THE PROTECTION OF UNDISCLOSED DATA

- the Brazilian experience –

The registration of medicines

The registration of medicines in Brazil requires the presentation of some scientific data, in order to guarantee the sanitary security, efficacy and quality of these products.

That legal requirement is related to the fact that, in Brazil, health products are strongly regulated by the government through its competent Agency.

The national Agency responsible for the analysis of these data is the National Sanitary Surveillance Agency – Anvisa.

The regulation system

The regulation of the health sector:

- the principle of the dignity of the human person (art. 1° of the Brazilian Federal Constitution - CF/88);
- the right of health (art. 196, CF/88);
- the social function of property (arts. 5°, XXII, and 170, II, CF/88).

The regulation of the health sector

The art. 6°, Law 9.782/99, determines that it is responsibility of Anvisa to promote and to protect the population's health through the sanitary control of the production and commercialization of products submitted to the sanitary surveillance.

The sanitary registration of medicines in Brazil

Accordingly to the Law 6.360/76, modified by the Law 9.787/99, there are in Brazil three kinds of medicines:

- The originator medicines;
- The similar medicines; and
- The generic medicines.

The registration of originator medicines

Accordingly to the art. 16, Law 6.360/76, the registration of **originator medicines** in Brazil requires the presentation of pre-clinical and clinical trials, in order to guarantee the **sanitary security, efficacy and quality** of the products.

The registration of originator medicines

In other words, if the active principle to be registered is a new one, the applicant must, in order to guarantee the protection to the public health, present the pre-clinical and clinical data, even if they are themselves confidential information.

Registration of similar and generic medicines

- **Similar medicine** – composed by the same active principle, it has the same concentration, pharmaceutical form, administration via, posology and therapeutic use of a originator medicine.

  Nevertheless it is not a pharmaceutical alternative to the originator product.

- **Generic medicine** – is a similar medicine which is a pharmaceutical alternative (therapeutically equivalent) to the originator product.

Registration of generic medicines

In order to demonstrate that a generic medicine is a **pharmaceutical alternative** to an originator drug, the Brazilian Law requires two essays:

- **the bioavailability; and**
- **the bio-equivalence studies.**

Bioavailability essay

Establishes the rate and extent at which an active principle is delivered from a pharmaceutical form and becomes available in the general circulation.

Bio-equivalence essay

Demonstrates that a generic and an originator medicine are composed by the same active principle, have the same pharmaceutical form, are pharmaceutically equivalent and have very similar (comparable) bioavailabilities.

In sum these two essays demonstrate that two medicines are pharmaceutical alternatives.

Registration of generic medicines in Brazil

As long as these two essays are sufficient to the registration of generic drugs, it means that the Brazilian legislation allows the **simplified registration** of this kind of medicine.

The simplified registration

The simplified sanitary registration of a generic medicine has the finality to diminish the time necessary to analyze the scientific documents submitted by the generic industry as well as to diminish the investments in trials which the applicant is supposed to present.

The objective is to avoid the duplication of trials (pre-clinical and clinical data) that the originator industry has already filed.

The simplified registration

- The simplified sanitary registration of a generic medicine is a procedure in accordance with the **collective interest** as long as it allows (once the patent protection is expired) the immediately commercialization of generic products.

The generic medicines

It is important to stress that the concept of collective interest guarantees at the same time the patent privilege and the simplified sanitary registration of generic medicines:

- **Patent** – collective interest in innovation;
- **Simplified sanitary registration of generic medicines** – collective interest in most effective access to medicines.

Undisclosed data and the International Law

Undisclosed data

In order to obtain the referred undisclosed data (pre-clinical and clinical trials), the originator industry must invest in R&D considerable amount of money and time.

That is the reason why these data distinguish the industry in comparison to its competitors and must be protect against unfair competition.

Undisclosed data and TRIPs

Accordingly to the art. 39.1 of the TRIPs Agreement:

"*In the course of ensuring effective protection against unfair competition as provided in Article 10 bis of the Paris Convention (1967),* ***Members shall protect undisclosed information*** *(…)*".

Undisclosed data and TRIPs flexibilities

Although these data have commercial value, the art. 39.3 of the TRIPs Agreement determines that the sanitary authority is allowed to use these information as long as there is protection against unfair competition:

art. 39.3 of the TRIPs Agreement

"**Members, when requiring, as a condition of 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, 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".

Undisclosed data and TRIPs flexibilities

In sum, the TRIPs Agreement protects the undisclosed data from unfair competition but does not determine absolute protection to them.

And it could not be different as long as the patent protection itself does not have absolute dimension (there are flexibilities), as stated in the art. 30 of the TRIPs Agreement and in the Doha Declaration.

Art. 30 - TRIPs Agreement

Exceptions to Rights Conferred

"**Members may provide limited exceptions to the exclusive rights conferred by a patent**, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties".

The Doha Declaration, item 4

"We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. (…) we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right **to protect public health and, in particular, to promote access to medicines for all**.

In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose".

The legal use of undisclosed data

In sum, although these data are property of the originator industry, the IPR system (through flexibilities) allows the sanitary authority to make use of them **as long as that use does not constitute an unfair competition act**.

Undisclosed data and TRIPs

On the other hand, as long as it is not established in the TRIPs Agreement that the undisclosed data should be protect in absolute terms (exclusivity period), concede that this kind of protection would be the adoption of a **“TRIPs Plus” measure** by the Brazilian government.

Undisclosed data and the Brazilian legislation

Social function of property

The use of undisclosed data by Anvisa is in accordance with the social function of property (art. 5°, XXIII, CF/88) which imposes limits to the way through which the owner can exercise his right of property.

- In sum, the right of property cannot act against the collective interest.

Social function of property

Art. 170, I and II, CF/88 – recognizes the property as a necessary tool to the economic development, as long as the social function of property is respected.

It means that the economic agents have the right of property as well as some responsibilities:

- In other words, the economic agents have **social responsibilities**.

Social function of property and the onus of the owner

The originator industry has the right to avoid that the competitors have access to its undisclosed data.

But it also has two onus:

- The first onus is to allow the analysis of its undisclosed data in order to guarantee the sanitary security, efficacy and quality of the products; and
- The second onus is not to avoid the use of these data by the sanitary authority (which is not an unfair use) when a generic application is presented.

Unfair competition

Accordingly to art. 10 bis of the Paris Convention:

"*Any act of competition* ***contrary to honest practices*** *in industrial or commercial matters constitutes an act of unfair competition*".

In other words, unfair competition is related to **bad faith, dishonest and anti-ethical practices**.

Unfair competition

Accordingly to the Brazilian legislation (art. 195, XIV, Law 9.279/96), a crime of unfair competition is committed by whom:

"divulges, exploits or uses, **without authorization**, the results of tests or other undisclosed data the elaboration of which involved considerable effort and which has been presented to government entities as a condition for approving the commercialization of products".

Unfair competition

Besides this provision there is an express authorization to the governmental disclose of confidential data in the Law 9.279/96 (art. 195, § 2°):

"The provisions of item XIV do not apply with respect to disclosure by a government entity competent to authorize commercialization of a product, **when necessary to protect the public**".

The due protection to undisclosed data

It is important to stress that, if there is no necessity to protect the public (art. 195, § 2°, Law 9.279/96 and art. 39.3 of TRIPs Agreement) the **Anvisa does not disclose the confidential data submitted by the originator industry**.

- The **Anvisa protects against unfair competition the undisclosed data** submitted by the originator industry.

The “use” of undisclosed data made by Anvisa

The “use” of undisclosed data

Premises:

- if the active principle is the same of an originator medicine;
- if the medicine is a therapeutic alternative (demonstrated by the bio-equivalence and bioavailability essays).

Conclusion:

- by **inference** (a logical inference) can the sanitary authority conclude that there is no necessity of a new presentation of the pre-clinical and clinical trials already filed by the originator industry.

The “use” of undisclosed data

In sum, to dispense the duplication of essays the sanitary authority **does not need to use (to analyze, to compare or to interpret the results)** the essays presented by the originator industry.

In other words, there is no use, *stricto sensu*, of the undisclosed data filed by the originator industry.

Data exclusivity consequences

Data exclusivity consequences

If there was exclusivity, generic producers would have to submit their own data to prove safety, quality and efficacy, which would oblige them to repeat the pre-clinical and clinical trails already filed by the originator industry.

Data exclusivity consequences

- The repetition of trials would delay the launch of generic products; and
- raise serious ethical questions, since it would expose people to essays purely for commercial reasons.
- In sum, the data exclusivity (protection in absolute terms) diminishes and delays competition, besides having anti-ethical consequences.

Bayer Inc. *vs.* Health Ministry (1999)

In that sense, even though the Canadian Law adopts the exclusivity regime for undisclosed data, the Canadian Federal Court of Appeal decided that:

"When a generic manufacturer files an ANDS, the safety and effectiveness of the generic product may be demonstrated by showing that the product is the pharmaceutical and bioequivalent of the innovator's product. ***If the generic manufacturer is able to do so solely by comparing its product with the innovator's product which is being publicly marketed, the Minister will not have to examine or rely upon confidential information filed as part of the innovator's NDS****. In such case, the minimum five year market protection referred to in the regulation will not apply".*

The “use” of undisclosed data

In sum, the mere **presumption** that it is unnecessary to duplicate the presentation of data does not mean that the sanitary authority relies upon these information or implicitly examines the confidential information filed by the innovator industry.

The linkage and the bolar exception

The linkage

Accordingly to the linkage, the sanitary authority is not allowed to accept an application of a medicine whose active principle is still protected by a valid patent.

This is a *sui generis* protection regime which is *per se* a “TRIPs Plus” measure which has no juridical justification as long as the sanitary examination has a completely different nature from that of the IP rights.

- The sanitary authority analyzes the **security, quality and efficacy** of a product instead of the requirements of patentability.

The linkage

Such a “TRIPs Plus” measure would have negative social consequences in a developing country like Brazil, as long as it delays the competition brought by the access to generic medicines.

The bolar exception

Put into force “TRIPs Plus” measures for the protection of undisclosed data and linkage between IPR and sanitary registration would disrespect the Brazilian IPR system which adopts the bolar exception.

The bolar exception allows the sanitary authority to examine the application of a generic medicine before the expiration of the originator’s patent.

The bolar exception

Accordingly to art. 43, VII, Law 9.279/96:

"acts done by unauthorized third parties relating to the patented invention **carried exclusively to produce information, data and test results to seek market approval in Brazil or abroad**, in order to exploit or commercialize the patented product after the term set by article 40 has expired **shall not constitute infringement of the patent owner exclusive rights**".

Conclusions

Conclusions

1. The use of undisclosed data made by Anvisa is based on the constitutional principles of the social function of property (art. 5°, XXIII, CF/88), as well as on the international compromises assumed by Brazil (arts. 30, 39.1 and 39.3 of the TRIPs Agreement and Doha Declaration);

2. This use is also in accordance with the Brazilian IP Law (arts. 43, VII, and 195, XIV, and § 2°, Law 9.279/96);

Conclusions

1. The simplified registration of generic medicines, normally, does not require the analysis, comparison or interpretation of undisclosed data filed by the originator industry;
2. Instead, the sanitary authority infers that as long as the medicine is a generic one (through bio-equivalence and bioavailability essays) it is unnecessary to duplicate the pre-clinical and clinical trials already filed by the originator industry;

Conclusions

1. The simplified registration of generic medicines is in accordance with the collective interest;
2. Anvisa has as a principle the protection against unfair competition of the undisclosed data submitted by the originator industry; and
3. The Brazilian legislation adopts the bolar exception instead of the linkage between sanitary registration and IPR.

Contacts for further information:
gresi@anvisa.gov.br

Thank you for your attention.