

GENERAL OVERVIEW ABOUT THE CURRENT EXTENSION OF TEST DATA PROTECTION IN LATINAMERICA¹

The term "Test Data " or "Registration Data" refers to the information gathered in the pre-clinical and clinical stages carried out for testing a drug that is to be provided to sanitary authorities in order to show the safety, efficacy and compliance with certain quality standards by the drug.

It is very important because only through such process it is possible to receive the authorization from the sanitary authority to market the drug, which constitutes a comparative advantage for the authorization holder.

As a background of the subject matter, it is worth pointing out that, like it had been the case in U.S. Law and most legal systems of Europe, before TRIPs was concluded in 1995 most legal regimes in Latin America did not provide any particular protection to such Test Data.

After the entrance in force of TRIPs (Article 39.3), most countries in Latin America enacted particular legislations providing legal protection in a similar way as it had been done in the U.S. under **Trade Secret Law (i.e. undisclosed valuable commercial information subject to reasonable efforts to keep it secret)**.

However, the most recent trend are **Exclusive Marketing Rights (or "Test Data Exclusivity)**, which refers to the fact that sanitary authorities are not able to disclose nor use test data protected in order to grant a health registration or marketing authorization to any person or legal entity who has not been authorized by the holder to use the data. Such exclusivity usually last 5 years in the case of pharmaceuticals and 10 years for agricultural chemicals. The main source of this source of legal protection are the Bilateral Free Trade Agreements (FTA) signed between the U.S. and some Latin-American countries/regions like Chile, Peru, Central America, Panama and others.

While in countries like Argentina and Brazil Test Data may be protected under the most traditional regime of Trade Secret Law, said protection is much more limited than that provided under Exclusive Marketing Rights.

¹ **Edited by Mariano Municoy (Lawyer at Moeller IP Advisors), August 2008.**

The information comprised in this article has been compiled, developed, and processed by different members and profesional related to Moeller IP Advisors.

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This is why those legislation (called “TRIPS-Plus”) setting forth exclusive marketing rights are so relevant for business and health purposes.

Here we offer an overview of the main characteristics of the particular legal regime in most countries of the region.

Mariano Municoy
Moeller IP Advisors

ARGENTINA

1.- Does regulatory test data protection through exclusive marketing rights exist in your country?

No but certain test data may be protected under Trade Secret Law .

2.- What are the conditions / requirements to get data exclusivity?

Since Exclusive Marketing Rights (based on clinical and pre-clinical trials), are not contemplated in Argentine Legislation, there are no requirements whatsoever.

However, at least formally speaking there is the legal protection under Trade Secret Law (Argentine Legislation N° 24,766), which has been invoked in many ongoing legal actions filed since but so far interpreted in a very narrow way. In these proceedings, the owner of test data has required the abstention of ANMAT to grant marketing authorization for a "similar drug" (since no real system of generics is in place for most drugs in Argentina given the lack of mandatory requirement for a similar drug to prove bioequivalence) containing a "new chemical entity" required by a third party. The unconstitutionality of the provision of the particular Law regulating the approval of similar products was also required claiming that Law 24.766 and National Decree 150/92 (regulating the processes of drug commercialization) were not TRIPs complying.

Moreover, it is important to point out that there may be other legal regimes for the data holder to seek legal protection such as authorial rights (that are similar to the copyright in the U.S.) and unfair competition (as a consequence of the use by non-authorized third parties of other people's efforts and results).

Unfortunately, the local judiciary has been very reluctant to accept an effective protection for test data so far.

3.- Which court is competent to decide on data exclusivity-related law suits?

It depends on the right invoked regarding the data protection.

For those legal proceeding where Law 24.766 (and National Decree 150/92); and/or TRIPs; and/or Patent Law 24.481 are invoked, the jurisdiction are the Civil and Commercial Federal Courts.

Regarding Authorial Rights (Law 11.723), the jurisdiction are the National civil courts, and in the case of unfair competition are the Federal Criminal and Correctional judges.

4.-Are there different kinds of data exclusivity (paediatric, orphan drug, new indications, new administration routes/formulations...) and do they differ in the respective requirements or exclusivity periods?

No.

5.- If there is no data exclusivity in place. Do you know if there are plans in your country to establish such a data exclusivity?

There are no projects regarding this issue so far. However, there is a sector lead by innovative pharmaceutical companies that is promoting the proper observance

of TRIPS Section 39.9 (Argentina is a member), which is the same that has filed the legal actions mentioned above.

Conversely, very important local laboratories have expressed their opposition to that position.

6.- Could you please provide citations and an English translation of the respective articles / rules of your national laws?

Art. 39 TRIPS:

"Members, when requiring, as a condition for granting the marketing authorization of pharmaceutical or of agricultural chemical products containing a new chemical entities, the submission of undisclosed test or other data, that involve a considerable effort, shall protect such data against unfair commercial use."

Unfortunately, Argentina has not carried out the statement of this regulation, being in permanent violation of the internationally undertaken obligations, since the legislation mentioned below, in what pharmaceutical products are concerned, sets forth greater restrictions to the data protection policy.

PHARMACEUTICAL PRODUCTS

General Principle:

Object of protection

- Information that certifies the efficacy and safety of the product.
- Secret
- With commercial value
- Object of reasonable measures to keep it secret
- It has to be the result of a significant technical and economical effort

Section 4 Law 24.766: *"For those cases which require approval of registration or marketing authorization of products that contain new chemical entities that do not have a previous registration in Argentina or in any other country, it is compulsory to submit to the health authority information that guarantees the efficacy and safety of the product. As long as such information includes **the requirements of Section 1** and is the result of a significant technical and economical effort, it shall be protected against any unfair commercial use as it is defined in the present law and cannot be disclosed."*

The requirements of Section 1 are (according with Sec. 39 Subsec. 2, TRIPS):

a) It must be **secret**, which means not being generally known nor easily accessible to those people within the circles where that information is usually used.

- b) It has to have **commercial value** due to its quality of secret; and
- c) It had been object of **reasonable measures** to keep them secret and adopted by the person that legally controls it.

Restrictions of the national law

According to Sec. 14 of the aforementioned Law, the same will be applicable regarding the information required in Section 4 from January 1, 1997, as long as the case refers to new products according to the terms of Section 4, Law 24.481. (It has to be a new invention – not covered within the prior art –, must involve inventive activity - when the creative process or its results are not derived from prior art normally known to a person skilled in the art field – and it is capable of industrial application - when the object matter of an invention leads to obtain an industrial result or product).

Note: Unfortunately this Section restrains the scope of the Confidentiality Law even more, since it restricts its scope to the information required in Section 4 from January 1, 1997, as long as the case refers to new products according to the terms of Section 4/Law 24.481 (let us bear in mind that that Section does not refer to the concept of "novelty" according to the patent law, but to the concept of "entity used for the first time").

Provisions regarding similar products. Non-existence of an exclusivity period.

Section 5 of the Confidentiality Law states: "For those products that have been registered or a marketing authorization has been granted in Argentina or in any country listed in Annex I, Decree 150/92 ², once the health authority has granted the approval in Argentina or in any country listed in Annex I Decree 150, the local health authority will proceed to approve or authorize the commercialization of similar products..."

Once the information required in this section has been submitted, the Ministry of Health and Social Action will have a **120 days continuous-time-period** to express itself, counted from the date of submission of the medicinal or pharmaceutical product. The approval of registration or marketing authorization set forth in the proceeding of approval for similar products stated in this article carried out by the local administrative authority **do not imply the use of confidential information protected by this law.**

Note: For the registration of similar products and contrary to the cases of new chemical entities, it is not required to submit information regarding the efficacy and safety of the product. This shortened proceeding allows to prove the safety

² USA, Japan, Sweden, Swiss Confederation, Israel, Canada, Austria, Germany, France, United Kingdom, Netherlands, Belgium, Denmark, Spain, Italy.

and efficacy of a pharmaceutical product with the simple presentation of a certificate of pharmaceutical product of a "similar" pharmaceutical product or any marketing evidence without the consent of the owner of the original registration.

CHILE

1.- Does regulatory test data protection through exclusive marketing rights exist in your country?

Yes, according to articles 89 to 91 of the Industrial Property Law, which refer to the information disclosed to the authority in order to obtain health registrations or authorizations. Likewise, Decree Nr. 153 dated July 20, 2005 from the Ministry of Health which "Establishes Mechanisms to protect data of "undisclosed" nature on the part of the Public Health Institute."

2.- What are the conditions / requirements to get test data exclusivity?

The protection is given to the undisclosed data, required by the authority when it demands undisclosed test data in order to authenticate the safety and efficacy of pharmaceutical or agricultural chemical products, related to a new chemical entity, which has not been previously approved by the competent authority. The protection applies to data of confidential nature, according to current legislation.

It is understood that the data protected are of undisclosed nature and that there have been taken reasonable measures in order to keep them in such condition so said data is not normally known nor can be easily accessed by people belonging to groups or community in which this kind of information is normally used.

It has to be understood that a new chemical entity is an active principle that has not been included before in any previous health registrations or authorizations or that has not been marketed in the National Territory before requesting a health registration or authorization.

It is understood as an active principle a substance endowed with one of more pharmacological effects or agricultural chemical uses, regardless the form, expression or disposal, including its salts and coordination compounds. Under no circumstances shall the following be considered as new chemical entity:

1. Uses or therapeutic indications, other than those authorized in other health registrations or authorizations of the same chemical substance.
2. Changes regarding the way a chemical substance is administered or divided into doses, which have not been authorized in other previous health registrations or authorizations.
3. Changes to pharmaceutical forms, formulations or combinations of chemical entities that have already been authorized or registered.
4. Salts, coordination compounds, crystalline forms or those chemical structures that are base on a chemical structure having a previous registration or authorization.

In order for the Applicant to benefit from the protection of this regulation, as an indispensable requirement, he/she must expressly indicate in the application for the health registration or authorization the "undisclosed" nature of the referred test data. If the Applicant omits the inclusion of this declaration in his/her application for health registration, said data will not be considered as "data exclusivity"

The protection granted by the law establishes that the competent authority will not be able to disclose nor use said data in order to grant a health registration or marketing authorization to any person or legal entity who has not been authorized by the holder in order to use them during a period of 5 years in the case of pharmaceuticals and 10 years for agricultural chemicals, counted from the date of the first health registration or authorization granted by the Public Health Institute or by the Agriculture and livestock Service (SAG by its Spanish acronym) as the case may be.

3.- Which court is competent to decide on data exclusivity-related law suits?
The competent courts are the ordinary courts of justice.

4.-Are there different kinds of data exclusivity (paediatric, orphan drug, new indications, new administration routes/formulations...) and do they differ in the respective requirements or exclusivity periods?

There are no different kinds of data exclusivity, which is only available for new chemical entity.

Under no circumstances shall the following be considered as new chemical entity:

1. -Uses or therapeutic indications, other than those authorized in other health registrations or authorizations of the same chemical substance.
2. -Changes regarding the way a chemical substance is administered or divided into doses, which have not been authorized in other previous health registrations or authorizations.
3. -Changes to pharmaceutical forms, formulations or combinations of chemical entities, which have already been authorized or registered.
4. -Salts, coordination compounds, crystalline forms or those chemical structures that are based on a chemical structure having a previous registration or authorization.

5.- If there is no data exclusivity in place. Do you know if there are plans in your country to establish such a data exclusivity?

There has been many discussions around this topic before and after its implementation.

6.- Could you please provide citations and an English translation of the respective articles / rules of your national laws?

Industrial Property Law N. 19.996-Arts. 89-90 91
Decree 153 of the Ministry of Health

CHILE

Industrial Property Law N. 19.996:

INFORMATION DISCLOSED TO THE AUTHORITY TO OBTAIN HEALTH REGISTRATIONS OR AUTHORIZATIONS

Article 89. - When the Institute of Public Health or the Agriculture and Livestock Service (SAG by its Spanish acronym) requires the submission of undisclosed information, test data or other information of data exclusivity nature, relative to safety and efficacy of pharmaceuticals or agricultural chemicals which use a new chemical entity, one which has not been previously approved by the competent authority, said information or data shall be considered as confidential pursuant the governing law.

The nature of “undisclosed” is deemed satisfied if the data has been subject to reasonable measures to be kept undisclosed and these data are not generally known to or easily accessible by, people within the circles in which this type of information is normally used.

The competent authority shall not disclose nor use such data in order to grant a health registration or authorization to someone who has not been authorized by the holder thereof for a period of 5 years for pharmaceuticals and 10 years for agricultural chemicals as from the first health registration or authorization granted by the institute of Public Health or the Agricultural or Livestock Service (SAG by its Spanish Acronym) as the case may be.

In order that the Applicant can be benefited from the protection under this article, the undisclosed nature of such test data shall be expressly indicated in the application for the health registration or authorization.

Article 90 *It is understood that a new chemical substance is that active principle which has not been included before in previous health registrations or authorizations granted by the Institute of Public Health or by the Agricultural and Livestock Service as the case may be, or that have not been marketed in National Territory prior to the health registration or authorization.*

For purposes of this paragraph, an active principle is understood as a substance endowed with one or more pharmacological effects or agricultural chemical uses, regardless of the form, expression or disposition thereof, including its salts and coordination compounds. Under no circumstances shall the following be considered as a new chemical substance

1. Therapeutic uses or indications other than those authorized in other prior health registrations or authorizations of the same chemical substance
2. Changes in the method of administration or forms of dosage from those authorized in other prior health registrations or authorizations of the same chemical substance.
3. Changes in authorized or registered pharmaceutical forms, formulations or combinations of chemical substances.
4. The salts, coordination compounds, crystalline forms or such chemical structures that are based on a chemical substance having a prior health registration or authorization.

Article 91. - Protection under this paragraph shall not apply when

- a) The holder of the test data as referred in article 89 had engaged in unfair practices declared contrary to fair competition, which were directly related to the use of exploitation of such information according to the firm or final binding decision of the Antitrust Court.
- b) Considering justified reasons of public health, national security, non-commercial public use, National emergency or other circumstances of urgent nature declared so by the competent authority; the protection set forth in article 89 can be terminated.
- c) The pharmaceutical or agricultural chemical product required an obligatory license pursuant to the stipulations in this law.
- d) The pharmaceutical or agricultural chemical product has not been commercialised within the National territory by the end of a twelve-month period counted from the date of the health registration or authorization granted in Chile
- e) The pharmaceutical or agricultural chemical product has a health registration or authorization abroad and has been in force for more than 12 months.

Decree 153 of the Ministry of Health

UNDERSECRETARIAT OF PUBLIC HEALTH

MECHANISMS ESTABLISHED FOR THE PROTECTION OF "UNDISCLOSED DATA"
BY THE INSTITUTE OF PUBLIC HEALTH

Number 153 –Santiago July 20, 2005 considering what has been stated in Decree Law N° 2763, 1979 and in the unique article of Law 19.996, which among other aspects, incorporated paragraph 2° of Title VIII of

Law 19039 about Industrial Property, the information submitted by the Industrial Property Department of the Ministry of Economy, by official notice N° 2692 dated April 12, 2005, which contains the opinions supported by entities of the field related to the subject, the proposal of the Institute of Public Health submitted by official notice N° 767, dated April 29, 2005, and by virtue of the authority vested in me by article 32 N°8 of the Political Constitution of the State I hereby declare the following

Decree

1°. - The present decree shall regulate the mechanisms applied by the Institute of Public Health in order to comply with the provisions of paragraph 2 of Title VIII of Law 19039, modified by Law 19.996.

2°. - For purposes of the present decree, a new chemical entity is understood as that active principle or substance endowed with one or more pharmacological effects, regardless of the form, expression or disposition thereof, including its salts and coordination compounds, which as of the date of the application for the health registration or authorization at the Institute of Public Health either of the following conditions are met:

a) If it has not been previously included in health registrations or authorizations granted by the Institute of Public Health

B) If it has not been commercialised in National territory

3°. Under no circumstances shall the following be considered as a new chemical entity

a) Therapeutic uses or indications other than those authorized in other prior health registrations or authorizations of the same chemical substance

b) Changes in the method of administration or forms of dosage from those authorized in other prior health registrations or authorizations of the same chemical entity.

c) Changes in authorized or registered pharmaceutical forms, formulations or combinations of chemical substances (entities)

The salts, coordination compounds (complexes), crystalline forms or such chemical structures that are based on a chemical substance (entity) having a prior health registration or authorization.

4°. - The Institute of Public Health shall have the obligation of maintaining as confidential information, the data originated from the undisclosed data, which has been submitted to a person or legal entity at the moment of applying for a health

registration or authorization of pharmaceutical product that uses a new chemical entity.

The studies that are intended to guarantee the efficacy and safety of the product, being understood by such, the pre-clinical studies: selective pharmacological in animals and toxicological in animals as well as the clinical studies, regardless the phase they belong to (one, two or three.)

5º. - The protection application of undisclosed information shall be submitted to the Institute, as a part of the application for the health registration or authorization through the form provided by the Institute of Public Health, which will be enclosed together with the declaration, which will be mentioned in the following number and it will be enclosed together with the antecedents of such attributed nature, notwithstanding the compliance of the rest of regulatory requirements of the case.

6º. - In order that the interested party can be benefited from this protection, it has to be enclosed a declaration on which the data having undisclosed nature are precisely indicated and which comply with the following requirements:

a) All the reasonable measures have been maintained in order to keep the data as "undisclosed."

b) Data that are not of general knowledge nor can be easily accessed to not even by people belonging to the circles in which that kind of information is normally used.

c) Being the holder of the undisclosed data or having the holder's authorization to use them.

d) The holder of the data has not been convicted according to the firm or final binding decision of the Antitrust Court for being engaged in unfair practices declared contrary to fair competition, which were directly related to the use of exploitation of such information

c) The non-existence of a health registration or authorization abroad, or in case of having one, it shall be indicated the date and place of the granting.

7º Within a term of 15 days, counted from the submitting date by means of justified resolution, the institute shall declare the inadmissibility of the protection application that is dealt with in this decree.

This inadmissibility shall only be founded in the non-compliance of the requirements referred in the law or that is clearly understood that the information is of general knowledge or can be easily accessed to in the terms exposed in letter b) of Nº7, or else, any of the circumstances appearing in number 11 of this decree may apply.

8° Once the health registration of a product using a new chemical entity is granted, the institute shall not use the information included in the protected data for the purposes of granting a health registration or authorization to other pharmaceutical product unless having the holder's authorization to use them.

According to article 89 of Law 19.039, the protection granted to the undisclosed Data will be extended from the resolution date in which the registration to the pharmaceutical product that uses the new chemical entity is granted and for a period of 5 years counted from that date.

In the case the granting of the requested registration for the pharmaceutical product is rejected, the Institute shall return to the applicant all the information regarding which undisclosed data protection has been requested

If the rejection is based on administrative or procedural reasons, with lack of health or public health content, the applicant will be notified of such situation and the applicant shall have a term of one month to overcome such objections. During this term, the information shall be maintained as confidential, however once this period has expired without having performed the administrative corrections, the procedure shall be as previously indicated.

9° -According to article 91 of the Law 19039 it shall not apply to grant or continue with the protection already granted in the following circumstances:

a) The holder of the test data or studies as referred in N°5 of this Decree has engaged in unfair practices declared contrary to fair competition, which were directly related to the use of exploitation of such information according to the firm or final binding decision of the Antitrust Court.

b) Considering justified reasons of public health, national security, non-commercial public use, National emergency or other circumstances of urgent nature declared so by the supreme decree of the Ministry of Health; which justifies the fact of terminating the granted protection.

c) The pharmaceutical product required an obligatory license pursuant to the stipulations in Law 19.039.

d) The pharmaceutical product has not been commercialised within the National territory by the end of a twelve-month period counted from the date of the health registration or authorization granted in Chile

e) The pharmaceutical product having a health registration or authorization abroad and has been in force for more than 12 months

10° The present decree will be in force from its publication date in the Official Gazette in case this was the same or subsequent to the date of entry into force, or else, to the latter, if this was subsequent to the present decree.

Let it be communicated and duly published, RICARDO LAGOS ESCOBAR,
President of the Republic, Pedro García Aspillaga, Health Minister

Which I hereby record for your information. Yours sincerely, Cecilia Villavicencio
Rosas, Under secretariat of Public Health

GENERAL CONTROLLERSHIP OF THE REPUBLIC
Legal Division

Being within the scope the decree N° 153, 2005 Ministry of Health

N° 54-923, Santiago November 22, 2005

COLOMBIA

1.- Does regulatory test data protection through exclusive marketing rights exist in your country?

Yes. Data exclusivity for pharmaceutical products (Decree 2085 of 2002) exists as well as for agrochemical products (Decree 502 of 2003) and both for a period of 5 years. The focus of this brief is on pharmaceutical products.

2.- What are the conditions / requirements to get data exclusivity?

The two main requirements are as follows:

- a) the active ingredient (molecule) may not have been previously included in the pharmacological norm in Colombia (published by INVIMA- the local Regulatory Agency)
- b) to obtain the data must have required a considerable effort for the applicant (this is based on a declaration made by the applicant to the effect)

3.- Which court is competent to decide on data exclusivity-related law suits?

Data exclusivity is an administrative decision issued by the health authority (INVIMA) . Therefore, any matters relating to the issuance of data exclusivity or registrations overlooking data exclusivity would be dealt with at the INVIMA, the Counsel of State (Supreme Court for Administrative matters) is the appropriate jurisdiction.

4.-Are there different kinds of data exclusivity (paediatric, orphan drug, new indications, new administration routes/formulations...) and do they differ in the respective requirements or exclusivity periods?

There is only one kind of data exclusivity and it is for a new chemical entity, understood as the active ingredient (molecule) which has not been previously included in pharmacological norms in Colombia, and its protection is for 5 years. No other protection is available .

5.- If there is no data exclusivity in place. Do you know if there are plans in your country to establish such a data exclusivity?

6.- Could you please provide citations and an English translation of the respective articles / rules of your national laws?

Decree 2085/2002

DECREE 2085 OF 2002

September 19, 2002

"Whereby regulations that relate to the information submitted to secure the sanitary registration of new chemical entities in the area of medical drugs are issued"

THE PRESIDENT OF THE REPUBLIC OF COLOMBIA

Exercising his constitutional and legal powers, specially those vested in him by Article 189 (11) of the Political Constitution, and in furtherance of Decree 1290 of 1994 and article 245 of Law 100 of 1993

CONSIDERING

That article 19 of Decree 677 of 1995 establishes that every medical drug, whether included in pharmacological norms or a new drug, requires a sanitary registration issued by the competent sanitary authority for the production, importation, exportation, processing, bottling, packaging, sale and commercialization thereof.

That article 20 of Decree 677 of 1995 establishes the technical and legal requirements for granting sanitary registration of medical drugs contained in pharmacological norms and article 26 of the said decree establishes the requirements for granting the sanitary registration of new medical drugs.

That article 25 of Decree 677 of 1995 establishes the process of sanitary registration of medical drugs contained in pharmacological norms.

That it is necessary now to regulate the treatment and protection of undisclosed information that is submitted for granting the sanitary registration of new medical drugs, specifically in respect of those related to new chemical entities in line with the rules of articles 26 et seq. of the aforementioned decree.

Now therefore, the President

DECREES

ARTICLE ONE: For the purposes of this decree, a new chemical entity is defined as the active principle that has not been included in Pharmacological Norms in Colombia.

PARAGRAPH. - Any new uses or any second uses shall not be deemed a new chemical entity, nor any novelties or changes regarding the following aspects:

Pharmaceutical forms, indications or second indications, new combinations of

known chemical entities, formulations, dosage forms, ways of administration, modifications involving changes in pharmacokinetics, conditions of commercialization and packaging and generally those involving new presentations.

ARTICLE TWO: Where the commercialization of a new chemical entity is approved, the related undisclosed information may not be used directly or indirectly as supporting information for the approval of a separate application relating to the same new chemical entity.

PARAGRAPH. - Generating the undisclosed information the use of which is protected hereby must have required considerable effort on the part of the person submitting it to the competent sanitary authority.

ARTICLE THREE: The protection of the regulated herein shall be as follows:

- 3 years counted as of the date of approval of commercialization in Colombia for those applications filed during the first year following the date on which this decree comes into force.
- 4 years counted as of the date of approval of commercialization in Colombia for those applications filed during the second year following the date on which this decree comes into force.
- 5 years counted as of the date of approval of commercialization in Colombia for those applications filed during the third year following the date on which this decree comes into force.

As long as this rule is fully observed, nothing shall preclude the use of summary approval procedures that are based on bioequivalence and bioavailability studies.

ARTICLE FOUR: The protection referred to herein shall not apply in the following cases:

- a) Where the holder of the sanitary registration of the new chemical entity authorizes the use of the undisclosed information as support of a separate application being filed after his own.
- b) Where the new chemical entity for which a sanitary registration is applied for is similar to another one authorized and commercialized in Colombia and the protection period set in article 3 above has expired.
- c) Where it is necessary to protect the public interest as determined by the Ministry of Health.
- d) Where the new chemical entity with a sanitary registration has not being

commercialized in the country during the first year after the said commercialization permit is issued.

ARTICLE FIVE: This decree shall come into force as from the date of its promulgation in the Official Gazette (Diario Oficial) and shall apply to all sanitary registration applications that are filed thenceforward.

PROMULGATE AND ENFORCE THE ABOVE

(Signed by the President and the Ministry of Health

COSTA RICA

1.- Does regulatory test data protection through exclusive marketing rights exist in your country?

There is no data exclusivity but protection under Trade Secret Law, which complies with article 39.3 of TRIPS.

2.- What are the conditions / requirements to Trade Secret Protection?

The information must be related with the nature, characteristics and objectives of the product and with the methods or processes of production in case of trade or industrial secrets. Test data protection applies to any information obtained as a result of a considerable effort and for undisclosed data required by the authority to grant the marketing authorization for a pharmaceutical or an agrochemical product. It will be protected against any unfair commercial use or any disclosure

3.- Which court is competent to decide on data exclusivity-related law suits?

For administrative issues the Industrial Property Office of Costa Rica

For penal issues the Penal Court of Costa Rica

4.-Are there different kinds of data exclusivity (paediatric, orphan drug, new indications, new administration routes/formulations...) and do they differ in the respective requirements or exclusivity periods?

The current law makes no distinctions with regard to data exclusivity

5.- If there is no data exclusivity in place. Do you know if there are plans in your country to establish such a data exclusivity?

There are some discussions on this topic which is addressed in the FTA signed between the U.S. and the CAFTA region of which Costa Rica is a member.

6.- Could you please provide citations and an English translation of the respective articles / rules of your national laws?

Law 7975 regarding Undisclosed information

COSTA RICA

Law 7975 - Undisclosed Information
Arts. 2° - 8° - 9° and 10°

The Legislative Assembly of the Republic of Costa Rica decrees:

Purposes

1. The purposes of the present law are the following:

- a. To protect the undisclosed information concerning commercial and industrial secrets.
- b. To contribute promoting the technological innovation and the transfer and spreading of technology, in mutual benefit of producers and users, of technological knowledge, in such a way to contribute to the socioeconomic welfare and the balance between rights and obligations.

Prescriptive Jurisdiction of Protection

2. Is to be protected the undisclosed information concerning commercial and industrial secrets that a person or legal entity holds confidentially to prevent the information legally under their control to be disclosed, acquired or used by thirds without consent, contrary to a fair commercial use, as long as such information goes together with the following:

a. It must be secret, which means not be generally known nor easily accesible to those people within the circles where that information is usually used.

b. That information has to be legally under the control of a person that has adopted reasonable and proporcional measures to keep it secret.

c. It has to have commercial value due to its quality of secret.

The undisclosed information refers especially to the nature, characteristics or purposes of the products and the methods or processes of production.

For purposes hereof the first paragraph of the present article and defined as opposite forms from fair commercial uses are the practices of breach of contracts, betrayal of trust, the instigation to a crime, and the acquisition of undisclosed information by thirds that had known the implication of those practices or had not known it due to a serious negligence. The information considered undisclosed has to be supported by documents, electronic or magnetic media, optic disc, microfilms, films or other similar elements.

Protection of data provided to obtain approval for the commercialization of pharmaceutical or agrochemical products

8. If, as a condition for the approval of the commercialization of pharmaceutical or agrochemical products that make use of new chemical entities, it is required to submit proof data or other non-disclosed information which production implies a considerable effort, the above mentioned data will be protected against any disloyal commercial use and disclosure, except for when the use of such data is required to protect the public or when measures are taken to guarantee the protection against any disloyal commercial use.

Notwithstanding the stated in the first paragraph of the present article, the authorities concerned are allowed to use proof data without disclosing the protected information, when it comes to studies included in the regulations about registration of drugs or agrochemicals to prevent practices that might lead the consumer to error or to protect the human life, health or safety, or the animal or vegetal life or health, or the environment in order to prevent the abuse of Intellectual Property Rights, or the turning to practices that might unjustifiably restrict the trade.

Protection of undisclosed information in legal or administrative proceedings

9. In any legal or administrative proceeding where one of the parties has to reveal undisclosed information, the authority concerned must adopt all necessary measures to impede its disclosure to third parties. None of the parties in the process is allowed to disclose or make use of such information.

Protection

10. The protection of undisclosed information does not grant any right similar as patents do. It is characterized by granting a restricted right of property as regards its possession and usufruct, as long as the provisions stated in the first paragraph of article 2 of the present law are observed.

CUBA

1.- Does regulatory test data protection through exclusive marketing rights exist in your country?

No. Cuba recognizes or issues Author Certifications for an invention while the protection rights apply only to the State.

As a contracting member state of TRIPS it has been demanded that Cuba should temper its commitment to those trades. Notwithstanding this, the new legislation related to patent and inventions protection is still pending. Data exclusivity is in anyway relying on Decree Law 68 dated May 14, 1983 modified through Decree Law 160, which basically modifies Art. 39 of Decree Law 68 that protected pharmaceutical and agrochemical products exclusively through the Author Certification for an invention.

This is a sui generis way of protection that recognizes inventorship to the authors, but offers exclusively protection rights to the cubean state, excluding them from the patent protection.

2.- What are the conditions / requirements to get data exclusivity?

Every natural person or legal entity can apply for a patent for pharmaceutical or agrochemical products. Once the patent was filed by the Cuban Patent Office, that will examine the application considering if it will be published or not. The Cuban Patent Office has 24 months to do so and to mention that it is a „Patent Application for a Pharmaceutical Product“

According to current regulation it becomes easier to file patent application but the patent protection is not regulated.

3.- Which court is competent to decide on data exclusivity-related law suits?

4.- Are there different kinds of data exclusivity (paediatric, orphan drug, new indications, new administration routes/formulations...) and do they differ in the respective requirements or exclusivity periods?

5.- If there is no data exclusivity in place. Do you know if there are plans in your country to establish such a data exclusivity?

The new regulation is waiting for approval but nobody knows exactly the content of the new regulation because it has only been considered by few people and either its text or its content itself have been modified several times. For this reason it is very difficult to comment or give an opinion on it, because it is really not known.

6.- Could you please provide citations and an English translation of the respective articles / rules of your national laws?

Decree Law 160 „ To make easier the submissions and changes of patent applications for pharmaceutical and agrochemical products“

CUBA

Decree Law 160

„To make easier the submissions and changes of patent applications for pharmaceutical and agrochemical products“

Article 1.-

It is accepted the filing of patent applications for pharmaceutical and chemical products for agriculture by the National Office for Inventions, Technical Information and Trademarks – herein after – „The Office“-

Article 2.- To modify Art. 39 of Decree Law 68 of 1983 , that herein after will read as follows:

„Article 39:

1.- It will be issued a Certification for the author of the invention , exclusively for the following inventions:

- 1) Plant varieties and animal breeds
- 2) Microorganisms strains
- 3) Nutrients and medicinal substances
- 4) Prophylactic methods, diagnostic and treatment of humans , animals and plants diseases
- 5) Chemical developed substances
- 6) Procedures that will require nuclear technology, the substances obtained and the ways of using nuclear energy
- 7) New uses of equipments, procedures and products
- 8) Objects that according to the established order are considered secrets

2.- Notwithstanding the aforesaid , for pharmaceutical products and for chemical products for agriculture, the applicant could choose any of the following options: for a Certificate of Patent or for the Certificate of Author of the Invention , in which case will apply the current regulation for each one. „

Article 3.-

1.-Any natural person or legal entity may apply for patents of pharmaceutical or for chemical products for agriculture.

2.- The applicants which are not permanent residents in the territory of Cuba must authorize a national representative

3.- In case the applications concerning to inventions were performed by a worker during his contract or employment relationship of services or with the effective

assistance of the legal entity that hires his services, the application will be filed in the name of the legal entity.

Article 4.-

1.- After filing the patent for a pharmaceutical or a chemical product intended for agriculture, the Office will proceed to examine if the submission includes the anticipated formal conditions in order to publish it after an 18 months term, counted since the date of submission or the priority date if one were invoked and previous to a 24 months term counted the same way.

2.- In each case, the publication will make special mention of the condition of „filing of a patent of a pharmaceutical product or a chemical product intended for agriculture“.

Article 5.-

The patent applicant for pharmaceutical products or chemical products intended for agriculture is obliged to inform the Office all the data relating to changes or modifications produced in relation with the applicant, his name and address, and his representative's.

Article 6.-

1.- For those submissions for certification for the author of an invention that have not been abandoned, refused or conceded relating to pharmaceutical products and chemical products intended for agriculture that have not been object of change according to the provisions included within the Decree-Law, will be of application the provisions included in the Decree-Law 68 of 1983.

2.- The same treatment will apply to the submissions for the certification for the author of pharmaceutical products or chemical products intended for agriculture that are submitted after the entrance in force of the stated here, notwithstanding that the aforesaid submissions are allowed at any time of the proceeding, to perform the change to a file of a patent.

Transitory provision

SINGLE: The people or legal entities that have required certifications for the author of an invention for pharmaceutical products or chemical products intended for agriculture that have not been abandoned, denied or conceded at the moment of entrance in force of the present Decree-Law and within the cannot-be-extended term of 3 months, counted since that date, are allowed to require the Office, previous payment of the corresponding fees, the change of their submissions for author of invention to a file of a patent.

To this end, those interested will perform all the modifications they consider pertinent in relation with the submission, as long as those modifications do not include new material.

DOMINICAN REPUBLIC

1.- Does regulatory test data protection through exclusive marketing rights exist in your country?

Yes regulatory test data protection through exclusive marketing rights exists according to Arts. 181- Law 20-00.

2.- What are the conditions / requirements to get data exclusivity?

To get data protection for marketing authorization the national competent authority in the Dominican Republic (HA in case of pharmaceutical products) requires the submission of undisclosed data concerning the efficacy and safety of a new pharmaceutical or agrochemical product for its marketing approval. The national competent authority shall not permit third persons without the consent of the person who provided the information to commercialize a product on the basis of :

- a) the information or,
- b) the approval granted to the person who submitted the information

When the national competent authority permits third persons to submit evidence concerning the efficacy and safety of a product that was previously approved in other country (i.e. evidence of prior marketing approval) , for the marketing approval of a new pharmaceutical or agrochemical product, it shall not permit third persons without the consent of the person who previously obtained such approval in the other country, to obtain authorization or market a product on the basis of:

- a) The evidence of prior marketing approval in the other country (country of reference) or,
- b) The information concerning the safety and efficacy that was previously submitted to obtain the marketing authorization in the other country.

To receive this protection the person providing the information in the other country shall seek approval in the Dominican Republic within five years after obtaining the marketing approval in the other country.

The information accessible within the public domain will not be considered as undisclosed data.

The data protection is of five years for pharmaceutical products and ten years for agrochemical products , counting from the date the approval was granted in the Dominican Republic.

Patent Linkage

1.- When requesting the marketing authorization of a new pharmaceutical product, it shall be submitted a notarized affidavit, including a list of all patents in full force in the Dominican Republic protecting the product or its authorized use, if any, including the term of such patents.

2.- When the national competent authority, as a condition for approving the marketing of pharmaceutical product, allows third parties to rely on evidence or information concerning the safety and efficacy of a product that was previously approved, such as evidence or prior marketing approval in the Dominican Republic or in another country, the national competent authority shall request any of the following:

- a) A notarized affidavit, declaring that the product or its approved use is not protected by a Dominican Republic patent.
- b) A written authorization from the patent owner authorizing the marketing of the product, if there is a patent in the Dominican Republic.
- c) A notarized affidavit declaring the existence of a patent, its expiration date and that the applicant will not enter into the market before the expiration of the patent.

If the application for the marketing approval of a product is filed with the documentation indicated in cases 2 a) or 2 b) , the national competent authority shall proceed with the marketing approval . If the application for the marketing is filed with the documentation indicated in case 2 c) , the national competent authority shall examine the application, but it shall not grant the marketing approval until the patent has expired.

The national competent authority shall inform the patent owner the identity of any other person who requests the marketing approval of a product that has been identified as having a patent that protects such product or its use.

3.- Which court is competent to decide on data exclusivity-related law suits?

The Civil and Commercial Chamber of the First Instance Court is competent to decide on data exclusivity related law suits

4.-Are there different kinds of data exclusivity (paediatric, orphan drug, new indications, new administration routes/formulations...) and do they differ in the respective requirements or exclusivity periods?

The data exclusivity is granted to a new product that is the one that does not contain a chemical entity that has been previously approved in the Dominican Republic.

5.- If there is no data exclusivity in place. Do you know if there are plans in your country to establish such a data exclusivity?

6.- Could you please provide citations and an English translation of the respective articles / rules of your national laws?

Art. 181 of Law 20-00 on Industrial Property (See complete text on the next page)

DOMINICAN REPUBLIC

Article 181. Information and data protection for marketing approval

1. When the national competent authority requires or permits, as a condition of approving the marketing of a new pharmaceutical or agricultural chemical product, the submission of undisclosed data concerning safety or efficacy of said product, the National Competent Authority shall not permit third persons, without the consent of the person who provided the information, to market a product on the basis of (1) the information, or (2) the approval granted to the person who submitted the information for at least five years for pharmaceutical products and ten years for agricultural chemical products from the date of approval in the Dominican Republic.

2. When the national competent authority permits, as a condition of approving the marketing of a new pharmaceutical or agricultural chemical product, third persons to submit evidence concerning the safety or efficacy of a product that was previously approved in another territory, such as evidence of prior marketing approval, said National Competent Authority shall not permit third persons, without the consent of the person who previously obtained such approval in the other territory, to obtain authorization or to market a product on the basis of (1) the evidence of prior marketing approval in the other territory, or (2) information concerning safety or efficacy that was previously submitted to obtain marketing approval in the other territory, for at least five years for pharmaceutical products and ten years for agricultural chemical products from the date the approval was granted in the Dominican Republic to the person who received approval in the other territory. In order to receive protection under this paragraph 2, it shall be required that the person providing the information in the other territory seek approval in the territory of the Party within five years after obtaining marketing approval in the other territory.

3. The national competent authority shall protect the undisclosed information against disclosure except where necessary to protect the public, and it may not consider the information accessible within the public domain as undisclosed data. Notwithstanding the foregoing, if any undisclosed information concerning safety and efficacy submitted to the national competent authority, or an entity acting on behalf of the national competent authority, for purposes of obtaining marketing approval is disclosed by such entity, the national competent authority shall protect such information from unfair commercial use in the manner set forth in this Article.

4. For purposes of this Article, a new product is one that does not contain a chemical entity that has been previously approved in the Dominican Republic. A chemical entity does not mean an inactive ingredient that is contained in a new pharmaceutical product.

Paragraph 1. Patent linkage

1. Any person that request the marketing approval of a new pharmaceutical product shall submit to the national competent authority a notarized affidavit by the time of the request of the marketing approval of a new pharmaceutical product, which may include a list of all patents of products in full force, if there are any, that protect such product or its authorized use, during the patent term in the Dominican Republic, including the term of such patents. The national competent authority shall establish a record which shall be available to the public, wherein may be listed all patents involving pharmaceutical products.
2. When according to Article 181, 1 and 2, the national competent authority, as a condition for approving the marketing of a pharmaceutical product, permits third persons, other than the person originally submitting safety or efficacy information, to rely on evidence or information concerning the safety and efficacy of a product that was previously approved, such as evidence of prior marketing approval in the Dominican Republic territory or in another country, said national competent authority shall request the submission of one of the following:
 - a) A notarized affidavit, declaring that there is no patent in force in the Dominican Republic that protects the product requested or its approved use.
 - b) A written authorization from the patent owner by which it is authorized the marketing of the product, if exist a patent in force in the Dominican Republic.
 - c) A notarized affidavit declaring that exists a patent, its expiration date and that the applicant will not enter into the market before the expiration of the patent.

The national competent authority shall require that these affidavit and marketing authorization be made with respect to patents, in as much as they exist, according to point 1 of this paragraph.

3. If the application for the marketing approval of a product is made with the documentation indicated in 2 a) or 2 b), the national competent authority shall proceed with the marketing approval. If the request is made with the documentation indicated in 2, c), the national competent authority shall examine the application, but it shall not grant the marketing approval until

the patent protection term has expired.

4. The national competent authority shall inform the patent owner of the request and the identity of any other person who requests the approval to enter into the Dominican market during the term of a patent that has been identified as claiming the approved product or its approved use.

ECUADOR

1.- Does regulatory test data protection through exclusive marketing rights exist in your country?

No but there is legal protection under Trade Secret Law that governs this topic in those countries members of the Andean Community. Moreover, the Trips agreement has been ratified by Ecuador and therefore it is part of national regulation.

Data protection under Trade Secret Law is set forth in Chapter II corresponding to Undisclosed Information – Art. 260 to 266 of the Andean Decision 486.

2.- What are the conditions / requirements to get data exclusivity?

According to Art. 260 of the Andean Decision 486

„Any undisclosed information that a natural or legal person has, shall be deemed as an entrepreneurial secret, which can be used in any productive, industrial or commercial activity, and which may be liable for transmission to a third party, to the extent that such information :

- a) is secret in the sense that, as an assembly, or in the configuration and exact arrangement of its elements shall not be known in general, neither shall it be easily accessible to the persons who integrate the spheres which normally handle the type of information involved;
- b) has a commercial value for being secret; and
- c) shall have been the subject matter of reasonable measures adopted by its legitimate possessor to maintain it secret.

Information on an industrial secret shall necessarily be referred to the nature, characteristics or purposes of the products, to the methods or processes for production, or the means or manners of distribution or commercialization of the products or the rendering of the services.

3.- Which court is competent to decide on data exclusivity-related law suits?

The infringement of any Intellectual Property right stated in the Ecuadorian and Andean Laws will derive in administrative and civil actions, without excluding criminal actions.

Civil actions can be filed before Contentious Court and Patents and Trademarks Office, criminal actions are filed before the courts with intervention of the Public Prosecutor's Office.

4.-Are there different kinds of data exclusivity (paediatric, orphan drug, new indications, new administration routes/formulations...) and do they differ in the respective requirements or exclusivity periods?

Data exclusivity is not divided into different types; all data exclusivity is considered under Intellectual Property Law and Andean Decision 486. However,

take note that the information provided to the Authorities is not disclosed to public.

Additionally, take note that Andean Decision 632 clarifies paragraph 266 of the Andean Decision 486 within establishing time periods during which a Member Country shall not authorize a third party, without the consent of the person who had originally presented such test data, to market a product based on that information.

Additionally, when negotiating the Free Trade Agreement with the United States, it was intended to encourage data exclusivity; but strong opposition was raised against this issue.

5.- If there is no data exclusivity in place. Do you know if there are plans in your country to establish such a data exclusivity?

6.- Could you please provide citations and an English translation of the respective articles / rules of your national laws?

Art. 260 to 266 of the Andean Decision 486

ECUADOR

Art. 260 to 266 of the Andean Decision 486

CHAPTER II OF THE ENTREPRENEURIAL SECRETS

Article 260. - Any undisclosed information that a natural or legal person has, shall be deemed as an entrepreneurial secret, which can be used in any productive, industrial or commercial activity, and which may be liable for transmission to a third party, to the extent that such information:

- a) Is secret in the sense that, as an assembly, or in the configuration and exact arrangement of its elements shall not be known in general, neither shall it be easily accessible to the persons who integrate the spheres which normally handle the type of information involved;
- b) Has commercial value for being secret; and
- c) Shall have been the subject matter of reasonable measures adopted by its legitimate possessor to maintain it secret.

Information on an industrial secret shall necessarily be referred to the nature, characteristics or purposes of the products; to the methods or processes for production; or to the means or manners of distribution or commercialization of the products or the rendering of the services.

Article 261. - For purposes of this Decision, such information that must be disclosed according to a legal provision or judicial order shall not be deemed an entrepreneurial secret.

Information provided to any authority by the person possessing it shall not be deemed in the public domain or disclosed through legal provision, when supplied for the purpose of obtaining licenses, permits, authorizations, registrations or any other acts of the authorities.

Article 262. - Whoever licitly controls an entrepreneurial secret, shall be protected against practices contrary to fair commerce, disclosure, acquisition or use of such secret, by third parties.

Unfair competition acts performed with respect to an entrepreneurial secret shall be:

- a) To use commercially, without authorization from its legitimate possessor, an entrepreneurial secret which has been accessed subject to an obligation of confidentiality originating from a labor or contractual relationship;
- b) Communicate or disclose, without authorization from its legitimate possessor the entrepreneurial secret referred to under a) above for its/his/her own, or a third party's advantage, or for harming or prejudicing such possessor;
- c) Acquire an entrepreneurial secret through illicit means or means contrary to honest commercial usage;

d) Use commercially, disclose or communicate an entrepreneurial secret acquired through the means under c) above;

e) Use commercially an entrepreneurial secret obtained from anyone knowing, or with the obligation of having known, that the person who communicated it acquired the secret through the means under c) above, or who had no authorization from its legitimate possessor to communicate it.

f) Communicate or disclose the entrepreneurial secret obtained pursuant to e) above for its/his/her own, or a third party advantage, for damaging the legitimate possessor of an entrepreneurial secret; or

An entrepreneurial secret is deemed to have been acquired through means contrary to honest commercial use, when the acquisition, among others, results from industrial espionage, the non-compliance of an agreement or another obligation, breach of trust, infidelity, failure to comply with the duty of loyalty or encouragement of performing any of such acts.

Article 263. - The protection of entrepreneurial secrets shall be enforceable for as long as the conditions under Article 260 exist.

Article 264. - Whoever legitimately possesses an entrepreneurial secret may transmit or authorize use to a third party. The third party authorized shall be obliged not to disclose the entrepreneurial secret through any mean, except when there may exist any covenant to the contrary with who transmitted or authorized the use of such secret.

In agreements where technical knowledge is transmitted on know-how, technical assistance or supply of basic engineering or detailed engineering, clauses on confidentiality may be included to protect the entrepreneurial secrets contained therein, provided that they are not contrary to the provisions on free competition.

Article 265. - Any person who due to its/his/her job, work, position, entrustment, performance of its/his/her profession or business relationship, shall have access to an entrepreneurial secret about whose confidentiality it/he/she may have been warned, shall refrain from utilizing it and from disclosing it without a justified reason and without the consent from the person who possesses the secret or from its authorized user.

Article 266. - The Member Countries demanding the submission of test data or other undisclosed information whose preparation involves a considerable effort, as a condition to approve the commercialization of pharmaceutical or agrochemical products using new chemical entities shall protect such data against any unfair commercial use. Furthermore, the Member Countries shall protect such data against any disclosure except when it is deemed necessary to protect the public or unless measures are adopted to guarantee protection of data against any unfair commercial use.

Member Countries may adopt measures to guarantee the protection included in this article.

EL SALVADOR

1.- Does regulatory test data protection through exclusive marketing rights exist in your country?

Article 144 of the Salvadorian Constitution establishes that international treaties of which the country is a member constitute laws of the republic.

As a member of the TRIPS, El Salvador is obliged to provide data exclusivity protection, in order to comply with Art. 10. Bis of the Paris Convention in regards to unfair competition acts.

The granting of the Free Trade Agreement between the United States, Central America and Dominican Republic (CAFTA-DR), in article 15.10 regulates the protection of such data.

In order to commercialize a pharmaceutical product in El Salvador, it is necessary to obtain a pharmaceutical product registration before the Superior Counsel of Public Health. (Art. 14 of the Health Code). As part of such registration it is necessary to file exclusive data.

2.- What are the conditions / requirements to get data exclusivity?

The submission of undisclosed data concerning safety and efficacy, the Party shall not permit third persons, without the consent of the person who provided the information, to market a product on the basis of (1) the information, or (2) the approval granted to the person who submitted the information for at least five years for pharmaceutical products and ten years for agricultural chemical products from the date of approval in the Party.

3.- Which court is competent to decide on data exclusivity-related law suits?

Criminal Courts would be competent for such trial, based on Article 231 of the Criminal Code.

If the disclosed information is used by a third party, the legitimate owner can initiate civil and criminal actions based on unfair competition and patent rights violation.

4.-Are there different kinds of data exclusivity (paediatric, orphan drug, new indications, new administration routes/formulations...) and do they differ in the respective requirements or exclusivity periods?

Due to the granting of the Free Trade Agreement between the United States, Central America and Dominican Republic, the granting of protection is as follows:

a: 5 years for pharmaceutical products.

b: 10 years for chemical agricultural products.

No other classification is made.

5.- If there is no data exclusivity in place. Do you know if there are plans in your country to establish such a data exclusivity?

6.- Could you please provide citations and an English translation of the respective articles / rules of your national laws?

Art. 144 of the Constitution of El Salvador

Art. 15.10 of the Free Trade Agreement between the United States of America-Central America and Dominican Republic (CAFTA-DR)

Art. 231 – Criminal Code

EL SALVADOR

Art. 144 of the Constitution of El Salvador

International treaties granted by El Salvador with other states or international organizations, constitute laws of the Republic, once they are in force, in accordance to the dispositions of the treaty and this Constitution.

The law cannot modify or eliminate what has been accorded in a treaty that is in force for El Salvador. In case of conflict between a treaty and the law, the treaty will prevail.

Art. 15.10 of the Free Trade Agreement between the United States of America- Central America and Dominican Republic (CAFTA-DR)

Article 15.10: Measures Related to Certain Regulated Products

1.

- a) If a Party requires, as a condition of approving the marketing of a new pharmaceutical or agricultural chemical product, the submission of undisclosed data concerning safety or efficacy, the Party shall not permit third persons, without the consent of the person who provided the information, to market a product on the basis of (1) the information, or (2) the approval granted to the person who submitted the information for at least five years for pharmaceutical products and ten years for agricultural chemical products from the date of approval in the Party.
- b) If a Party permits, as a condition of approving the marketing of a new pharmaceutical or agricultural chemical product, third persons to submit evidence concerning the safety or efficacy of a product that was previously approved in another territory, such as evidence of prior marketing approval, the Party shall not permit third persons, without the consent of the person who previously obtained such approval in the other territory, to obtain authorization or to market a product on the basis of (1) evidence of prior marketing approval in the other territory, or (2) information concerning safety or efficacy that was previously submitted to obtain marketing approval in the other territory, for at least five years for pharmaceutical products and ten years for agricultural chemical products from the date approval was granted in the Party's territory to the person who received approval in the other territory. In order to receive protection under this subparagraph, a Party may require that the person providing the information in the other territory seek approval in the territory of the Party within five years after obtaining marketing approval in the other territory.
- c) For purposes of this paragraph, a new product is one that does not contain a chemical entity that has been previously approved in the territory of the Party.

- d) For purposes of this paragraph, each Party shall protect such undisclosed information against disclosure except where necessary to protect the public, and no Party may consider information accessible within the public domain as undisclosed data. Notwithstanding the foregoing, if any undisclosed information concerning safety and efficacy submitted to a Party, or an entity acting on behalf of a Party, for purposes of obtaining marketing approval is disclosed by such entity, the Party is still required to protect such information from unfair commercial use in the manner set forth in this Article.

2.

Where a Party permits, as a condition of approving the marketing of a pharmaceutical product, persons, other than the person originally submitting safety or efficacy information, to rely on evidence or information concerning the safety and efficacy of a product that was previously approved, such as evidence of prior marketing approval in the territory of a Party or in another country, that Party:

- a) Shall implement measures in its marketing approval process to prevent such other persons from marketing a product covered by a patent claiming the previously approved product or its approved use during the term of that patent, unless by consent or acquiescence of the patent owner; and
- b) Shall provide that the patent owner shall be informed of the request and the identity of any such other person who requests approval to enter the market during the term of a patent identified as claiming the approved product or its approved use.

Art. 231 – Criminal Code

Disclosure or revelation of an industrial secret.

Who discloses the invention subject of patent application or industrial or commercial secret, being legally or contractually obliged not to disclose, will be sanctioned with a prison sentence of 2 months to a year.

If the secret is used for his/her own profit the sanction will be augmented in a third part of the maximum sentence.

If the defendant has an official in the government or is a public servant and the actions are made due to his/her position, the functionary will also be removed from his/her office for a 6 month to 2 years term.

GUATEMALA

1.- Does regulatory test data protection through exclusive marketing rights exist in your country?

Yes, regulatory test data protection through exclusive marketing rights exists in this country.

2.- What are the conditions / requirements to get data exclusivity?

General Conditions:

In any administrative case, in order to obtain data exclusivity or protection for the information that have not been disclosed about the safety and efficacy of products, it is necessary that the individual person or the interested legal entity, that are submitting the information or data to the correspondent authority, must do so under the constitutional rule that allows them to request precisely that such information is submitted under confidential guarantee, in this way, the authority who gets this information , will become responsible to maintain the confidentiality of the information or data provided.

Requirements:

The Industrial Property Law establishes that any individual person or legal entity may obtain the approval to commercialize a new pharmaceutical or agrarian chemical product, and to do so, it is necessary:

- a. To file, upon authority request, evidence data or not disclosed data regarding the safety and efficacy of the product. The authority will not approve the commercialization to any party that does not have the owner's consent. The authority may authorize the commercialization for a period of 5 years for pharmaceutical products and for a period of 10 years for agrarian chemical products counted since the approval date in our country.
- b. To file, upon authority request, information regarding the safety and efficacy of a product previously approved in any other country; the health authority may require the previous commercialization approval in such country. The authority will not grant a marketing approval to any party that does not have the owner's consent or the marketing approval in other country. The authority may grant the exclusive marketing approval for a period of 5 years for pharmaceutical products and for a period of 10 years for agrarian chemical products counted since the approval date in our country.
- c. To obtain the protection related on the above literal b), the administrative authority will demand that the owner of the evidence data or the person or legal entity entitled with the marketing authorization in other country, shall

request the approval or marketing authorization in Guatemala within the 5 years after receiving the marketing authorization in the other country.

Exceptions to the obligation of data exclusivity:

1. **Pharmaceutical products:** When it is needed to protect the security in the use of the products, the life or the health or in cases of national emergency duly declared.
2. **Agrarian products:** In cases of national emergency duly declared or to protect the security in the use of the products, the health or the human, animal or vegetal life or the environment.
3. When the owner or entitled person of the information not disclosed, or evidence data, or the sanitary registry, have given its written consent with legalized signature.

It is understood by:

- a. **Information not disclosed and / or evidence data:** Information or data that may have or may not have, total or partially, the character of business secret and that will be used to demonstrate the safety and efficacy of a pharmaceutical or chemical agrarian product.

New Product: Any product that contains a new chemical substance that has not been previously approved in the country

3.- Which court is competent to decide on data exclusivity-related law suits?
The Civil and Penal Courts, depending on the case

4.-Are there different kinds of data exclusivity (paediatric, orphan drug, new indications, new administration routes/formulations...) and do they differ in the respective requirements or exclusivity periods?

The competent authority will not grant exclusivity data protection in cases of pharmaceutical or chemical agrarian products when they refer to new uses or second uses.

5.- If there is no data exclusivity in place. Do you know if there are plans in your country to establish such a data exclusivity?

6.- Could you please provide citations and an English translation of the respective articles / rules of your national laws?

Decree 34/2004 – Arts. 1° -2° and 3°

GUATEMALA

DECREE 34-2004

CONGRESS OF THE REPUBLIC OF GUATEMALA

REFORMS TO THE LAW OF INTELLECTUAL PROPERTY, DECREE NUMBER 57-2000 OF THE CONGRESS OF THE REPUBLIC AND ITS REFORMS

Article 1. - Article 177 of the Law of Intellectual Property, Decree Number 57-2000 of the Congress of the Republic, will be reformed by Article 1 of Decree Number 9-2003 of the Congress of the Republic, which will read the following:

"Article 177. Proof data or other non-disclosed information protection

When as a condition for the approval of commercialization of pharmaceutical, chemical or agrochemical products that make use of new chemical entities, the pertinent authorities require the presentation of proof data or other non-disclosed information which production presuppose a considerable effort, that proof data and other non-disclosed information will be protected against any disloyal commercial use and disclosure.

The people or legal entities affected by acts of disloyal commercial use are allowed to make use of the existing legal procedures.

Article 2. - The following cases are exempt from the obligation of non-disclosure of proof data or other non-disclosed information:

- a) For pharmaceutical products, whenever it is necessary to protect the safety in their use, life or health; in those cases of national declared emergency or to assure the appropriate supplying of medicines or to impede anti-competitive declared practices, unless measures are adopted in order to guarantee the protection of the data against all disloyal commercial use.
- b) For agrochemical products, whenever it is necessary to assure the nutrition or alimentary safety of the population; in those cases of national declared emergency or to protect the safety in their use, health or human, animal or vegetal life, or to avoid serious damages to environment, or to impede anti-competitive declared practices, unless measures are adopted in order to guarantee the protection of the data against all disloyal commercial use.

Article 3. - Article 177 bis of the Law of Intellectual Property, added by article 2 of Decree Number 9-2003 of the Congress of the Republic, will be reform and will read the following:

"**Article 177 bis.** According to the present law, the following will be understood:

- a) Proof data: All the information presented to competent authorities in relation with the file of submission for registration of pharmaceutical or

agrochemical products which include a new chemical entity, and required to prove the quality, efficacy and safety. This information must have not been undisclosed by any means, written, oral or virtual, national or international, and it is necessary that it had been obtained through researches that involve a considerable effort.

- b) New product: It is the one that includes in its prescription a new chemical entity as active ingredient, and that has not been approved for its use, commercialization and distribution in Guatemala or any other country in the world.
- c) New chemical entity: All compound that has not been presented or described in the past in any national or international publication, and that has not been authorized for its use and/or commercialization in any country of the world.

HONDURAS

1.- Does regulatory test data protection through exclusive marketing rights exist in your country?

Yes, regulatory test data protection through exclusive marketing rights exists under the the Implementation Law of the Free Trade Agreement of the Dominican Republic – Central America and the United States (DR-CAFTA)

2.- What are the conditions / requirements to get data exclusivity?

Data exclusivity applies to a new product considered the product that does not contain a chemical entity that has been previously approved in Honduras. The person that applies for a new pharmaceutical product has to submit to the national authority a List of the patents that cover the product or its approved use.

3.- Which court is competent to decide on data exclusivity-related law suits?
Criminal and civil courts

4.-Are there different kinds of data exclusivity (paediatric, orphan drug, new indications, new administration routes/formulations...) and do they differ in the respective requirements or exclusivity periods?

There are no different kinds of data exclusivity and there is a five years period

5.- If there is no data exclusivity in place. Do you know if there are plans in your country to establish such a data exclusivity?

6.- Could you please provide citations and an English translation of the respective articles / rules of your national laws?

Implementation Law of the Free Trade Agreement of Central America & Dominican Republic (DR CAFTA)- Decree N° 16-2006: Arts. 19-20-21-22-23-24

HONDURAS

Implementation Law of the Free Trade Agreement of Central America & Dominican Republic (DR CAFTA)-

Decree N° 16-2006

TITLE IV – Measures related to certain regulated product

UNIQUE CHAPTER: About Test Data Protection or Non disclosed Data Protection

Article 19: If the national authority grants the marketing authorization of a new pharmaceutical product or chemical agricultural product, based on non disclosed data related to the safety and efficacy of this product that is submitted directly to this authority (and the data are not based on safety and efficacy data previously submitted for an approved product in other country), the national authority will not allow third parties, that do not have the consent of the person who provided the information, to market the product based on (1) the data provided or (2) the approval granted to the person who submitted the data during a period of five (5) years for a pharmaceutical product or ten (10) years for an agrochemical product from the approval date in Honduras.

Article 20 : If the national authority grants the marketing authorization of new pharmaceutical products or agrochemical products, based on evidence of safety and efficacy data of a product previously approved in other country, such as the previous marketing authorization evidence in such other country, the health authority will not allow that third parties, that do not have the consent of the person who got the previous approval in the other country, get the approval based on (1) the marketing authorization evidence previously granted in the other country or (2) information based on safety and efficacy data previously submitted to get the approval of the product in the other country, during five (5) years for a pharmaceutical product or ten (10) years for an agrochemical product counted since the date the national authority approved or granted the marketing authorization in Honduras, to the person that got the approval in the other country.

In order to receive protection in accordance with this article, it will be required that the person who provided the information in the other country, request the marketing authorization of the product in Honduras within the five (5) years counted from the date the product received the marketing approval in the other country.

Article 21: In order to apply Articles 19 and 20 of this Law, it shall be understood as a new product, the product that does not contain a chemical entity to which it had been previously granted a marketing authorization in Honduras.

Article 22: The person who applies for a marketing authorization of a pharmaceutical product shall submit to the national authority a list of all the patents that cover the product or its approved use.

Article 23: The national authority has to protect the test data and the information non disclosed against its disclosure , excpet when it will be necessary to protect the public health. In such case, it has to protect the test data or non disclosed information against any dishonest use by third parties, according to articles 19 and 20 of this Law.It could not be considered undisclosed data the information that is of public access.

MEXICO

1.- Does regulatory test data protection through exclusive marketing rights exist in your country?

No but protection exists under Trade Secret Law.

2.- What are the conditions / requirements to get data exclusivity?

To be able to obtain protection on data exclusivity rights in Mexico, it is necessary to be the owner or licensee of a Patent for a pharmaceutical or agro-chemical product, which contains a new chemical entity, and to submit the same before the Federal Commission for the Protection against Sanitary Risks (COFEPRIS in its Spanish acronym). A request for marketing authorization of a product that is prepared on the specifications of that Patent will be filed, together with security and efficiency tests for the particular product. Documents containing security and efficiency tests will be regarded confidential and thus, for the term of five years, as from the date of grant of marketing authorization to the holder of the data, the same will not be disclosed to any third party and will not be available for use by anyone to acquire marketing authorizations.

3.- Which court is competent to decide on data exclusivity-related law suits?

Data exclusivity in Mexico entails two different responsibilities for the authorities: non-disclosure and non-reliance.

If non-disclosure obligations were violated by a Mexican Authority, it would be possible to file criminal charges against the official who illegally disclosed the protected information. Besides, it would be possible to seek damages before a Civil Court against the Mexican Government. It is to note that either action would avoid the negative consequences that the illegal disclosure would otherwise provoke.

If non-reliance obligations were not observed by COFEPRIS, it would grant a third party a marketing approval for a product. In this case, the best course of action would be to file an administrative procedure of nullity against such approval before COFEPRIS. If COFEPRIS denies such nullity, the next step would be to file a nullity appeal against the decision rendered by COFEPRIS, before the Federal Tribunal for Administrative Matters. If the plaintiff succeeded on appeal, the Tribunal would order COFEPRIS to revoke the previously granted approval, on grounds that the same was illegally granted.

4.-Are there different kinds of data exclusivity (paediatric, orphan drug, new indications, new administration routes/formulations...) and do they differ in the respective requirements or exclusivity periods?

Under the Mexican Law, there is only one kind of data exclusivity protection and one way to gain the same, which is by filing security and efficiency tests of a

product which is intended for marketing, before the Federal Commission for the Protection against Sanitary Risks. Of course, such product has to be prepared on the specifications of a Patent covering a pharmaceutical or agro-chemical product that uses a new chemical entity.

Could you please provide citations and an English translation of the respective articles / rules of your national laws?

Mexican Industrial Property Law

Article 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.

Health Supplies Regulations

Article 167-*bis*. - The solicitant of a Registration for an allopathic medicine should file, together with the request, the documents that prove the ownership of the Patent of the substance or active ingredient or that it counts with the respective license, both filed before the Mexican Patent Office.

Alternatively, and according to the list of products established in Article 47 bis of the Rules of the Industrial Property Law, the solicitor will be able to manifest, under oath, that it meets the applicable dispositions on Patents matters regarding the substance or active ingredient subject of the request. In this case, the Ministry of Health will request immediately the technical cooperation of the Mexican Patent Office for, under its competence, inform it in no longer than ten working-days after the petition is received, if such request invades the rights of valid Patents. If the Mexican Patent Office concluded that exist valid Patents on the substance or active ingredient of which the solicitor is not owner, it will inform the Ministry of Health so it request the solicitor to demonstrate the ownership of the Patent or the respective license to exploit the same. The Ministry of Health will give the solicitor a term no smaller than five days, counted from the day of service, to demonstrate such facts. If the solicitor did not comply with the request, the Ministry of Health would withdraw the request and therefore would inform the solicitor the reason of that determination so, if the solicitor wished, could bring the matter to the next competent authority. The lack of response by the Mexican Patent Office under the time given it to do so will be understood in a favorable way to the solicitor.

With out prejudice of the dispositions established in the two precedent paragraphs, it will be possible to request the registration of a generic regarding a medicine which substance or active ingredient is protected by a Patent, with the porpoise of realizing research, tests and the correspondent experimental production, during the last three years before the validity of the Patent expires.

In this case, the Sanitary Registration will be granted only after the validity of the Patent expires.

The information that articles 167 and 167 bis of this Rules refers to, that are considered confidential or reserved according to the international treaties of which Mexico is signatory and other applicable legal dispositions, will be protected of any divulgation to any other particulars.

Trade-Related Aspects of Intellectual Property Rights Agreement

Article 39. -

3. - Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products that utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.

1 North American Free Trade Agreement

Article 1711. -

5. - If a Party requires, as a condition for approving the marketing of pharmaceutical or agricultural chemical products that utilize new chemical entities, the submission of undisclosed test or other data necessary to determine whether the use of such products is safe and effective, the Party shall protect against disclosure of the data of persons making such submissions, where the origination of such data involves considerable effort, except where the disclosure is necessary to protect the public or unless steps are taken to ensure that the data is protected against unfair commercial use.

6. - Each Party shall provide that for data subject to paragraph 5 that are submitted to the Party after the date of entry into force of this Agreement, no person other than the person that submitted them may, without the latter's permission, rely on such data in support of an application for product approval during a reasonable period of time after their submission. For this purpose, a reasonable period shall normally mean not less than five years from the date on which the Party granted approval to the person that produced the data for approval to market its product, taking account of the nature of the data and the person's efforts and expenditures in producing them. Subject to this provision, there shall be no limitation on any Party to implement abbreviated approval procedures for such products on the basis of bioequivalence and bioavailability studies.

PANAMA

1.- Does regulatory test data protection through exclusive marketing rights exist in your country?

Yes.

2.- What are the conditions / requirements to get data exclusivity?

The only requirement is to send a letter requesting the protection of data exclusivity when submitting clinical research data (Phase I ,II and III) to the authority.

3.- Which court is competent to decide on data exclusivity-related law suits?

It will depend on the following issues:

-If data exclusivity is obtained illegally from the client company, the competent courts are the I.P. Courts.

-If data exclusivity is obtained illegally from the Secretary of the Health Office, competent court is Penal Court.

-If data exclusivity is obtained in an unspecified way, competent court is Administrative Court.

4.-Are there different kinds of data exclusivity (paediatric, orphan drug, new indications, new administration routes/formulations...) and do they differ in the respective requirements or exclusivity periods?

Not for pharmaceutical products. However, the requirements for pesticides and herbicides are different.

5.- If there is no data exclusivity in place. Do you know if there are plans in your country to establish such a data exclusivity?

6.- Could you please provide citations and an English translation of the respective articles / rules of your national laws?

Executive Decree 305/2003

PANAMA

Executive Decree 305/2003

It regulates the submission of clinical trials for obtaining the marketing authorization for a pharmaceutical product and modifies Executive Decree 178 dated July 12, 2001.

ARTICLE 1: Law 1 dated January 10, 2001 establishes that the marketing authorization of pharmaceutical products, including the registration of new indications for pharmaceutical products already registered that are not included under the accepted references mentioned in article 29 of the aforesaid Law, the National Office of Pharmacy and Drugs will require the submission of clinical trials and the summary in Spanish of all the phases of clinical research (I, II and III), respectively.

ARTICLE 2: Being the case of an innovative pharmaceutical product that had submitted the info mentioned in Article 1 of this Executive Decree, no other sanitary registration for a pharmaceutical product containing the same active ingredient or ingredients will be granted for a period of time of 5 years counting since the granting of the sanitary registration of the aforementioned innovative product, unless the applicant: 1) submits their own clinical trials according to the requirement of Art. 1 of this Executive Decree, 2) proves to have the authorization of the owner or holder of the clinical trials that support the first registration, or 3) proves that the description of the registered pharmaceutical product is contemplated within the references accepted in accordance with Article 29 of Law 1 dated January 10, 2001.

ARTICLE 3: Article 12 of Executive Decree 178 dated July 12, 2001 reads the following:

Article 12. CLINICAL TRIALS (FOR INNOVATIVE PRODUCTS, NEW INDICATIONS AND THOSE RULED BY THE HEALTH AUTHORITY). Being the case of innovative products, the submission of clinical trials and the summary of all the phases of clinical research (I, II and III) will be required.

For new indications or modifications in the monographies of previously registered pharmaceutical products, it is required to submit the clinical trials that endorse this new indication, as long as these are not mentioned in the references accepted by the Health Authority.

ARTICLE 4: This Decree will become in force from the moment of its promulgation in the Official Gazette.

LEGAL FOUNDATION: Numeral 14 of art. 179 of the Political Constitution, Law 1 dated January 10, 2004, Law 23 (15/07/1997) and Executive Decree 178 dated July 12, 2001.

PERU

1.- Does regulatory test data protection through exclusive marketing rights exist in your country?

Yes. It has just been passed in these days as part of the implementation of the Free Trade Agreement between Peru and U.S.A.

2.- What are the conditions / requirements to get data exclusivity?

Regarding pharmaceutical products, the conditions required by the FTA agreement are:

- That the Party requires, as a condition for approving the marketing of a pharmaceutical product that contains a new chemical entity, the submission of undisclosed test or other data necessary to determine whether the use of such products is safe and effective
- That the origination of such data involves considerable effort
- That the disclosure of the data is not necessary to protect the public
- No person other than the person that submitted the data may, without the latter's permission, rely on such data in support of an application for product approval during a reasonable period of time (usually 5 years) after their submission.

3.- Which court is competent to decide on data exclusivity-related law suits?

We will have to wait for the internal regulation to determine that.

The administrative body that grants approval for the marketing of a pharmaceutical product is DIGEMID – Dirección General de Medicamentos, Insumos y Drogas, which is part of the Ministry of Health.

However, these suits should ultimately be decided by civil courts

4.-Are there different kinds of data exclusivity (paediatric, orphan drug, new indications, new administration routes/formulations...) and do they differ in the respective requirements or exclusivity periods?

The data protection applies only for new chemical entities.

5.- If there is no data exclusivity in place. Do you know if there are plans in your country to establish such a data exclusivity?

6.- Could you please provide citations and an English translation of the respective articles / rules of your national laws?

Legislative Decree N° 1072 /2008

PERU

LEGISLATIVE DECREE N° 1072 /2008

THE PRESIDENT OF THE REPUBLIC

That, the Trade Promotion Agreement between Peru and USA approved by Legislative Resolution N° 28766, published in Official Bulletin El Peruano on June 29 of 2006, establishes a free-trade region pursuant to Art. XXIV of the General Agreement on (customs) Tariffs and Trade of 1994 and the Art. V of the General Agreement on Trade in Services (GATS), with the aim of stimulating the expansion and diversification of the trade of goods and services between the parties and protecting the Intellectual Property Rights, among which the ones related to industrial property are included. These must be incorporated to the Peruvian legislation in this matter.

That, it is necessary to develop a protection regime of test data or others not disclosed in the proceeding of sanitary registration of pharmaceutical products.

That, the Congress of the Republic through Law No. 29157 has given the faculty to the Executive Power to legislate diverse matters forming part of the undertakings derived from the Trade Promotion Agreement between Peru and USA and to improve the economical competitiveness for the better use of said Agreement.

Pursuant to the dispositions in Art. 104° of the Politic Constitution of Peru:

With the approval voting of the Ministers` Counsel

With the task of keeping the Congress of the Republic notified.

The following Legislative Decree has been given:

PROTECTION OF TEST DATA OR OTHERS NOT DISCLOSED FOR PHARMACEUTICAL PRODUCTS

Article 1°. - PROTECTION OF TEST DATA OR OTHERS NOT DISCLOSED

Sanitary Authority is to demand as condition for obtaining the sanitary registration of a pharmaceutical product containing a new chemical entity, the filing of test data or others not disclosed necessary to determine the security and effectiveness of said product, it will protect that information against disclosure, when generation thereof has demanded considerable efforts.

Article 2°. - THE NEW CHEMICAL ENTITY

A new chemical entity will be that fraction, biologically active, responsible of the pharmacological or physiological action of an active agent that at the moment of the application for the sanitary registration has not been included in sanitary registration previously granted in the country

The following will not be considered as new chemical entity, in any case:

1. The therapeutic uses or indications different from those authorized in other previous sanitary registrations of the same chemical entity or combinations of known chemical entities.
2. The changes in the way of administration, forms of dosage, modifications in the pharmacokinetics, in the time of dissolution and bioavailability, authorized in other previous sanitary registrations of the same chemical entity.
3. The changes in the pharmaceutical forms or formulations of chemical entities already registered.
4. The salts (including hydrogen bond salts), ether, compounds, chelates, clathrates, isomers, metabolites, co-crystals, polymorphs, solvates, pure forms, size of particles, pro-pharmaceuticals, or those chemical structures whatever its form, disposition or expression based on a previously registered chemical entity.
5. The combination of new chemical entity and an already known one.

Article 3°. - CONDITIONS AND THE PROTECTION TERM

The protection term will be normally of 5 years counted as from

1. The date in which the sanitary registration was granted in national territory or,
2. As from the date of the first approval for commercialization, if the sanitary registration is based in the approval for commercialization granted in other country and it's granted within 6 months of filing the complete application case with the Sanitary Authority,

The Sanitary Authority, with the purpose of determining the protection term, will consider the nature of the information and the efforts and costs demanded for its production.

No person, different from the one who filed the information will be able, without authorization from the latter, to use the test data or other not disclosed, to support an application for obtaining a sanitary registration during the protection term established in the present Law.

Article 4°. - EXCEPTIONS AND LIMITATIONS TO THE RIGHT OF PROTECTION

1. Notwithstanding what's stated in the present Law, the Sanitary Authority, officially or upon request, will be able to authorize one or more thirds to use or base themselves in the test data or other non-disclosed information submitted in

the sanitary registration or in the sanitary registration granted in reference, according to:

- a. The Declaration relating to the Agreement about ADPIC and Public Health (WT/MIN (01)/DEC/2)(The "Declaration");
- b. Any exception to any disposition of the ADPIC Agreement granted by members of the WTO according to the Agreement of WTO to apply the Declaration; and,
- c. Any amendment to ADPIC Agreement in order to implement the "Declaration".

Nothing of what is stated in the present Law will impede that a third requires a sanitary registration of a pharmaceutical product which test data or other non-disclosed information is protected, on the condition that he uses his own test data as evidence of the safety and efficacy of the product, independently of the information submitted by another solicitor within the period of protection of the other data solicitor; as long as the Sanitary Authority does not base its decision in test data or other non-disclosed information previously protected, and

4.The Sanitary Authority is allowed to disclose test data or other information if that should be required to protect the public health, as long as it takes the measures to avoid its disloyal commercial use.

5. The exercise of the rights stated in the present Law is subjected to the observance of the dispositions related to competition, in force in Peru.

Article 5º: SHORTENED PROCEDURE

In observance to what's stipulated in the present Law, nothing will limit the implementation of shortened procedures for the sanitary registration of pharmaceutical products based on bioequivalence and bioavailability studies.

Article 6º - END OF THE PROTECTION

The protection stated in the present law can be cancelled when within an administrative or legal procedure it is determined that the protection has been granted in contravention to the provisions of this Law.

Once the period of protection of test data and non-disclosed information has expired, any person can lean on such information in order to sustain their submission for a sanitary register.

Article 7º - ADMINISTRATIVE APPEAL

The administrative acts capable of contradiction performed under the protection of the present Law can be reconsidered or appealed before the respective competent instance.

The interposition of the appeal will not suspend the effects of the questioned act.

Article 8°. - TRANSPARENCY MEASURES

The information filed about the identity of the applicant of a sanitary registration and about the test data of pharmaceutical products or others will be published in the official diary "El Peruano" once and shall be on behalf and borne by the applicant for third parties to file oppositions if they deem that their rights are affected, enclosing the respective information, and within the 30 working days after the publication of the application.

The Sanitary authority shall publish in its website all granted sanitary registrations stating, if corresponding, if there exists the protection of test data or other non-disclosed data, novel chemical entity, granting date, and expiration date of the protection.

FINAL SUPPLEMENTARY PROVISIONS

FIRST: Validity:

This legislation decree shall be valid as from the validity date of the Trade Promotion Agreement signed between Peru and United States of America.

SECOND: Regulations:

This legislative decree shall be regulated within a term no longer than 180 days, starting from its publication in the Official Diary "El Peruano".

THIRD: Previously approved Pharmaceutical product:

The provisions of the present legislative decree shall not be applicable to a pharmaceutical product that includes a chemical entity approved in Peru for use in a pharmaceutical product before its validity date.

URUGUAY

1.- Does regulatory test data protection through exclusive marketing rights exist in your country?

No.

Notwithstanding Uruguay is a member of WTO, and approved TRIPS by Law N° 16.671, of December 13, 1994, there are no provisions regarding data exclusivity either at the legislative level or in decrees or implementing regulations.

Insofar, and despite the fact that obtaining test data for pharmaceutical products is the outcome of costly and laborious clinical trials and tests, and entails considerable effort, expense and innovation, Article 39.3 of TRIPS has been interpreted by the drug approval regulatory authority of Uruguay (Ministry of Health) as meaning the obligation to protect data from commercial use and disclosure, but not as prohibiting usage of the data by the regulatory authority in the approval process for a subsequent second competing product marketing approval.

The current rule for approval of pharmaceutical products (Decree N° 324/999 dated October 12, 1999) provides for protection of confidential technical information and clinical trial data, stating that when filed before the regulatory authority for the purposes of obtaining approval of a pharmaceutical product, the applicant may "declare that it constitutes undisclosed information pursuant to the current legal requirements". It does not contain however any other provisions or guidelines regarding the scope of protection afforded and what usages may be deemed to be forbidden.

Notwithstanding the foregoing, Decree 324/999 also foresees that the regulatory authority may rely on the former registration of a similar active ingredient to grant approval of a second product under an abbreviated procedure, in line with the above described interpretation of article 39.3 of TRIPS by the Ministry of Health in the sense that use of data by the regulatory authority is not prohibited.

2.- What are the conditions / requirements to get data exclusivity?

3.- Which court is competent to decide on data exclusivity-related law suits?

4.-Are there different kinds of data exclusivity (paediatric, orphan drug, new indications, new administration routes/formulations...) and do they differ in the respective requirements or exclusivity periods?

5.- If there is no data exclusivity in place. Do you know if there are plans in your country to establish such a data exclusivity?

The issue of data exclusivity has been the subject of hot debate in recent years, and specifically, when the possibility of Uruguay signing a Free Trade Agreement

with the United States was considered in 2006. At that time, the requirement of data exclusivity and the linkage between patent rights and pharmaceutical products regulatory approval which was contained in the draft FTA Agreement was a high-profile point of discussion and was objected as inconvenient by the local pharmaceutical industry and also in some government-related studies. The FTA offer was finally turned down by the Uruguayan government, and we are not aware of any current or future plans to establish data exclusivity protection by the authorities.

6.- Could you please provide citations and an English translation of the respective articles / rules of your national laws?

As stated above, there are no local rules regarding data exclusivity

VENEZUELA

1.- Does regulatory test data protection through exclusive marketing rights exist in your country?

No but test data is protected by Trade Secret Law applied to industrial secrets and data protection for pharma-chemical or agrochemical goods. The criteria refers to undisclosed information especially protected against unfair commercial use.

Information whose disclosure is the result for a legal provision or court order shall not be considered an industrial secret.

Information provided to any authority or disclosed by legal provision by the person in lawful possession of it shall not be considered public property if that person supplies the information for the purpose of obtaining licenses, permits, authorizations, registrations or any other legal acts.

2.- What are the conditions / requirements to get data exclusivity?

The protection granted to data exclusivity is subjected to the existence of „ a considerable effort“, consequently to get the referred protection , the following conditions are required:

a. The existence of a considerable effort shall be demonstrated, meaning the existence of an effort in the process of developing a product until the final marketing phase .

b. That protection be oriented to an unfair commercial use.

3.- Which court is competent to decide on data exclusivity-related law suits?

The suits related to data exclusivity are decided by the Supreme Tribunal of Justice

4.-Are there different kinds of data exclusivity (paediatric, orphan drug, new indications, new administration routes/formulations...) and do they differ in the respective requirements or exclusivity periods?

No, only for new chemical components.

5.- If there is no data exclusivity in place. Do you know if there are plans in your country to establish such a data exclusivity?

6.- Could you please provide citations and an English translation of the respective articles / rules of your national laws?

The legislations that protect data exclusivity (industrial secrets) are The Constitution , the Andean Decision 486, the Free trade Agreement concluded between Mexico, Colombia and Venezuela and the Marrakech Agreement (TRIPS)

Section 18-22 of the Free trade Agreement deals exclusively with the Data Protection pharmaceutical or agrochemicals goods

VENEZUELA

The legislations that protect data exclusivity (industrial secrets) are The Constitution , the Andean Decision 486, the Free trade Agreement concluded between Mexico, Colombia and Venezuela and the Marrakech Agreement (TRIPS)

- Andean Decision 486 - "CHAPTER II - On Industrial Secrets provides:

Article 260. - An industrial secret shall be considered to be any undisclosed information within the lawful control of an individual person or legal entity that may be used for any productive, industrial, or commercial activity and that is capable of being transmitted to a third party, as long as that information:

- a) Is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question;
- b) Has commercial value because it is secret; and
- c) Has been the subject of reasonable steps by the person lawfully in control of the information, to keep it secret.

The information constituting an industrial secret may be related to the nature, characteristics, or purpose of the products, production methods or processes, or the means or forms of distribution or marketing of goods or rendering of services.

Article 261. - For purposes of this Decision, information whose disclosure is the result of a legal provision or court order shall not be considered an industrial secret.

Information provided to any authority or disclosed by legal provision by the person in lawful possession of it shall not be considered public property if that person supplies the information for the purpose of obtaining licenses, permits, authorizations, registrations, Or any other legal acts.

Article 262. - Persons shall have the possibility of preventing an industrial secret lawfully within their control from being disclosed to, acquired by, or used by third parties in a manner contrary to fair trade practices. Performance of any of the following acts in respect of an industrial secret shall be considered unfair competition:

- a) Using, without the authorization of the person lawfully in control of that information, an industrial secret to which the third party had access under a confidentiality obligation resulting from a contractual or labor trade practice;
- b) Communicating or disclosing, without the consent of the personal lawfully in control of that information, the industrial secret referred in subsection a) with the intent of obtaining advantages for oneself or another party or of causing injury to the person in control of that information;

- c) Acquiring an industrial secret by means that are unlawful or contrary to trade fair practices;
- d) Using, communicating, or disclosing an industrial secret acquired in the way described in subsection c);
- e) Using an industrial secret obtained from another person, while knowing, or negligently failing to know, that the party who communicated the secret had acquired it by use of the means cited under subsection c), or did not have consent to communicate it from the person lawfully in control of that information;
- f) Communicating or disclosing an industrial secret obtained in the way described under subsection e), for the benefit of oneself or a third party or to injure the person lawfully in control of that industrial secret.

An industrial secret shall be considered to have been acquired by means contrary to fair trade practices where such acquisition is the result of industrial espionage, breach of contract or other obligations, breach of trust, breach of a duty of secrecy, or inducement to breach.

Article 263. - Protection of an industrial secret shall last so long as the conditions set out in article 260 exist

Article 264. - Any person lawfully in control of a trade secret may transfer it to a third party or authorize its use by a third party. That authorized user shall be under the obligation not to disclose the industrial secret by any means, unless otherwise agreed to with the person having transferred or authorized use of that secret.

Agreements for the transfer of technological know-how, technical assistance, or the provision of basic or detailed engineering may include confidentiality clauses to protect the trade secrets contained

Therein, provided that such clauses are not contrary to antitrust provisions on free competition.

Article 265- Persons with access to an industrial secret by reason of their work, employment, job, professional performance, or business relationship and warned of the confidentiality thereof, shall refrain from making use of it or disclosing it without just cause and without the consent of the owner or authorized user of that secret.

Article 266. - Member Countries, when requiring, as a condition for approving the marketing of pharmaceutical or of agricultural chemical products, which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Member Countries shall protect such data against disclosure, except where necessary to protect the public or unless steps are taken to ensure that the data is protected against unfair commercial use."

Section 18-22 of the Free trade Agreement deals exclusively with the Data Protection pharmaceutical or agrochemicals goods:

"1. If as a condition for approving the marketing of goods or property pharmaceutical or agrochemical use a new chemical component, a Party requires the submission of data or other experiments that have not been published and which is needed to determine its safety and efficacy, this Party will protect the data provided their generation involves considerable effort, except where the publication of such data is necessary to protect the public or when action is taken to ensure data protection against unfair commercial use.

2. Each Party shall, in respect of the data referred to in paragraph 1 submitted after the date of entry into force of this Treaty, any person other than that which can be filed without permission of the latter, having this data to support an application for approval of an asset over a reasonable period after its presentation. To this end, for reasonable period it shall be understood a period of no less than five years from the date on which the party has granted to the person who produced the data, approval to place the good in the market, taking into account the nature of the data and efforts and expenses of the person for generations. Subject to this provision, there is nothing to prevent a party from conducting summary procedures of approval for those assets on the basis of bioequivalence studies or bioavailability."

- Constitution of the Bolivarian Republic of Venezuela:

"TITLE III - Duties, Human Rights And Guarantees - Chapter III:

Article 48: The secrecy and inviolability of private communications in all forms are guaranteed. The same may not be interfered with except by order of a competent court, with observance of applicable provisions of law and preserving the secrecy of the private issues unrelated to the pertinent proceedings.

Article 60: Every person is entitled to protection of his or her honor, private life, intimacy, self-image, confidentiality and reputation. The use of electronic information shall be restricted by law in order to guarantee the personal and family intimacy and honor of citizens and the full exercise of their rights.

TITLE III - Chapter VII. Economic Rights - Article 115:

The right of property is guaranteed. Every person has the right to the use, enjoyment, usufruct and disposal of his or her goods. Property shall be subject to such contributions, restrictions and obligations as may be established by law in the service of the public or general interest. Only for reasons of public benefit or social interest by final judgment, with timely of fair compensation, the expropriation of any kind of property may be declared."