australia, Malaysia, Peru, the United States and Vietnam. Mexico and Canada have now also been invited to participate.

The negotiations were concluded on October 2015 and the agreement was signed on February 4 2016 in Auckland, New Zealand. Trump has since issued a decree and the United States retired from the TPP on January 23 2017. On January 23 2018, 11 countries decided to execute the TPP 11 without the United States and with certain provisions suspended.

The agreement was signed in Chile on March 8 2018.

Free trade agreements

European Union

In May 2016 the European Union and Mexico began negotiations to modernise their free trade agreement, the so-called TLCUEM. The first round of negotiations took place in Brussels in June 2017, followed by six further rounds, with the final round in Mexico in February 2018. Negotiations are very close to being finalised.

EFTA

In January 2016, as part of the 46th Annual Meeting of the World Economic Forum in Davos, Switzerland, the Mexican government and the EFTA countries signed a joint declaration on the start of negotiations for the revision of their free trade agreement.

Delegations from the EFTA states and Mexico held the first round of negotiations in Geneva, Switzerland to conduct a comprehensive review of their existing free trade agreement. The second round took place in Mexico in May 2016. In January 2017 Mexico and EFTA held the third round of negotiations in Lugano, Switzerland to review their trade agreement.

NAFTA

After more than 23 years, Mexico, Canada and the United States decided to review NAFTA's terms. NAFTA was originally signed in:

- Ottawa on December 11 and 17 1992;
- Mexico City on December 14 and 17 1992; and
- Washington DC on December 8 and 17 1992.

It entered into force on January 1 1994.

The first round of NAFTA renegotiations was held on August 16 2017 in Washington DC. Since then six further rounds have been held, with the final round to take place in Mexico in April 2018.

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Alejandro Luna F joined Olivares in 1996 and became a partner in 2005. He has been instrumental in the firm's IP litigation, regulatory and administrative litigation practices. He is co-chair of the life sciences and pharmaceutical law and industry group and coordinates the litigation department. Mr Luna has successfully litigated for pharmaceutical patents and pioneered administrative court actions to seek recognition of data package exclusivity rights (protection for safety and efficacy data), which are not specifically recognised in Mexican law. Mr Luna has been a key player at the heart of Mexico's IP legal system, as one of the few true patent-regulatory litigation experts in Mexico. He acts on behalf of his clients as an attorney and lobbyist.

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Erwin Cruz has been a member of the Olivares life science law group since 2008, helping clients to add value to their businesses and projects in Mexico. He achieves this commitment not only by obtaining exclusive rights for clients, but also by developing and successfully implementing strategies to enforce exclusive rights and fair trade rules against potential infringers. He also provides highly qualified regulatory assistance relating to product marketing, labelling and advertising. He has extensive expertise in IP rights and regulatory compliance in the pharmaceutical, agricultural and software industries. He participates regularly in national and international conferences and meets key authorities. Mr Cruz has written several articles on litigation and regulations for pharmaceuticals, biotechnologies, agribusinesses, food and beverages.

Data package exclusivity

Data package exclusivity is a legal instrument to protect clinical data and the information required to prove that products comply with the necessary safety and efficiency standards for approval with marketing registrations for medicines and agrochemicals.

For more than 23 years Mexico has worked with NAFTA regarding data package exclusivity. NAFTA imposes the obligation to recognise no less than five years of data protection for new chemical entities, while Mexican domestic law remains silent about the mechanism to recognise and enforce data package exclusivity, with the exception of an internal memo by the regulatory agency which carries practically no legal weight.

Based on TRIPs, NAFTA and the hierarchy of the international treaties in Mexico's legal system, a legal strategy has been fashioned to obtain the recognition of data package exclusivity for products which deserve protection. Decisions are now recognising and ordering the Federal Commission for the Protection against Sanitary Risk (COFEPRIS) to grant marketing authorisations and observe and recognise data package exclusivity for the products of interest (including new formulations, indications, biologics and orphan drugs). Case law now recognises data protection for biologics (a situation that was refused by the regulatory agency for many years) and has also been ordered by the courts to recognise more than five years of protection for biologic products.

The eventual execution by Mexico of obligations in international treaties expressly recognising data protection, with the correct wording to define the scope of protection and the corresponding duration, will provide the desired legal certainty.

It is neither arbitrary nor capricious that innovator companies desire data protection of:

- 12 years for biologic products;
- 10 years for agrochemicals;
- five years for pharmaceutical chemical products; and
- three years for new formulations and indications.

The proper establishment of the obligations in this regard would provide the legal scenario required to drive innovation in Mexico. In this respect, negotiators should consider that after 23 years, Mexico still has no law or regulation establishing the scheme of attainment, enforcement and duration of data protection.

Patentable subject matter

Mexican patent law, in general terms, complies with international standards regarding patentable subject matter. Nevertheless, there are some aspects of domestic law which require clarification, including the patentability of new uses of known products. It is common practice for the Mexican Institute of Industrial Property (IMPI) to grant patents for second medical uses; however, the obligation contained in an international treaty regarding such inventions as patentable subject matter would provide legal certainty.

It is also necessary to elucidate through the treaties some of the statutory prohibitions of patentability in Mexican law (ie, provide improved

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definitions in treaties for such concepts as 'essential natural processes', 'software *per se*' and 'living subject matter').

Plant patents and traditional knowledge are also under discussion.

Patent term extensions

The new generation of international treaties include provisions to avoid unreasonable delays in the granting of patents and marketing authorisations. Through diverse mechanisms, the different jurisdictions involved in treaty renegotiations have contemplated patent term adjustments derived from unreasonable delays during patent prosecution and unreasonable curtailment on patent protection due to regulatory processes.

If it is considered that existing Mexican IP law expressly limits the life term of a patent to 20 years from the filing date, then Mexican IP law and the Health Law are likely to be amended if there is a general provision establishing the patent compensation terms for delays in the process of regulatory approvals or the granting of the patent in any of the free trade agreements.

The Mexican authorities in charge of granting drug approvals and patents, COFEPRIS and IMPI, comply with international standards. However, it is believed that there is no reason to disregard a mechanism to force the authorities to continue with this practice where the authorities delay the corresponding grants.

The wording of the treaties should be accurate to avoid any misinterpretation which could result in abuse or ineffectiveness.

Linkage Regulation

In 2003 the Linkage Regulation was enacted in Mexico. According to this, every six months IMPI must publish a list in the *Gazette* of those patents which cover allopathic medicines.

COPEPRIS must observe the patents that are listed in the *Gazette* according to the generic name of the active ingredient before granting marketing authorisations to third parties which are different from the titleholder, or alternatively request additional information from the applicant. In case of doubt regarding an eventual violation of patent rights, COFEPRIS can request technical support from IMPI for the scope of the patent rights. The regulation excludes from the *Gazette* only those patents that cover processes of manufacture and formulation of drugs.

It has been contested that this interpretation is wrong through constitutional actions to obtain the publication of patents covering formulations and second uses. The Supreme Court agreed with this broader interpretation. However, COFEPRIS observed formulation patents in the linkage gazette process of approvals for generics, which are strict only in the observance of compound patents. Some pharmaceutical companies and brokers began requesting and obtaining import permits granted by COFEPRIS for bulk amounts of patented active ingredients.

Patent linkage is a mechanism established by the TPP and is subject to negotiations in other treaties (eg, NAFTA). In Mexico, the statistics demonstrate that after the implementation of the patent linkage system, the number of patent infringements – especially wilful patent infringement of pharmaceutical products – diminished considerably. The number of wilful infringements of compound patents was reduced to zero, while before linkage there were more than 20 compound patents being infringed by different companies and infringing products.

Therefore, if Mexico is willing to have an approval system aligned closer to the law, instead of the pre-linkage 'wild west', then the patent linkage system should receive the support of international treaties.

Bolar exception

Under the Health Law, an importer of raw materials for pharmaceutical products requires an import permit granted by the Ministry of Health through COFEPRIS.

Provisions regarding imports of active pharmaceutical ingredients make no reference to linkage provisions in order to prevent a violation of patent rights by granting the permits. The applicant for an import permit need not declare whether the imported product is patented or prove the existence of a licence or authorisation by the patent owner. The situation becomes even more critical when there is no obligation on the importer to mention or declare the products' destination.

Import permits for huge quantities of infringing products (eg, active ingredients) imported in bulk have been issued under the baseless argument that the imports are covered by the Roche-Bolar exception. Such significant amounts exceed the scope of Roche-Bolar, which is only for the purpose of conducting tests for the approval process.

Consequently, patent owners have been forced to attempt several different approaches to attack

these violations to their IP rights, including patent infringement actions, where coordination between the patent and customs offices is not always ideal. The vague Roche-Bolar exception provided in the regulation has liberated infringers from corresponding sanctions when it was clear that the import had a commercial purpose.

In NAFTA and other international treaties, the scope of the Roche-Bolar exception has been discussed in order to encourage generics to obtain the corresponding marketing authorisations immediately after the expiration of the corresponding patent. The manner in which to avoid abuse of the exception to introduce infringing products into Mexico and other jurisdictions has also been discussed.

Patent enforcement and damages

A recent Supreme Court decision decided that the 40% rule to claim damages derived from the violation of an IP right is not automatic or punitive and the claimant should prove the actual damages. Subsequently, the long road of patent litigation and damages is now more complicated due to this burden of proof.

The renegotiation of NAFTA and other international treaties is an opportunity to include correct wording to fix the main three drawbacks in the enforcement system, namely to:

- avoid bifurcation or duplication of two consecutive, not alternative, proceedings (there are seven stages in total) to obtain a decision on damages;
- lift injunctions by a counterclaim; and
- remove unnecessary IMPI internal technical reports to decide patent cases.

International treaties in Mexico hold relevant legal weight, especially in connection to human rights (eg, IP rights). With renegotiations of international treaties, Mexico has an exceptional opportunity to review and amend its entire IP system. For the innovation and creative industry, an efficient, enhanced and improved IP system would always be welcome. *iam*

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