



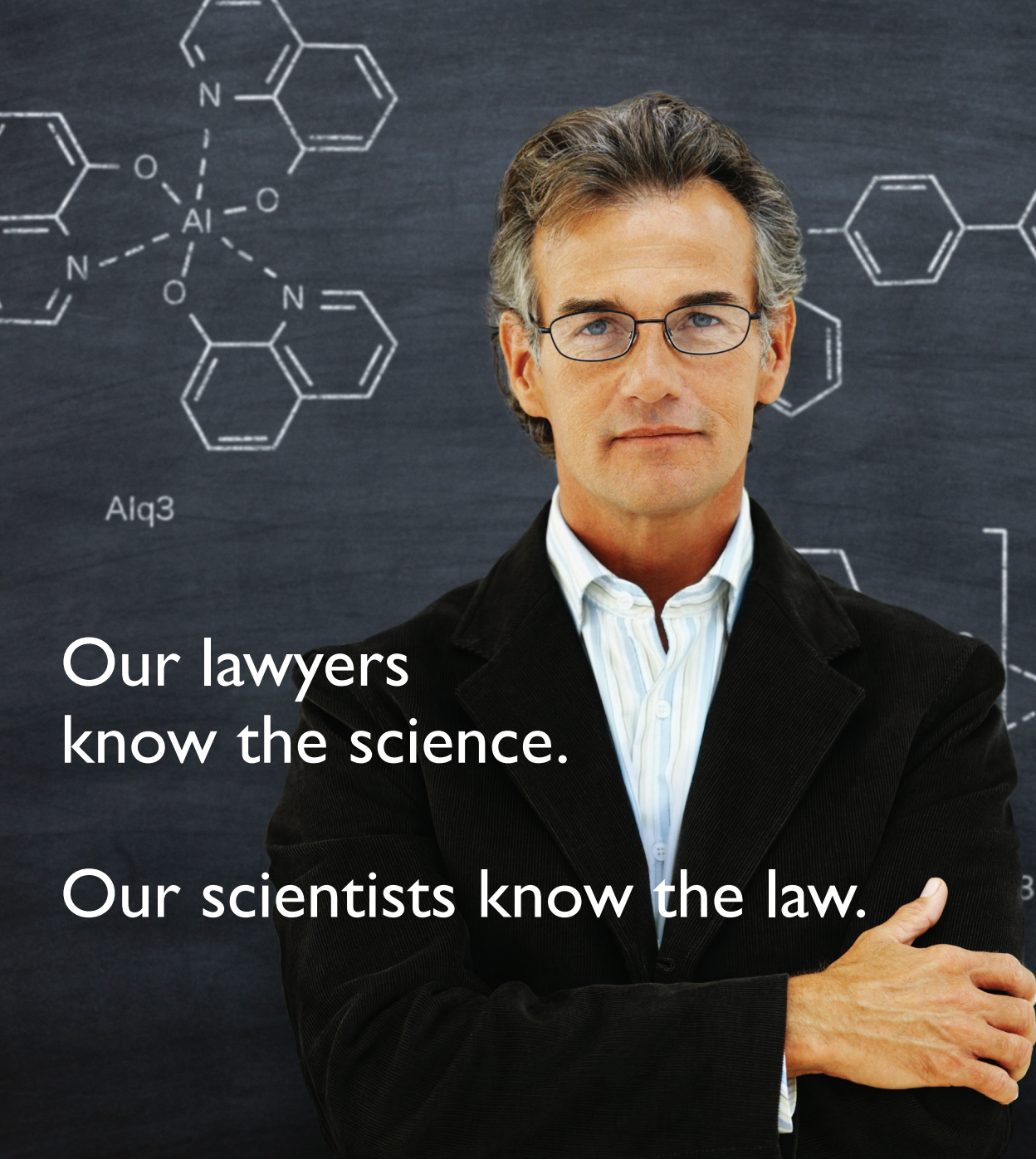
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*Key issues for senior
life sciences executives*

IP rights protection and enforcement strategies for plant
innovations in Mexico

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OLIVARES

IP rights protection and enforcement strategies for plant innovations in Mexico

By Abraham Díaz, Erwin Cruz and Pedro Herrera, Olivares

Biotechnology has made significant contributions to the advancement of medicine, agriculture and industry. This includes both the development of naturally occurring materials (eg, genetically engineered biological materials) and the enhancement of manufacturing methods (eg, engineered fertilisers and pesticides).

IP systems, such as patent and plant variety protection systems, aim to support innovation and ensure that innovations are publicly accessible. These systems encourage investment by providing rights holders with time-limited exclusive rights over the exploitation of their innovations, which should ensure appropriate returns. IP systems therefore play a key role in fostering innovation.

Agro-industry in Mexico has been growing at a fast pace as a result of several factors, including the country's diversity of climate, flora and fauna and proximity to one of the world's largest markets – the United States. According to World Trade Organisation statistics, Mexico accounted for 7.2% of the world's total exports of agricultural products in 2015. In a January 2017 press release the Mexican government noted that the country is the world's 12th largest food producer.

Patent and plant variety protection is available for plant-related innovations in Mexico; however, each system has specific characteristics that should be considered in order to ensure sufficient protection. For example, the plant variety system protects propagating or reproductive material of a new plant variety, regardless of the technology used to obtain it. This system does not cover all related aspects (eg, methods to obtain new plant varieties). In contrast, the patent system can protect relevant plant components, including

enhanced cells, engineered genetic sequences and methods to obtain and use these materials.

The enforcement of plant variety rights in Mexico can differ significantly from that in other jurisdictions. This is because some plant varieties are commercialised by established companies and cultivator associations, while many others are cultivated and marketed by individuals with small plots of land.

It is therefore crucial to develop dynamic protection strategies for plant-related innovations in Mexico which take account of the features of both protection systems. Securing broad protection will help to prevent infringement and facilitate flexible enforcement approaches.

Patent protection

The Mexican Institute of Industrial Property (IMPI) prosecutes and grants patents. It has exclusive jurisdiction to hear patent infringement actions and counter-invalidity actions at first instance. Federal courts review patent cases on appeal.

In addition to international IP treaties to which Mexico is a signatory – such as the Agreement on Trade-Related Aspects of Intellectual Property Rights, the North American Free Trade Agreement, the Paris Convention and the Patent Cooperation Treaty – the Industrial Property Law and its regulations constitute the primary body of patent law in Mexico. In contrast to other jurisdictions, IMPI has not issued examination guidelines and federal courts have established few binding precedents regarding patent eligibility.

Articles 16(I), (II) and (V) of the Industrial Property Law exclude from patent protection:

- essentially biological processes for obtaining, reproducing and propagating plants;

- biological and genetic material found in nature; and
- plant varieties.

Accordingly, it may at first seem that patent protection is unavailable for material derived from plants. However, these exclusions should be read carefully and not be extended to other materials or technologies, such as improved biological processes and genetically engineered materials. IMPI usually evaluates whether all or part of a claim set of a patent application falls within the patent eligibility exceptions. Moreover, Mexico is a signatory to the Budapest Treaty and accepts deposits of biological materials, which confirms that patent applications can be filed claiming enhancements of biologic processes and materials.

Although there are no examination guidelines, IMPI usually mirrors the best practices of the US Patent and Trademark Office (USPTO) and the European Patent Office (EPO). The Industrial Property Law allows IMPI to request patent applicants to submit a substantive examination or letters patent granted abroad which correlates to the subject matter claimed in Mexico. It is helpful for applicants to provide additional assistance to IMPI in order to determine whether all of the corresponding subject matter is patentable.

Moreover, IMPI has engaged in the Patent Prosecution Highway (PPH) programme with leading patent offices worldwide. Through this programme, IMPI can accept examinations carried out by foreign patent offices as valid in Mexico, under certain conditions. IMPI currently has more than 10 PPH agreements in place, including with the world's five largest IP offices: the USPTO, the EPO, the Japan Patent Office, the Korean Intellectual Property Office and the State Intellectual Property Office of China. The PPH programme can therefore be a useful tool for patent applicants to support the patentability in Mexico of plant-related inventions that are already protected abroad.

Notably, the EPO's recent decision to stay all proceedings in examination and opposition cases in which the invention is a plant or animal obtained by an essential biological process may affect similar applications under prosecution before IMPI. According to an EPO press release, this stay derives from a recent notice of the European Commission relating to certain provisions of the EU Biotechnology Directive (98/44/EC). IMPI is expected to carefully review the corresponding applications and not to apply the patentability exclusions to eligible materials and technologies.

Plant variety protection

The National Service of Certification and Identification of Seeds (SNICS), a sub-division of the Ministry of Agriculture, Livestock and Rural Development, is responsible for prosecuting and granting plant variety rights. The SNICS also has exclusive jurisdiction to rule on plant breeders' rights infringement actions and counter-invalidity actions at first instance. Federal courts review these cases on appeal.

In addition to the 1978 Act of the International Union for the Protection of New Varieties of Plants (UPOV 1978) – to which Mexico is a signatory – the Federal Plant Varieties Law, the Federal Seeds Law and their regulations constitute the primary body of law governing plant varieties. Federal courts have established few precedents regarding plant breeders' rights. However, technical guides are available which are useful for descriptions of some species.

Mexico extends protection to plant varieties of all plant genera and species. According to SNICS statistics, 2,314 applications were filed and 1,619 applications were granted in 2016. Applications came from many different countries, although a large number originated from Mexico (832 applications/531 certificates granted), the United States (727 applications/540 certificates granted) and the Netherlands (404 applications/309 certificates granted).

Although the standards of UPOV 1978 apply in Mexico, the Plant Varieties Law has certain characteristics that make it align more closely with the most recent UPOV Act (UPOV 1991). For example, Article 2(IX) of the law defines a 'plant variety' as the sub-division of a species that comprises a group of individuals with similar characteristics that are considered stable and uniform.

The requirements for protection are the same as in other UPOV 1978 member states: the plant variety must be new, distinctive, homogeneous and stable, and have an acceptable denomination or variety name.

The grace period to maintain novelty is one year after the variety sale in Mexico and four years after its first sale overseas (or six years for vines, forest and fruit trees and ornamentals). Priority can be claimed within one year of first filing abroad.

The Plant Varieties Law provides that breeders' rights allow the rights holder to exclusively exploit a plant variety for production, reproduction, distribution or sale, as well as for the production of other plant varieties and hybrids for commercial

purposes. This includes essentially derived varieties as considered by UPOV 1991.

The Plant Varieties Law follows the terms of protection provided by UPOV 1978:

- 18 years for perennial species (forest and fruit trees, vines and ornamentals) and their rootstocks; and
- 15 years for all other species.

Once the applicant has met the requirements of novelty and denomination, the SNICS issues an office action indicating that an application for plant variety rights is under prosecution and that the applicant is therefore presumed to be the holder of the corresponding rights. Plant breeders cannot bring actions against unauthorised third parties infringing their rights until they receive the plant breeder's certificate.

Patent infringement and preliminary injunctions

Conditions for infringement

The Industrial Property Law grants patentees the right to exclusive exploitation of the patented invention and to exclude others from making, using, offering for sale or importing the covered invention. In a patent infringement action, the claimant must prove that either of the following is being done without its authorisation:

- Producing, offering for sale or importing the patented invention – a manufacturer can infringe directly, while infringement by sellers requires prior notice of the infringement. If a claimant claims infringement of a patented process, the defendant must prove use of a process other than the patented process. The Industrial Property Law contains no grounds to apply the contributory infringement doctrine.
- Using the patented invention – the claimant must prove that the wording of the patent's claim or claims covers the allegedly infringing product or process. The Industrial Property Law provides that the scope of the claims is determined by their wording, aided by the description and drawings. The burden of proving authorised use lies with the defendant.

Claims and remedies

Proving patent infringement in Mexico is difficult, since Mexico follows a strict civil law system which has formalistic rules for both evidence and proceedings. A patent infringement claim must be submitted to IMPI. The claim is served on the alleged infringer, which then has 10

working days to respond and, if applicable, bring a counterclaim. The response is then served on the claimant, which may refute it. The evidence is then analysed and a decision is issued. The decision can be challenged before the federal courts. IMPI is an administrative authority; as such, there is no judge or jury participation in patent infringement actions.

IMPI can take certain preliminary measures while investigating the infringement (Article 199*bis* of the Industrial Property Law). These include ordering:

- the recall of infringing goods or prevention of their circulation;
- the withdrawal from circulation of infringing articles, including tools used in the manufacture, production or obtaining of infringing articles;
- the suspension or cessation of all acts that violate the law, committed by the alleged transgressor or by a third party; and
- the suspension of services or closure of an establishment, where other measures are insufficient to prevent or avoid a violation of rights.

If the plaintiff requests IMPI to issue a provisional injunction, a bond will be fixed as a warranty for possible damages to the defendant. Defendants can request that the injunction be lifted by posting a 40% higher counter-bond.

Administrative infringements can incur penalties ranging from a fine of up to 20,000 times the minimum daily wage (about \$70,000) to final closure of the infringer's establishment (Article 214 of the Industrial Property Law). Repeated infringement is also considered a criminal offence (Article 223 of the Industrial Property Law).

Once an infringement has been declared and cannot be appealed, the claimant can bring an additional civil action for damages and lost profits accrued from the date on which the existence of the infringement can be proved (Article 221*bis* of the Industrial Property Law). The civil courts impose a tariff scheme specifying the costs that can be claimed for reasonable attorneys' fees, regardless of whether these reflect the actual fees charged.

Plant breeders' rights infringement and preliminary injunctions

Conditions for infringement

Article 48 of the Plant Varieties Law provides that the following activities constitute infringement:

- modifying the denomination of a protected plant variety without the ministry's authorisation;

- falsely representing oneself as the creator of a plant variety;
- divulging or commercialising a plant variety as though it were of foreign origin where this is not the case, or divulging or commercialising a plant variety as though it were of national origin where this is not the case;
- opposing inspections conducted in accordance with the Federal Law on Vegetal Varieties;
- commercially exploiting the features or content of a protected plant variety and attributing these features or content to another plant variety; and
- violating preliminary injunctions issued under the Federal Law on Vegetal Varieties.

Claims and remedies

As with proving patent infringement, proving plant breeders' rights infringement in Mexico is difficult on account of the country's strict civil law system and formalistic rules for evidence and proceedings. A plant breeders' rights infringement claim must be submitted to the SNICS. The claim is served on the alleged infringer, which then has 30 working days to respond and, if applicable, bring a counterclaim. That response is then served on the claimant, which may refute it. The evidence is then analysed and a decision is issued. The decision can be challenged before the federal courts. The SNICS is an administrative authority; as such, there is



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Abraham Díaz co-chairs the IT industry group and has a wealth of knowledge across the IP spectrum. Although he spends most of his time on IP litigation, he works frequently with the enforcement of plant breeders' rights.

He counsels clients on all IP-related matters, including trademarks, unfair competition, copyrights, trade dress, advertising, trade secrets, plant breeders' rights and online IP issues.

He also advises on data privacy compliance matters, including the implementation, auditing and testing of privacy management programmes and the detection and handling of privacy breaches. His internet experience includes handling domain disputes under the Uniform Domain Name Dispute Resolution Policy and the Local Dispute Resolution Policy, as well as advising on the development of websites and the protection of online content.



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Erwin Cruz has been a member of the Olivares life science law group since 2007, assisting clients to add value to their businesses and projects in Mexico. He achieves this commitment not only by obtaining patent and plant variety protection, but also by developing and successfully implementing strategies to enforce exclusive rights against potential infringers. He also provides highly qualified regulatory assistance relating to product marketing, labelling and advertising.

He holds an LLM in biotechnology, law and ethics (first class) from the University of Sheffield (United Kingdom) and has extensive expertise on IP rights and regulatory compliance relating to the agricultural, pharmaceutical and software industries. He frequently participates in international and national conferences and meets key authorities in these industries.

no judge or jury participation in infringement actions.

It is also possible to request the SNICS to issue a preliminary injunction ordering:

- the withdrawal from circulation or a prohibition against circulation of a plant variety or propagating material that infringes plant breeders' rights;
- the withdrawal from circulation of objects, crates, containers, packages, paperwork and advertising material that infringe plant breeders' rights;
- the seizure of any property affected by a violation of plant breeders' rights; or
- the suspension or cessation of any acts that violate the Plant Varieties Law.



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Pedro Herrera is an associate at Olivares. His practice focuses on drafting and prosecuting patent applications, reporting and preparing responses to office actions, patentability searches, freedom-to-operate studies and technical opinion letters in various areas of chemistry, drugs and biotechnology, and analysing patent validity and infringement issues as well as IP litigation. He is an experienced chemical engineer and holds a law degree.

In accordance with the Plant Varieties Law, where the plant variety or its propagating material is being traded, all traders must refrain from disposing of it as of the date of notification of the injunction. Producers, nursery workers, manufacturers, importers and distributors are subject to the same obligation and are responsible for immediately recovering plant varieties or propagating material that has already been traded.

The chapter on preliminary injunctions in the Plant Varieties Law is almost identical to the relevant provisions in the Industrial Property Law and the SNICS has thus adopted many of IMPI's practices with regard to the issuance of injunctions. For instance, in order to obtain a preliminary injunction, it is necessary to post a bond or security to cover any damages that may be caused to the defendant. Defendants can request to lift these injunctions by posting a counter-bond, but the Plant Varieties Law does not provide further parameters.

Administrative infringers can be subject to a fine of up to 10,000 times the minimum daily wage (approximately \$35,000), depending on the specific infringement. Imprisonment is not an available penalty.

Once an infringement has been declared and cannot be appealed, the claimant can bring an additional civil action for damages and lost profits. The civil courts impose a tariff scheme specifying the costs that can be claimed for reasonable attorneys' fees, regardless of whether these reflect the actual fees charged. **iam**



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