LEVY & SALOMÃO
ADVOGADOS

Competition Policy and Life Cycle Management Strategies

The Brazilian experience

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Regulatory Framework

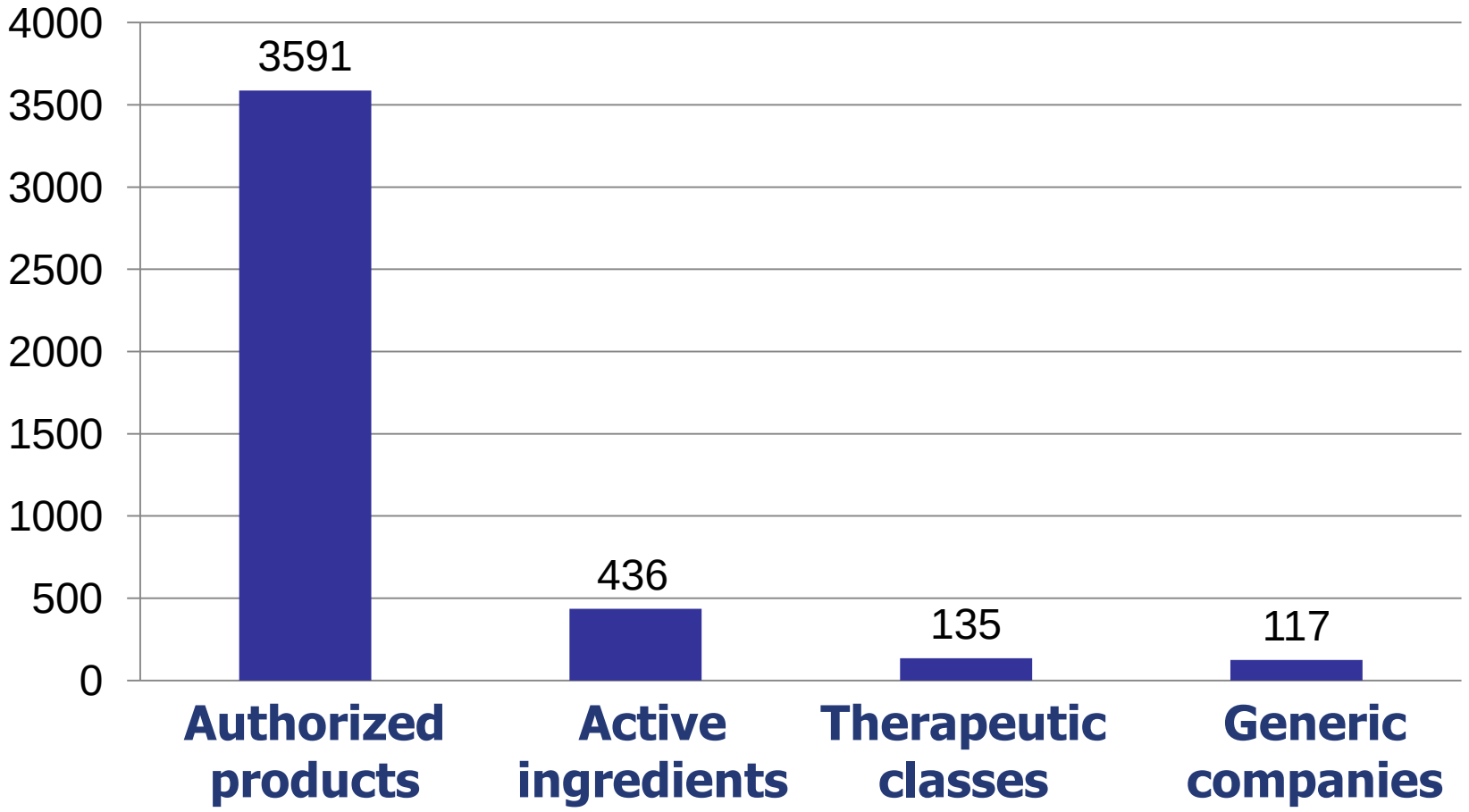
- Law 5,772/1971 explicitly prohibited drug patenting
- TRIPS created an obligation for Brazil to protect drug patents, with transitional rules ("pipeline" patents)
  - The "pipeline" allowed patent requests to be automatically approved based on the date of the first foreign filing
- Maximum period for patent protection is 20 years
- 3 types of drugs:
  - Originator
  - Generics
  - Branded Generics

Regulatory Framework

- Starting from 1999, pharmacists may automatically substitute prescriptions for a brand to a generic
- Several provisions aim to promote competition:
  - Doctors with the public health system shall include in the prescription the active ingredient rather than the originator product
  - Government shall organize bids listing the active ingredient rather than the originator product
  - Entry price for generics has to be at least 35% under the price of the originator product (prices are regulated by CMED)
  - Originator companies shall supply samples to generic competitors to allow them to produce generics

Generic Drugs in Brazil – Overview

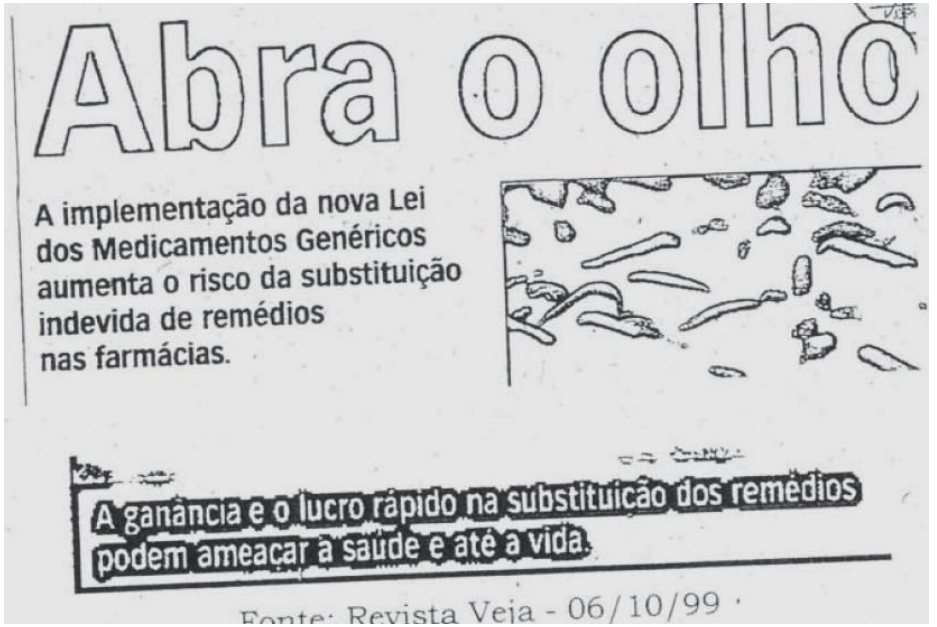
As of November 2013



Source: Pro-genéricos

1. Campaign against generics (1/2)

- **In 1999, following the approval of the Law on Generic Drugs, 19 branded companies allegedly colluded to prevent generic entry. They allegedly agreed to boycott distributors that would agree to distribute generics and engaged into a public campaign against the use of generics**


Abra o olho

A implementação da nova Lei dos Medicamentos Genéricos aumenta o risco da substituição indevida de remédios nas farmácias.

A ganância e o lucro rápido na substituição dos remédios podem ameaçar a saúde e até a vida.

Fonte: Revista Veja - 06/10/99

1. Campaign against generics (2/2)

- **CADE sanctioned the companies in 2005 to pay 1 to 2% of their turnover in the year before the initiation of the investigation**
- **In 2011, a federal judge reversed CADE's decision based on the lack of evidence of anticompetitive conduct. CADE appealed from this decision and a final decision is pending**
- **In August 2014, CADE imposed a fine of roughly €1.5 million against Merck for having taken part in the same meeting and not voiced out its disagreement (tacit collusion)**

Even today generics are viewed with skepticism by part of the population

- According to a research conducted by *Instituto de Ciência Tecnologia e Qualidade* in 135 cities in 2014, 30% of consumers do not trust generics, and 65% of consumers do not trust branded generics
- 42% of the upper class prefers to buy originator drugs over generics
- The government is investing in campaigns and has recently decided do create a seal to attest the quality of branded generics

Public campaigns and aggressive pricing strategy

2. Extension of pipeline patent protection

- In 2007, Pró-generics filed a complaint against Sanofi-Aventis claiming that it has abused its market power by presenting a request to extend a "pipeline" patent related to *Plavix* (prevents blood cots after a heart attack/stroke)
  - The issue is related to the initial date to start counting the 20-year patent protection
  - The issue was settled in April 2010, when the Superior Court of Justice decided that the date of the first foreign filing is the one valid, even if the filing was later withdrawn (Viagra case)
- CADE dismissed the case in 2012, concluding that the IP Law provisions allow two possible interpretations and the one argued by Sanofi-Aventis was reasonable

3. Extension of EMR due to new use

- In 2007, Pró-generics filed a complaint against Eli Lilly for allegedly abusing its rights regarding Gemzar (cancer treatment) to prevent generic entry
- Eli Lilly filed six different claims before the judicial courts to enforce its rights and required one additional period of exclusive marketing rights (5 years) given the discovery of a new use for the drug (breast cancer treatment)
  - An injunction ensured an additional protection for 8 months
- CADE's SG found a violation; case now pending before CADE's Tribunal (on the other hand, similar investigation was dismissed against Aventis in 2013)

4. Refusal to deal

- In 2011, Pró-generics filed a complaint against Janssen Cilag claiming that it has directed its distributors not to supply samples of Velcalde to generic companies (Eurofarma)
- Although recognizing that taking measures not to supply the originator drugs to competitors would amount to an antitrust violation, CADE dismissed the case in 2013 stating that no evidence of illegal conduct was found (Eurofarma acquired 211 samples of the originator drug in 2011)

5. Abuse of Data Protection Rights

- In 2010, Pró-generics filed a complaint against Lundbeck claiming that it has allegedly abused its data protection rights regarding Lexapro
  - Through judicial claims, Lundbeck aimed to prevent Brazil's FDA from using data related to Lexapro's files to issue authorization for generic drugs
- Investigation is still pending
- Similar case pending against Genzyme initiated by Germed in 2009

6. Ring-fencing

- In 2011, Pró-generics filed a complaint against AstraZeneca for allegedly abusing its power due to patent violation claims against Germed/Brazil's FDA regarding a number of drugs, namely Crestor, Nexium, and Seroquel. AstraZeneca was accused of engaging into ring-fencing practices regarding its IP holdings to deter entry
- Investigation is still pending

7. Launch of second generation drugs

- In 2008, Pró-generics filed a complaint against Abbott for allegedly abusing its power due to (i) patent violation claims against Cristália Produtos Químicos e Farmacêuticos regarding anesthetics and (ii) the launch of a new antiviral drug (Meltrex, which replaced Kaletra), not considered to be an improvement over the original drug
- Investigation is still pending

Conclusion

- Pró-generics association has been proactively filing a number of complaints before CADE
- It seems that CADE has not been shy about intervening, though there are a fair number of investigations that has been dismissed
- 2013 CADE/Brazil's FDA Cooperation Agreement shows that CADE is expected to devote more resources to the pharmaceutical sector, which seems to rank high in CADE's priorities

Three issues that deserve attention

- Level of sanctions imposed by CADE for anticompetitive conduct
  - For unilateral cases, it is reasonable to expect fines of up tot 5% of the turnover in the year preceding the investigation and possibly a prohibition from participating in public procurement proceedings for at least five years
- Individual liability (officers and directors at risk)
- Private claims

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