AN OVERVIEW OF PHARMACEUTICAL AND AGROCHEMICAL DATA PROTECTION

Brazilian and Latin American Cases

Gabriel Di Blasi
DATA PROTECTION
CONCEPT AND GENERAL ASPECTS

Data Protection ≠ Data Exclusivity

- Provides protection of undisclosed test data generated by clinical trials and submitted to regulatory authorities.
- Legally and economically necessary for the drug development process.
- Prevents regulatory authorities and third parties from inadequately using data submitted by innovative companies.
CONDITIONS FOR DATA PROTECTION.

- Data submission to the regulatory authorities is a prerequisite for marketing approval.
- The generation of the data has to involve a considerable effort.
- The drug should be a new chemical entity.
- The value of the data is related to its secrecy.
DATA PROTECTION
TRIPS

- Article 39.3
  - Protection against disclosure.
    - Exception: to protect the public. (MANDATORY SHARING OF THE DATA UPON ADEQUATE COMPENSATION)
  - Protection against unfair commercial use.
DATA PROTECTION TRIPS

- Some options for the members to use the correct implementation of article 39.3
  
  a. Exclusivity time limit for the use of data
  
  b. Cost-sharing or other mechanism to provide adequate compensation
PROTECTION OF DATA PROTECTION

- TRIPs-plus agreements- Flexibilities to the TRIPS agreement.
  - Stronger protection for submitted data.
  - Patent Term extension.
  - Linkage between patent protection and product registered number (Orange book).
  - Restrictions on patent nullity.

- Incentive to Innovation
DATA PROTECTION IN BRAZIL

HUMAN BEING

VETERINARIAN AND AGROCHEMICAL
DATA PROTECTION IN BRAZIL

- For human being use:

  Main aspects - (XIV art. 195, 9.279/96)

- Requirements for protection;
- Granted rights;
- Unfair competition considered as a crime;
- No exclusivity time limit for the use of data;
- No administrative procedure to prevent the disclosure of data;
- Civil Tort – losses and damages;
- Disclosure by regulatory authority for public health.
PHARMACEUTICAL REGISTRATION

Types of Pharmaceutical Products Registration
Law No. 6.360/76

Reference

Generic

Similar or (Me Too)
DATA PROTECTION IN BRAZIL
Brazilian Courts Understanding

In favor

➤ The Brazilian Regulatory Authority (ANVISA) has to demand that the tests required in the legislation are performed

➤ Regardless of the kind of drug, to which registration is granted, it must have its safety and efficacy scientifically proved:

Against

➤ The authorization for the marketing of generic and similar drugs disclaims the submission of the tests required for the reference drugs
DATA PROTECTION Y IN BRAZIL

- For veterinary and agrochemical use:

Main aspects - Law 10.603/02

- Originated by the Provisional Act 69/02.

- Protection of undisclosed information only concerns veterinarian and agrochemical products.

- Establishes an exclusivity period for data confidentiality of drugs for animal use and agrochemicals.

- Compulsory use may be granted, in case of misuse by the originator.
PATENT LINKAGE

• Brazilian case:
  
  – No patent linkage: The procedure for the market approval does not require any information from BPO regarding Intellectual Property Rights of the pharmaceutical product.
  
  
  – Industrial Property Law, article 43, VII.
DATA PROTECTION IN LATIN AMERICA

- The Andean Pact – Bolivia, Ecuador, Peru, Colombia and Venezuela (Art. 266, decision 486/00)
- Treaty of Group of 3 – Colombia, Mexico and Venezuela (Arts. 18-22, Treaty)
- FTAs in Latin America:
  - Period of protection: 5 years at least
  - New pharmaceutical products
  - Prevent Similar products
  - Protection of undisclosed information
# DATA PROTECTION IN LATIN AMERICA

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<td>(*) Priority Watch List Countries –USTR</td>
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<td>(**) No Patent Linkage or Deficient Patent linkage system</td>
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<td><strong>10-years</strong></td>
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<td>special 301 submission 2010</td>
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<td>International Federation of Pharmaceutical Manufacturers &amp; Associations – IFPMA</td>
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CONCLUSION

- Strong patent and data protection for pharmaceuticals as a benefit for innovation.
- In Brazil there is peculiar legal treatment to human being pharmaceutical use in comparison to agrochemical and veterinarian use;
- Brazilian Courts decisions related to the drug registration are not final and conclusive yet;
- Data protection and Patent linkage can be regarded as two of the hottest and controversial issues for the developing countries, especially for Latin America.
Thank you!

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