



Practical Issues and Trends of the Mexican Patent System

November, 2008

Topics to discuss

✓ **Practices in patent prosecution.**

- Prosecution timeline and filing recommendations.
- Pharmaceutical and biotechnology inventions.
- Computer implemented inventions.

✓ **Patent enforcement and compliance.**

- Mexican linkage system for drugs.
- Experimental use exemption.
- Latest developments in Data Exclusivity provisions for drug approval.
- Recommendations related to patent litigation.

✓ **Licensing.**

- Competition law
- Compulsory licensing
- Recommendations on License registration before patent office

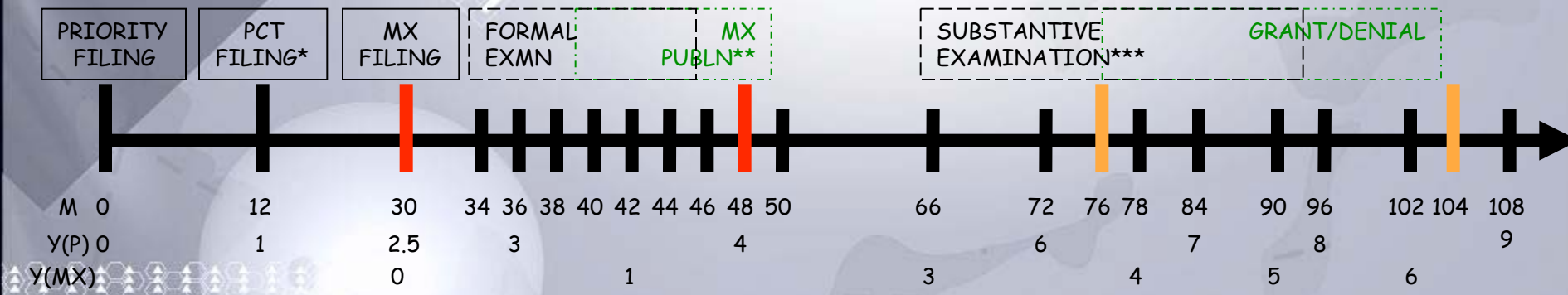
✓ **Trends in Mexico:** A new bill at the Mexican Congress (Proposed Sep, 2008)

✓ **Trends in Latin America:** Comments on FTA's, patentable subject matter, linkage and data protection

Prosecution Timeline in Mexico

MX Filing based on PCT International Application

(International Stage times not shown)



*IF PRIORITY WAS NOT PCT APPLICATION
 ** OR EARLIER IF FORMALITIES ARE COMPLIED WITH FAST
 *** DEPENDENT ON DATE OF PUBLICATION

Current Practices of the MIIP in Patent Prosecution

- ✓ **Issues to consider in filing applications:**
 - National Phase due date in Mexico for PCT is 30 months. Month 31 had been accepted without legal basis. Currently the MIIP is rejecting such applications.
 - Making amendments during PCT International Phase reduces formalities for changes to the filing of a copy of Form IB-306

ARTICLE 15. INVENTION

Every **human creation** that allows **transforming matter or energy** existing in nature for the advantage of mankind in the **satisfaction of its concrete necessities.**

ARTICLE 16. INVENTIONS NOT PATENTABLE

- **Essentially biological** processes for the production, reproduction and propagation of plants and animals.
- Biological and Genetic material as exists in nature.
- Animal breeds.
- The human body and the living parts that conform it.
- Plant Varieties*

ARTICLE 19. WHAT IS NOT AN INVENTION

- Theoretical and Scientific principles
- Discoveries consisting of uncovering things that naturally exist even if they were previously unknown.
- Schemes, plans, rules and **methods for performing** mental acts, games or **businesses**.
- **Mathematical Methods.**
- **Computer Programs.**
- Information Display Forms.
- Aesthetical Creations and literary or artwork.
- **Diagnosis, Surgical or Therapeutic Methods.**
- Obvious juxtaposition, variation or new use of known inventions.*

✓ **General practice for all inventions**

- The term “approximately” in claims has been objected systematically
- Markush practice has been restricted to allow as less embodiments as possible within one patent. Examples are being used to determine the allowable scope.
- Addition of subject matter incorporated in US continuation in part applications is always rejected by the MIIP.

✓ **General practice for all inventions**

- Often the MIIP refers to foreign examinations in support to patentability analysis. Usually considers USPTO and EPO Offices (preferably EPO), and increasingly Asian offices such as China, Korea and Japan. Specially in the pharmaceutical and biotechnology areas, the MIIP issues often objections not brought before by foreign patent offices.
- PCT “A” documents are sometimes required by the MIIP to be submitted. According to the Mexican IPL, every document filed in a different language should be filed together with the translation thereof.

✓ **Pharma/Chemical inventions**

- The MIIP has been issuing objections on general language such as “lower alkyl”, “heteroaryl” and the like.
- Claims to metabolites or prodrugs have been objected to, when the structure or chemical identity of the same is unknown.

✓ Pharma/Chemical inventions

- Try to convert the therapeutic treatment method claims into Swiss style format.
- Do not include omnibus and product by process claims.
- Avoid claims of the type: “A process for preparing a pharmaceutical composition comprising *intimately mixing the active compound with an acceptable carrier*” or the like.

✓ **Computer implemented inventions**

- Business methods, mathematical methods and computer programs are expressly excluded from patentability under Mexican IPL.
- Although the MIIP has not developed a clear criteria, the office usually objects to claims directed to such methods or programs systematically when they are claimed per-se.
- Some patents have been issued when they are claimed as part of a system, or embodied in other tangible element such as a machine.
- Have in mind the requirement of “transforming matter or energy” in the Mexican definition of invention.

- ✓ Regulations on Health Supplies of the Law on Health (RHS)
 - Obligation to attach information to the Application for Health Approval proving patent ownership or license to the active substance or ingredient.
 - If not the patent owner or licensee, an statement of compliance of IP law subject to confirmation by the MIIP.
 - Applications for generics allowed within 3 years before expiration of the patent but register only granted upon actual expiry of the patent.
 - Dossiers are protected against disclosure to third parties.

- ✓ Regulations of the Industrial Property Law (RIPL)
 - Applicable to patents granted to allopathic medicaments
 - Mandates a publication of a list of products **by the MIIP (unique feature of the Mexican system)**
 - The list is according to the active principle
 - The list should state the term of the corresponding patent
 - The list should **link the generic denomination to the pharmaceutical identity of the active principle and its identification in the patent.**
 - **Excludes** expressly “processes of production or of formulation”

✓ The implementation of the system

- Active Principle patents – published straightforwardly
- Formulation (product) patents – publication rejected systematically by the MIIP but later published through appeals.
- Use of active principle to manufacture medicaments for treating diseases – publication rejected systematically but some published later through appeals.
- List of the MIIP actively used for government purchases

✓ Hints for generic companies:

- Be aware of pipeline patents which might have a different term than that stated in the original title when the patent issued.
- Have in mind the three years provided by the law to start the registration process.
- Consider in the product development strategy and the label projects other formulation or use patents for the same principle in order to avoid infringement.

Linkage System

✓ Hints for pharma patent holders:

- Evaluate filing claims of the type “A medicament for treating disease X characterized by comprising active principle Y” (UK – EPO 2000 approach). They will be rejected by the MIIP under lack of novelty but litigation through appeal might be worthy, given the reluctance of the MIIP to linkage for formulation and use patents.
- Ensure linkage within your company. Inform and train your regulatory team about patents covering the products they are registering and link patent numbers to actual products per country.
- Obtain in Mexico separate health approvals for each new use or formulation of a known drug.

Experimental Use Exemption

✓ Industrial Property Law, Art. 22 fraction I

“Patents shall have no effect against:

I. A third party that, in the academic or private fields, and with non-commercial purposes, performs scientific or technological research activities, purely of experimental, essay or teaching nature, and for which that party produces or uses a patented product, or uses a patented process.”

- Clinical studies are scientific research purely of essay if approval of the drug is not sought.
- The commercial purpose is configured upon filing an application for health approval for sale
- The exception always applies Universities and institutes that are non-for-profit entities

Data Protection vs. Data Exclusivity

✓ NAFTA Art. 1711(5) –TRIPS standards?

*“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.”*

Data Exclusivity vs. Market Exclusivity

✓ NAFTA Art. 1711(6)

*“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 ...”*

✓ CAFTA Art. 15.10 1.(a)

*“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,..”*

Mexico's Compliance to NAFTA/TRIPS standards in Data Protection

- ✓ The Mexican authorities rationale:
 - Dossiers are confidential (Linkage reforms meet compliance with Art. 1711(5))
 - As nobody but the owner can obtain access to the information provided to Health Authorities, nobody can rely on information that it does not know for an approval.
 - The information of the owner is protected and Art. 1711(6) is complied with. Information of third parties must have been obtained through self efforts.
 - Mexico need not provide 5 years exclusivity.



Mexico's Compliance to NAFTA/TRIPS standards in Data Protection

- ✓ An explanation based on the market:
 - Mexican Health Authorities (MHA) **had to** receive as scientific evidence public information independently of the origin.
 - Before February 2008, there were three kinds of drug: Innovators (Proprietary information on safety and efficacy), Generics (Based on bioequivalence testing) and Lookalikes (Based on public information).
 - Consequences: unlawful competition from lookalikes to anyone else.
 - As of February 2008, lookalikes have been prohibited.



Mexico's Compliance to NAFTA/TRIPS standards in Data Exclusivity

- ✓ The facts and the current scenario:
 - The MHA have never issued a generic approval during the first 5 years as of the first registration. This is a proof of a factual compliance.
 - As of February 2008, lookalikes have been prohibited through changes in regulations.
 - In our opinion, such changes are beneficial for data exclusivity provisions and can be the basis for challenging an approval within the first 5 years as of the grant of the first approval granted to a new drug in Mexico.
 - There are other voices that claim that the same changes open the door to non-compliance of data exclusivity.
 - The final outcome is still to be seen.

About patent litigation in Mexico

- ✓ Mexico is a Civil Law country. Infringement and nullity actions are **both** administrative trials **before the MIIP** with two instances of appeal. Damages recovery require further civil litigation based on MIIP decisions.
- ✓ There are some preliminary measures against infringers such as seizure of infringing goods and the like. The MIIP requires bonds to implement the measures and there are counter-bonds available to the infringer in order to lift the measures.
- ✓ The Mexican IP system is effective enough to enforce patents but still inefficient in terms of time for damages recovery.

About patent litigation in Mexico

- ✓ Patent litigation in Mexico is scarce both for nullity and infringement actions. At least 95% of patents are from foreign entities. Litigation usually settles abroad and includes Mexico.
- ✓ Linkage litigation against the MIIP has increased availability of criteria for interpretation of patents, such criteria is not mandatory yet.
- ✓ Damages recovery is at least 40% based on **public selling price by statute** but is almost impossible due to long litigation (**at least** 10 years for a final decision) and lack of experience of courts in handling IP matters.
- ✓ A specialized administrative court for IP has been announced but not implemented yet. It might improve litigation standards.
- ✓ Infringement defense tools such as prior user rights and experimental use exemption are available in Mexico.

Licensing patents in Mexico

- ✓ Patent licenses are not regulated for content in Mexico. General contract law applies and registration before the MIIP is optional.
- ✓ Competition law has been recently modified to make clearer that the anti-competitive use of IP rights might be within the scope of the law.
- ✓ The Mexican Antitrust Commission seems to be focusing in IP related transactions increasingly. It is very likely to follow international discussions on patent pooling, cross-licensing, grant-backs and the like.
- ✓ Compulsory licensing is available in Mexico upon petition to the MIIP if the invention is not practiced within 3 years as of grant or 4 years as of filing, whatever is longer. The MIIP is entitled to determine royalties and all the license terms.

Licensing patents in Mexico

- ✓ The use by a licensee in Mexico is considered made by the patent owner ONLY if the license is registered before the MIIP. This is important for licensees in order to benefit from linkage and avoid compulsory licensing.
- ✓ “Public utility” licensing is available in Mexico for causes related to national emergency or security, which includes medicines for “priority attention diseases”.
- ✓ “Priority attention diseases” are those declared as such by an entity called “General Health Council”, which is a collegiate entity of the Mexican government. Depending on how this provisions are implemented in a real case, they are likely to be challenged by patent owners based on non-compliance of TRIPS as they could be even against the Doha Declaration depending on MIIP performance.
- ✓ Not a single compulsory license or public utility license has been issued in Mexico although few petitions have been made related to compulsory licensing.

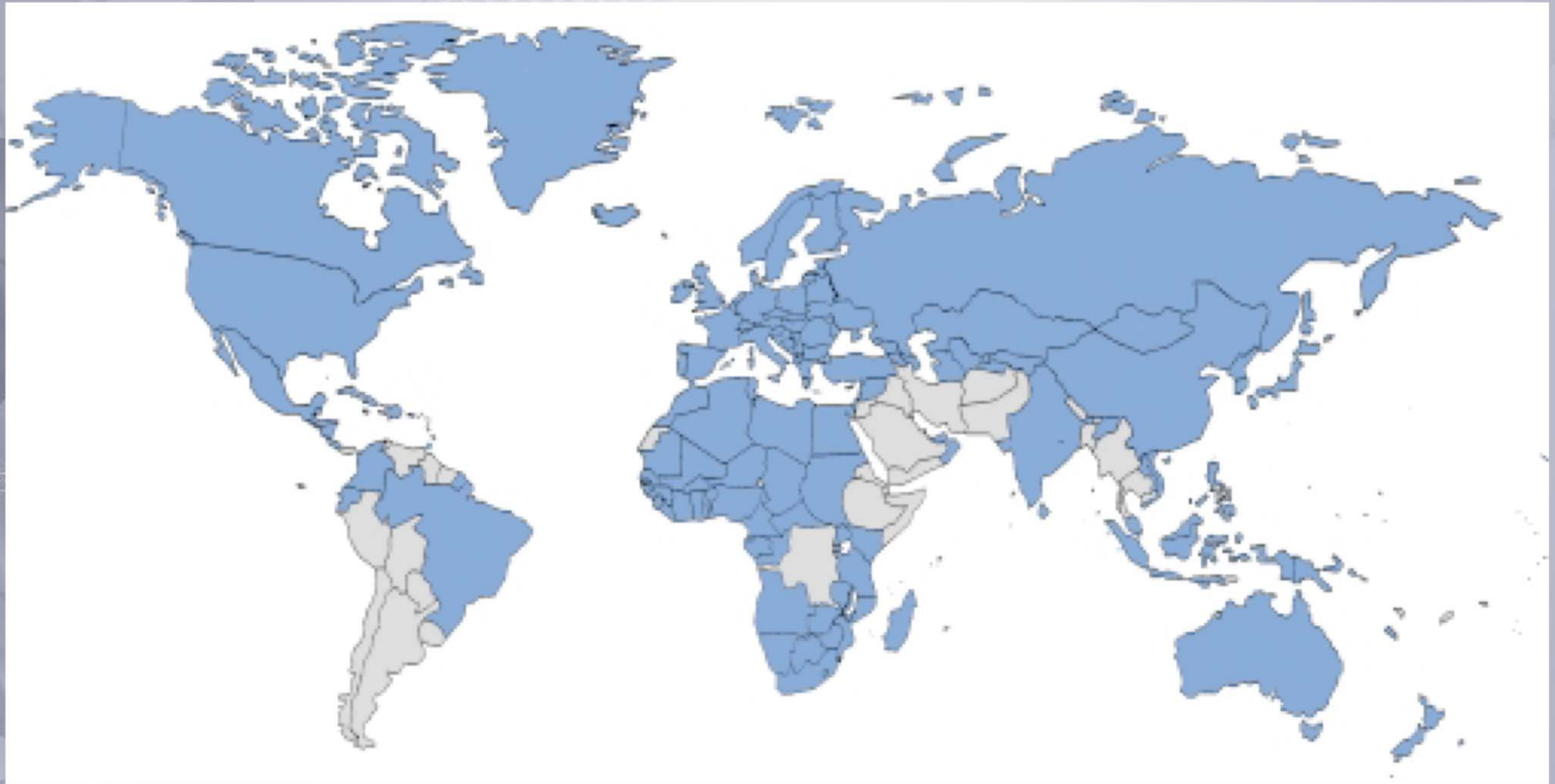
Trends in Mexico – The Bill under discussion

- ✓ The major changes in prosecution are related to:
 - Time limits for filing divisional applications and amendments to claims.
 - Possibility of filing certified copies issued in electronic format.
 - The possibility to implement a proceeding through which the public would be able to submit to the MIIP information affecting patentability of a published application.
 - Some definitions and wording has been clarified for interpretation.
 - Terms for replying office actions are increased to 3 months plus an equal term extension.
- ✓ The major change in patentable subject matter is related to computer implemented inventions. The bill opens the possibility of claiming the same when there is a “technical contribution”.
- ✓ The major change in patent interpretation is the substitution of the word “product” for the broader term “invention” in the provisions related to exhaustion of rights and infringement.

Trends in Mexico – The Bill under discussion

- ✓ It is clarified that parallel imports of patented inventions are prohibited.
- ✓ The main change in patent litigation is the clarification of a nullity cause to avoid the possibility of nullity of a patent based on formalities.
- ✓ Issues that remain the same:
 - Contributory infringement not available. Therefore, claims directed to the user of an invention would be likely to remain unenforceable in practice.
 - Mexico remains 30th month country under the PCT. 31st month patents received and even granted by the MIIP remain under risk.
 - No rules or references to substitute the lack of decisions or criteria to interpret patent claims. Inherency and equivalents not available by statute and decisions from courts are not available in connection to the same.
 - Lack of rules for co-ownership related to use of the invention, assignment or licensing.
 - Possibility of patenting non-obvious new uses.

Latin American PCT Countries



- ✓ Practically all countries in LA comply with patentability to all areas of technology TRIPS compliant. Generally, LA countries exclude from patentability computer programs, business methods, therapeutic/surgery methods and second medical uses.
- ✓ Generally, EP practice more compatible with LA.
- ✓ Some countries accept Swiss style claims.
- ✓ Biotech inventions generally patentable

- ✓ The majority of LA countries are Civil Law.
- ✓ Generally, LA countries have administrative proceedings for patent litigation, that is, infringement and nullity actions are prosecuted before the patent office.
- ✓ Instances of appeal vary among LA countries, but generally a decision will have two further instances of appeal.

Patent Litigation – Latin America

- ✓ Often, trademark attorneys handle patent litigation - tend to misuse concepts.
- ✓ Appeal judges have deficient IP knowledge and even less regarding patents.
- ✓ Precedents and court decisions are scarce. High level patent disputes are often settled according to foreign litigation/negotiations.
- ✓ Damages trials are generally a separate proceeding requiring a final decision on patent infringement

- ✓ Care to take before starting an infringement action:
 - That licenses and ownership is properly registered before the corresponding Patent Office.
 - If the infringement is based in product analysis, that you have possibilities of technically analyzing the product by a LOCAL expert, the time-frame to do so and the feasibility of proving infringement for the formulated product (specially in the case of new salts).

Understanding LA Pharmaceutical Markets

¿INNOVATOR?

¿INTERCHANGEABLE
GENERICS?

¿LOOKALIKE?

¿COPYCATS?

¿GENERICS?



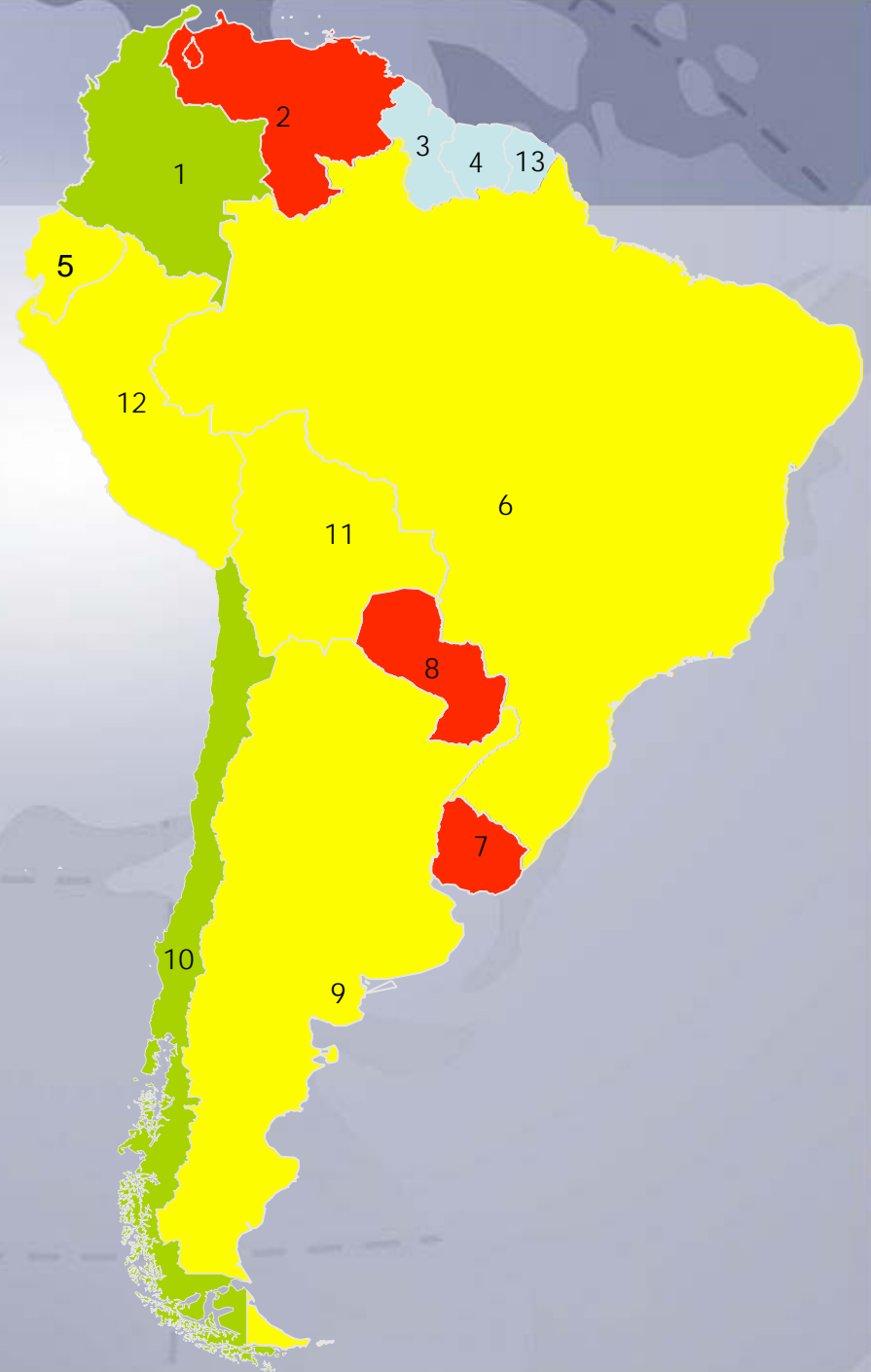
Generics, as understood by LA Health Authorities, are generally not based on bioequivalence testing = not “based upon innovator’s info”

Data Protection/Exclusivity in Latin America

- ✓ Mexico: Enforcement possible as of 2008 in spite of NAFTA (1994)
- ✓ CAFTA Countries: Enforcement improving upon implementation of the treaty

- 1 Colombia
- 2 Venezuela
- 3 Guyana
- 4 Suriname
- 5 Ecuador
- 6 Brazil
- 7 Uruguay
- 8 Paraguay
- 9 Argentina
- 10 Chile
- 11 Bolivia
- 12 Peru
- 13 French Guiana (France)

South America: Data Protection



Not available

Laws in place, Enforcement Poor

Towards better enforcement

Available

- 1 Colombia
- 2 Venezuela
- 3 Guyana
- 4 Suriname
- 5 Ecuador
- 6 Brazil
- 7 Uruguay
- 8 Paraguay
- 9 Argentina
- 10 Chile
- 11 Bolivia
- 12 Peru
- 13 French Guiana (France)

South America: Linkage



Not available

Laws in place, Enforcement Poor

Towards better enforcement

Available

Licensing Regulations

LEVEL OF GOVERNMENT CONTROL TO
TECHNOLOGY TRANSFER ACTIVITIES

NEED TO REGISTER,
HIGH RISK OF COMPULSORY
LICENSING
GOVERNMENT RESTRICTIONS TO
CONTRACT CLAUSES

VENEZUELA

BRAZIL

ARGENTINA

MEXICO
CHILE

REGISTRATION VOLUNTARY OR NOT NEEDED,
TRIPS STANDARDS FOR COMPULSORY LICENSING
FREEDOM TO CONTRACT
ANTITRUST REGULATED MARKETS

TIME - EVOLUTION ACCORDING TO WEALTH LEVELS AND TECHNOLOGY LEVEL,
ADOPTION OF INTERNATIONAL TREATIES

Hints and remarks for Latin America

- ✓ Latin American countries are huge markets for pharmaceuticals and are growing in health coverage, economy and development.
- ✓ Consider that it is less likely to infringe a patent to an R&D tool in Latin America.
- ✓ Watch the WIPO developments in access to Genetic Resources under the Convention on Biological Diversity.



Thank you

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