

Clarke, Modet & C^o

ESTABLISHED IN 1879



Global Patent Developments

A general overview on Brazil

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Arbitration and other ADRs

Brazilian Law allows arbitration to solve disputes on Patent License Agreements;

Arbitration is **allowed** to solve infringement matters as long as:

- the infringement refers to a patent object of an agreement signed by the parties (infringer and infringed party) and
- the agreement contains a specific clause on arbitration stating that a decision will not be ratified by a Court;

Arbitration is **not allowed** to decide on the validity of patents due to three main reasons:

- the decision declaring the validity or nullity of a patent right is "erga omnes" (effects against third parties)
- industrial property rights are exclusively granted by the State;
- the matter is considered as of public interest.

Generics in Brazil

Brazil has a strong generic industry - financially healthy companies, aggressive marketing and active associations (Ex.: ABIFINA - Brazilian Association of Fine Chemistry - and Pro-Genéricos)

Historic issues has caused the growing of Brazilian generic industry:

- Specific law admitting generic medicines;
- Risks of compulsory licenses of patents granted - Ex.: (Ex.: EFAVIRENZ);
- Decisions rendered by Courts rejecting Pipeline Patents in Brazil;

Major Consequences:

- the increasing of generic companies on pharmaceutical industry;
- major foreign pharmaceutical companies has been acquiring Brazilian laboratories in order to increase their "market-share" in Brazil;

ANVISA

ANVISA - The Brazilian National Agency of Sanitary Surveillance

Specific provisions on Brazilian IP Law allows ANVISA to interfere on the prosecution of pharmaceutical patents:

“Article 229 - C - The grant of patents for pharmaceutical products and processes shall depend on prior consent from the National Agency of Sanitary Surveillance (ANVISA)”

In principle, ANVISA's action should be limited to the analysis of the issues closely related to its institutional purposes, i.e. public health issues. The above provisions are in force, but they have been questioned in Court individually by pharmaceutical companies;

ANVISA has ceased (at least temporarily) to render opinions on patent applications. The cessation, though, is not due to legal issues, but to the fact that ANVISA is currently adjusting its analysis with the Brazilian Patent and Trademark Office's tasks.

ANVISA: Recent Cases

MERCK FROSST CANADA LTDA X ANVISA:

Case decided by the Federal Court of Appeals of the Federal District :

“The main goal of Article 229 - C of the Brazilian Industrial Property Law is to allow ANVISA to render a prior opinion regarding public health in order to avoid the registration of pharmaceutical products and processes which may cause risks to public health. ANVISA must limit its analysis to public health issues, while the analysis of patent requirements must be rendered by the Brazilian Patent and Trademark Office.” (Decision rendered on October 03, 2011);

MAX-PLANCK-GESELLSCHAFT ZUR FOEDERUNG DER WISSENS-CHAFTEN x ANVISA

Case decided by the Federal Court of Appeals of Rio de Janeiro:

“It is not reasonable to conclude that the main requirements of a pharmaceutical patent need to be analysed by two different public agencies. This could be considered as unnecessary bureaucracy, which may cause conceptual, economic and human damages. The understanding that ANVISA is legally entitled to decide on patent requirements is equivalent to subtract all independency the Brazilian PTO enjoys to proceed with such analysis.” (Decision rendered on May 25, 2011).

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