



February 8, 2018

Elizabeth L. Kendall  
Assistant U.S. Trade Representative for Innovation and Intellectual Property  
Office of the United States Trade Representative  
600 17th Street NW  
Washington, DC 20508

*Submitted via Regulations.gov* < USTR-2017-0024 >

**Re: 2018 Special 301 Review: Identification of Countries Under Section 182 of the Trade Act of 1974: Request for Public Comment and Announcement of Public Hearing; Docket ID No. USTR-2017-0024; 82 FR 61363 (December 27, 2017).**

Dear Ms. Kendall:

CropLife America (CLA) welcomes the opportunity to comment on the subject Federal Register notice, dated December 27, 2017, requesting identification of countries under Section 182 of the Trade Act of 1974 or non-statutory categories of Priority Watch List (Special 301 Report) that deny adequate and effective protection for intellectual property rights (IPR) or deny fair and equitable market access to U.S. products. CLA is the national trade association representing the developers, manufacturers, formulators, and distributors of plant science solutions for agriculture and pest management in the U.S. Our member companies collectively spend \$2.6 billion to \$3.2 billion<sup>1</sup> each year on research and development of new crop protection products and developing health and environmental safety data in support of registering and marketing these products in the U.S. and around the world. We provide here a synopsis of acts, policies, and practices in countries that restrict adequate and effective protection of IPR, namely protection of safety and efficacy data, and, therefore, deny fair and equitable market access to CLA member companies.

### **ARGENTINA**

In Argentina, there is no enforceable data exclusivity protection for agricultural chemical products.

Additionally, amendments to Argentina's Patent Act (2004) reversed the burden of proof for issuing preliminary injunctive relief in patent litigation. The plaintiff must retain an expert witness to determine patent validity, prove actual damage, and demonstrate that damages to plaintiff outweigh potential damages to the defendant, in order for a preliminary injunction to be granted.

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<sup>1</sup> See PHILLIPS MCDUGAL, THE COST OF NEW AGROCHEMICAL PRODUCT DISCOVERY; R&D EXPENDITURE IN 2014 AND EXPECTATIONS FOR 2019, 22 (March 2016), <https://goo.gl/RWhZPK>.

Also, the Argentine Government has amended the criteria for granting patents on biotechnological inventions. A joint Resolution of the Agricultural Working Group and the Patent Office (Resolución INPI No 283/2015) establishes guidelines/instructions, which prevent patenting parts of plants (seeds, cells, flowers, etc.), plant components, animal parts (organs, animals, tissue, and cells), and animal components. This is contrary to Argentina's obligations under the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

Argentina still is not a member of the Patent Cooperation Treaty (PCT). Ratification of the PCT would reduce costs and facilitate patent procurement in Argentina. This is important, since there is a considerable backlog in granting patents, on average 10 to 12 years. The Argentine Patent Office, INPI, currently is reviewing patent applications filed between 2004 and 2008.

## **CHILE**

Chile's regulatory requirements for agricultural chemical products undermine effective data exclusivity protection. Chilean Law N° 19.996 (amending Law N° 19.039), Article 89, provides 10 years of data exclusivity protection for new agricultural chemical entities. Left alone, Article 89 would be fully compliant with the U.S.-Chile Free Trade Agreement of 2004. However, Article 91 paragraph e) prevents the enforcement of data exclusivity protection if an application for marketing approval of an agrochemical product is filed in Chile more than 12 months after the date that the product was first registered in another country.

This 12-month review window for product launch in Chile cannot be met if registrants are to consider all the multiple variables behind business and marketing decisions, such as pest migration, resistance, and timeframes required to extend authorized label uses of products to different crops. If the Chilean novelty threshold becomes a standard in Chile or elsewhere, it would be an insurmountable barrier to data protection.

The issue could be solved by an Industrial Property Bill proposed in the Chilean Congress. However, the current draft of the Bill still contains the 12-month window provided in the current Law. In light of the situation, CLA requests that Chile be considered a priority country on the Special 301 Report.

## **COLOMBIA**

Registrants are concerned about the management of confidential business information (CBI) submitted to the National Competent Authority, ICA, which grants marketing approvals. All data submitted to ANLA, the Authority in charge of granting environmental approvals for crop protection products, are placed in the public domain, despite the fact that some studies should receive CBI consideration. Action to safeguard CBI contained in regulatory dossiers filed with National Competent Authorities is required.

Counterfeiting of crop protection products is also a significant issue in Colombia.

## **COSTA RICA**

The Costa Rican Executive issued Decree 40059-MAG-MINAE-S to regulate pesticide evaluation proceedings, and it will amend Decree 33495 when the 6-month moratorium expires later in 2017. This amendment is designed to introduce regulatory data exclusivity protection pursuant to the Dominican Republic-Central America Free Trade Agreement (CAFTA-DR). It is recommended that USTR confirm whether the new regulation satisfies CAFTA-DR obligations.

## **ECUADOR**

Ecuador issued the Organic Law of the Social Economy Knowledge (Ingenios Law), which radically changes the scope of intellectual property protection and directly contradicts the TRIPS Agreement. As a consequence, legal uncertainty prevails among intellectual property owners. The main issues with the Ingenios Law are:

- It replaces the Ecuadorean Institute of Intellectual Property with a new entity under the direct control of the President of the Republic, with uncertain membership, structure, and operational procedures. The new entity should be in place by 9 March 2017. Within 6 months, a Regulation for 13 areas of intellectual property should be issued.
- The Ingenios Law considers knowledge a public interest asset with unlimited access, in contradiction to IPR privately held.
- The Ingenios Law is more restrictive than existing CAN Decision 486 that should be binding for Ecuador. The Ingenios Law bars from patent protection “polymorphs, metabolites, pure forms, isomers, and the product of genetic resources that have not been investigated in Ecuador.” Restrictions of protection based on the place of investigation violates the principle of national treatment (Article 3 of GATT, Article 17 of GATS, and Article 3 of TRIPS).<sup>2</sup>
- Under the Ingenios Law, a patent can be annulled if the origin of genetic resources is not reported. Also, it provides that if “forgery, omission, or deliberate obstruction to patent examination is found, it is also considered as ground for cancellation.” The causes for cancellation, added to those provided by CAN Decision 486, are broad in nature and subject to broad interpretation.

Regarding regulatory data protection, Ecuador signed a Trade Agreement with the European Union that includes 10 years of data exclusivity protection for new chemical entities contained in agricultural chemical products, which is consistent with the US FTA. However, the Protocol of Accession of Ecuador provides that data exclusivity protection will not enter into force until January 2022. The Ingenios Law contains similar provisions but does not indicate when protection should be in place.

## **MEXICO**

Mexico’s Industrial Property Act, Article 86/bis, grants only 5 years of regulatory data exclusivity protection for new agricultural chemical products. Thus, there is an asymmetry between Mexican legislation on intellectual property and that of peer countries in the North

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<sup>2</sup> *Principles of the Trading System*, WORLD TRADE ORGANIZATION, <https://goo.gl/q6jj2x> (last visited Feb. 8, 2018).

American Free Trade Agreement (NAFTA), U.S. and Canada, which grant 10 years of data exclusivity protection. Such inconsistency blocks trade facilitation efforts, such as joint reviews of agricultural chemical products performed by the three NAFTA members under the Technical Working Group on Pesticides. CropLife America recommends that the issue be discussed with Mexican counterparts in any upcoming trade dialogue with the southern neighbors.

## **PARAGUAY**

In 2010, Paraguay passed Law 3.519 that establishes 5 years of CBI protection for agrochemical products, but only if the first global registration is sought in Paraguay. Law 3.519 also states that any regulatory information found in the public domain (*e.g.*, information available in reading rooms for transparency purposes) would not be eligible for intellectual property protection.

All agrochemical products approved for marketing in Paraguay have to undergo re-evaluation, including submission of CBI. The re-evaluation process allows the government to have reference profiles in place to determine equivalency of me-too applications. In the absence of confidentiality safeguards, registrants have the choice of either revealing their CBI or losing their licenses to market.

The issue remains unsolved, so it is recommended to include Paraguay as a priority country.

## **PERU**

The United States-Peru Trade Promotion Agreement (USPTPA), Article 16.10, provides data exclusivity protection for agricultural chemical products. In compliance with USPTPA obligations, the Peruvian Government passed Legislative Decree 1074 in 2009 to establish 10 years of data exclusivity protection for new agricultural chemical products.

However, regulatory agencies have stepped away from effectively enforcing data exclusivity protection because of Supreme Decree 001-2015 that required regulatory evaluation of agricultural chemical products by three different agencies (Agriculture, Health, and Environment). The three agencies, alleging data confidentiality, fail to collaborate with IPR holders when me-too registrations are suspected of infringing their data exclusivity rights. IPR holders cannot take legal action because they do not have access to the potentially infringing me-too product dossiers.

## **URUGUAY**

Uruguay fails to provide adequate and effective IP protection for agricultural chemical products, and therefore, US innovators face numerous unsurmountable challenges in Uruguay including:

- restrictive patentability criteria;
- substantial backlog and delays in patent examination and grants;
- lack of provisional protection for patents during patent pendency;
- rampant and undeterred infringement of agricultural chemical products;
- lack of adequate and effective protection for regulatory test or other data submitted by agricultural chemical producers; and

- failure to effectively enforce foreign-held IP, thus providing national firms with unfair competitive advantage.

Patents in the agricultural chemical and biotechnology sectors face a substantial backlog resulting in long delays to obtain protection and registrant rights. The authorities take 11 years to start examining a patent application, and Uruguay does not provide provisional protection for pending patents. It also does not provide for patent-term extension. Uruguay has restrictive guidelines for examining chemical patents. It applies similarly restrictive criteria to biotechnology inventions, and it prevents patenting parts of plants, plant components, animal parts, and animal components, contrary to its obligations under TRIPS. This interferes with the ability to protect innovations based on living matter and natural substances.

Uruguay has not adhered to the PCT, which would benefit patent innovators, including US innovators in IP-intensive industries. Even though the national government sent a draft Bill to the Parliament on March 2017 to access PCT, no meaningful progress has been made.

On October 2016, the national government commenced a Patent Prosecution Highway (PPH) pilot program for patent examinations, but it has a limited scope.<sup>3</sup> The PPH does not extend to other IP offices such as the European Patent Office (EPO) or the United States Patent and Trademark Office (USPTO).

Uruguay fails to protect innovators against infringements during patent pendency, since a 2013 legislative amendment eliminated the right to claim damages for infringement resulting from filing or publishing a patent application (article 99 of Patent Law No. 17.164).

Because Uruguay does not protect patent-pendency infringement, the vast majority of innovations—including those of US innovators—are defenseless. This has fostered rampant and undeterred infringement of a high number of valuable innovations and new agricultural chemical products during patent pendency (which extends for over 11 years). By the time the applications reach a grant stage and the restrictive patentability criteria have been overcome, their value as IP assets and their commercial value will have already substantially diminished. A clear sign of this disheartening situation is the virtual lack of patent enforcement cases in Uruguayan Courts, since very few patents are granted, and by the time they are, their value has been severely damaged.

Uruguay fails to provide effective protection against the unfair commercial use of undisclosed test and other data generated to obtain marketing approval for agricultural chemical products. Novel product registrants are not able to enforce exclusivity rights. The national regulatory authority for the approval of agricultural chemical products (DGSA) openly grants marketing approvals to me-too products, relying on first registrants' data.

Further, the national regulatory authority (DGSA-MGAP) has blocked access to public information requests filed by patent innovators—including US innovators—to access and review the legality of product registration records obtained by national generics companies. This occurs

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<sup>3</sup> Only affects members of the PROSUR regional cooperation system on IP—Argentina, Brazil, Chile, Colombia, Ecuador, Paraguay, Peru, and Uruguay—many of which face a substantial patent processing backlog.

despite the fact that the Access to Public Information Unit (UAIP) of the Presidency of the Republic has already ruled against the DGSA.

For all these reasons, it is recommended that Uruguay be considered a Priority Country in the Special 301 Report.

## **INDIA**

The Pesticide Management Bill of 2017 is intended to enact legislation enhancing IPR in line with India's TRIPS obligations but is yet to be finalized for presentation before Parliament. The data for new molecule technology introduced into India, however, has been eliminated in the draft bill.

Clause 49 of the draft bill further authorizes the Central Government to fix prices of pesticides. This attempt to control prices by placing pesticides under the Essential Commodity Act is a step backward, as it will discourage companies from introducing new agricultural innovations and technologies into the country.

The continued lack of regulations over Bio-Pesticides and Bio-Stimulants remains an issue as these products, while certified as having no chemical content, include products which do contain some unregulated chemicals. These bio products are not registered with the Central Insecticide Board, and manufacturers proceed as if these products are not covered under the India Insecticide Act.

Counterfeit pesticides in India account for approximately 30% of pesticide sales volume, posing an export ban risk, since India exports agricultural produce (\$26 Billion in food grains and \$2 Billion in fruits and vegetables) treated with pesticide products lacking appropriate labels.

While India has taken steps to improve its IPR regime recently with a new IPR Policy in 2016, the current legal structure for the protection of CBI and other data remains inadequate and discourages the introduction of new crop protection and other related technologies.

## **CHINA**

The new Pesticides Regulations, which took effect in 2017, led to many improvements in pesticides management and control. These regulations assigned responsibility of pesticide administration to the Ministry of Agriculture and specified the government has the duty to license pesticide sales and eliminate illegal pesticides.

The Regulations require sellers to secure a license before selling pesticides online or offline, but the Regulations were unclear in defining "sales" and whether "export" is regarded as "sales." Some online platforms allow exporters to sell pesticides abroad, but whether they have exporter's sales licenses is unknown.

Further, the new Regulations do not clearly indicate that ICAMA has the duty to check the IP background of the applications for new pesticide registration.

## **THAILAND**

The Thai Department of Intellectual Property (DIP) acknowledges the patent registration and re-registration backlog (particularly affecting pesticides) and that concern has been raised by both international and the Thai private sector.

In 2017, improvements in the registration and re-registration process have been realized. However, the backlog remains significant, considering that more re-registrations are scheduled to be undertaken in 2018.

The ongoing registration and re-registration issue will foster an increase of counterfeit and illegal pesticides used on Thai domestic and export crops, as the inability to access legally-registered pesticides will result in farmers and growers seeking access to illegal and counterfeit pesticides.

## **VIETNAM**

The Vietnam Ministry of Agriculture and Rural Development (MARD) implemented the Government's Decree No. 75/2009/ND-CP, providing for only five (5) years of regulatory data protection.

The status of registration for pesticides remains slow and unclear. There is no regulation that provides registrants with clear and predictable guidelines and timelines for approvals. This situation hinders agricultural innovations and new technology from entering Vietnam and further fosters a demand for counterfeit and illegal crop protection products in the market.

## **CAMBODIA**

The Cambodian government has yet to enact ten (10) years of regulatory data protection and to ensure that protection is properly enforced.

## **INDONESIA**

The Ministry of Agriculture has to improve regulations pertinent to the registrations process, aligned with the International Code of Conduct.

Permentan 39, the guiding national pesticide regulation, has no provision covering protection of regulatory data.

## **BANGLADESH**

There remains no stated provision for data protection, CBI protection, or patent protection. Clause 29(2)(e)(i) of "The Pesticide Ordinance (Amended), 2007" (formerly "The Pesticide Ordinance, 1971") merely mentions "safeguarding of secrecy of the formula of any brands of pesticides disclosed to it."

## **THE EUROPEAN UNION**

The European Court of Justice's judgment of 23 November 2016 in *Stichting Greenpeace and Pesticide Action Network Europe v. Commission* presents a real and immediate threat to the protection of commercially sensitive information and documents, which the plant protection industry has submitted to EU regulators over many years.

These submissions were made in order to satisfy mandatory data requirements under EU law for the granting of market approvals for products and/or the maintenance thereof. Specific safeguards regarding the protection of confidentiality of commercially sensitive information, including intellectual property, have been provided under the applicable regulatory regimes for plant protection products and biocides. These safeguards are emphasized in Regulation (EC) No 1049/2001 concerning access to documents, which is also the mechanism for processing requests for "environmental information." All of these safeguards reflect obligations under primary EU law (measures of the highest legally binding pedigree); articulated CLA Comments, Docket No. USTR-2015-0022, 2/3/2016 Page 8 of 8; in the Treaty on the Functioning of the EU; and the Charter of Fundamental Rights. These bind EU institutions and bodies. In addition, as all EU member states are members of the WTO and are bound by TRIPS requirements, this judgement, unless overturned on appeal, puts the European Union in contravention of TRIPS article 39.3, which specifies that trade secrets submitted for regulatory purposes to government agencies must be protected against unfair commercial use. The case has been sent back to the General Court for further review in accordance with the high court's decision. The hearing is set for March 23, 2018.

Should you have any questions or wish to discuss this matter further, please contact me directly at [dnelson@croplifeamerica.org](mailto:dnelson@croplifeamerica.org).

Thank you for your consideration of these comments.

Respectfully,



Douglas T. Nelson  
Senior Advisor for Trade, Intellectual Property & Strategic Issues

Cc: Sung Chang  
Daniel Lee