



Pharmaceutical Sector in Brazil –
Eli Lilly do Brasil Ltda.
GSK / Novartis

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Case Eli Lilly : Sham Litigation

- Medicine: Gemzar (*gemcitabine hydrochloride*)
- Eli Lilly was charged of strategically abusing its petition rights before public agencies (the National Industrial Property Institute – INPI and the Brazilian Health Surveillance Agency – ANVISA) and before the judiciary aiming for exclusive marketing rights (EMR) of the medicine GEMZAR
- Information omitted by plaintiffs // association involved
- The case involved the discussion about patent rights (industrial property) and health law, as well as the implications to the Brazilian market. The relevant market presented wide range of inelasticity of demand, with low substitutability of the drug, which is indicated for breast cancer treatment

Case Eli Lilly: Sham Litigation

- Temporary monopoly of the sales between July 2007 and March 2008 was revoked as a result of an understanding from the Superior Court of Justice that considered it to cause serious harm to public health and economy
- Lawsuit against the National Health Surveillance Agency (ANVISA) to obtain the exclusive rights over the sales of the medicine, even being aware that the patent request is exclusively related to its production process and not to the final product

Case Eli Lilly : Sham Litigation

- *PRÓ-GENÉRICOS* is an association of the generic drugs' industry. The parties are important players in the market and are used to litigate against each other.
- The analysis aims to identify if the measures taken by the plaintiff to defend its market interests would be reasonable or not, based on the premise that generic drugs have an economic advantage (lower price) if compared with the reference brand drug.
- Due to the monopolistic period, the medicine Gemzar was sold for BRL 540 (around USD 152). After the end of the monopoly, it was traded for BRL 189 (around USD 53).

Case Eli Lilly : Sham Litigation

CONCLUSIONS:

- Eli Lilly succeeded in obtaining governmental provisions through false information and intentional omission
- Lawsuits: conflict situation to the Brazilian institutions of industrial property (INPI) and health surveillance (ANVISA)
- The company also proved it had anticompetitive intentions, expecting to create direct or collateral damage to the competitor by changing the initial object of analysis (purification process) to another (final product), a circumstance that could guarantee significant market and commercial gains to itself
- Eli Lilly unfairly extended the effects of the right of exclusivity to other therapeutic purposes not covered by the judicial decision, which was restricted to the treatment of breast cancer.

Merger GSK/Novartis

- Joint venture for trade of over-the-counter products
- Notification: October 2014
- Horizontal overlap
 - Dermatological antifungals
 - Non-narcotic Analgesics
 - Antipyretics
 - Antismoking products (high concentration)

Merger GSK/Novartis

- Settlement
 - Structural remedies:
 - Sale of assets located in Brazil related to GSK's Niquitin brand, available in Brazil in tablets and patches. It included intellectual property rights, licenses and contracts related to the brand;
 - Behavioral remedies:
 - physical and electronic barriers between the companies;
 - compliance training;
 - monitoring mechanisms to prevent the undue sharing of information related to the joint venture with Novartis;
 - monitoring by an external lawyer of all meetings in which representatives of Novartis take part;
 - the prohibition to Novartis representatives in the joint venture to be employed by Novartis;
 - a restriction on information-sharing about Novartis' business with people involved in the joint venture.

- Standards of analysis
- Regulation and competition
- Competition discussions in health sector is not restricted only to intellectual property



Thank you!

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