Patent Law in Brazil: An update

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1. Introduction – statistics
2. Patent prosecution highlights
3. The backlog & expediting examination
4. ANVISA and prosecution of pharma & biotech patents
5. Mailbox Patents
Patents in Brazil: evolution since 2009

Yearly average increase of 30% versus limited new hires of examiners

Source: National Institute of Intellectual Property (INPI)
### Patents granted by type of industry

**Period: 2008-2012 & Prosecution timeline**

<table>
<thead>
<tr>
<th>Industry</th>
<th>Average Time to Final Decision[1]</th>
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<tbody>
<tr>
<td>Technology</td>
<td></td>
</tr>
<tr>
<td>Pharma</td>
<td>9-11 years</td>
</tr>
<tr>
<td>Mechanical</td>
<td>6-8 years</td>
</tr>
<tr>
<td>Electronics</td>
<td>9-11 years</td>
</tr>
<tr>
<td>Chemistry</td>
<td>8-10 years</td>
</tr>
<tr>
<td>Biotechnology</td>
<td>9-11 years</td>
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**Average Time to Final decision of patents granting is 8/9 years depending on the Industry**

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Term of Protection & Non-Statutory Subject-Matter

**Invention:** Valid for 20 years from the filing date OR **10 years from the date of grant, the longer**

The following subject-matter is not considered an invention: Therapeutic or diagnostic methods (in the human or animal body).

- The “Swiss-style” is the format currently accepted by the PTO.

A few years ago the PTO adopted a very strict position in connection with amendments voluntarily submitted after the examination request.

According to this position, the addition of new classes or categories of claims or new embodiments after the examination request would not be acceptable. The same applies to divisional applications filed after the examination request of the main case.

Amendments should be filed before the examination request
Patent Legislation

The Patent Legislation in LATAM is more similar to the European Patent Law

**Comparison with the US Patent Law**

- There is no concept of Provisional Applications.
- There is no concept of Continuation in Part Applications: The scope is defined since the filing date.
- The Designs are Registrations different from the Patents (no inventive step required): In USA are Design Patents.
- The plant varieties Protection is not like the Plant Patents in USA.
Practical considerations in claim drafting

- Consider that the examiners are very strict about limitation of the claims to the illustrative examples, therefore
  - **Include as many illustrative examples as possible in the specification**

- Consider the strict position adopted by the examiners regarding amendments after the examination request, therefore
  - **Include as many categories of claims before the examination request**

- Consider that examination costs for more than 15 claims are quite expensive and for more than 30 are extremely expensive, but
  - **Multiple dependent claims are acceptable**

- EP granted claims are well seen by BR examiners, therefore
  - **Consider the advantages of filing restrictive amendments to conform the BR claims to the granted EP claims**
Green Patents - Pilot

- Now available for PCTs – New Resolution still not published

- Scope: similar to WIPO green inventory, excluding the following fields: a) administrative, regulatory or design aspects, and b) nuclear power generation

- Limited to the firsts 500 granted cases or until April 16, 2015

- Clarke Modet & Cº’s case of success: BR 1020120327562, from DSM IP Assets B.B. one of the first cases granted
Fighting the backlog

Otávio Brandelli took over as the new PTO’s president on December 17, 2013.

Priority: valuing the servers and running public tenders to hire new examiners to reduce the backlog.

Further to the announced tenders, the examination of patents is now organized in 5 different lines for examination:

1. Utility models
2. First filing in Brazil (non PCT)
3. PCT with Brazil as International Authority
4. other PCTs
5. e-PEC applications (Argentina, Chile, Colombia, Ecuador, Paraguay, Peru, Suriname, Uruguay)

First choice in the lines: priority examination
### How to accelerate the granting of patents

- Potential infringement;
- Applicant is 60 years old or older;
- The grant of the patent is a condition for obtaining financial resources from official national fostering or credit institutions;
- National emergency or public interest;
- Green patents – Pilot;
- Preliminary opinion on patentability - Pilot;
- Cases "of interest of" the National Health System;
- HIV, cancer and neglected tropical diseases.
### ANVISA – Events

#### ANVISA

<table>
<thead>
<tr>
<th>Event</th>
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<tr>
<td><strong>Law 10.196/01</strong></td>
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<tr>
<td>Union's Attorney General (AGU) opinion public health issues</td>
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<tr>
<td>Report from the IP Inter-ministerial Working Group - New flow</td>
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<tr>
<td>New resolution RDC 21/2013</td>
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<tr>
<td>Civil Action aiming at the nullity of AGU's Opinion is dismissed by the first instance's judge</td>
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</table>
Prosecution Flow for Pharma related inventions and Clarke, Modet & Cº’s statistics

Application is filed

Formal examination

Pharma product or process?

Yes

Application is sent to Anvisa

No

Examination and decision issued by the BR PTO

Publication of the result in the BR PTO’s Gazette

Application is filed away based on the denial of Anvisa’s consent

INPI

Application is examined

Prior consent granted?

Yes

Publication of Notice in the Union Gazette

No

Application is sent back to the BR PTO

ANVISA

Application is sent back to the BR PTO

Publication of Notice in the Union Gazette

Denied by ANVISA

Approved by ANVISA

Pending

25%

5%

70%
The patent application is considered contrary to public health when:

I - The pharmaceutical product or process involved in the application is a risk to health;

II - The product or process is of interest to pharmaceutical policies for access to medicines and pharmaceutical care within the National Health System and does not meet the patentability requirements and other criteria established by the IP Law.
Strategic products for the National Health System

- Decrees 1,284/2010 (currently used) and 3,089/2013 (new list)
  - List updated every 2 years / at the discretion of the Minister of Health revisions and updates may be held at any time

- Antibiotics, antifungal and antitumor produced by biotech
- Monoclonal Antibodies
- Antiretroviral
- New drugs and biomolecules produced by biotech for viral diseases, neglected diseases and cancer
- Human insulin

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Is it possible to avoid ANVISA?

Case of success: Animal Health

Original claim 1: A compound of formula

\[
\text{(NC)}_m \text{O} \text{N} \text{H} \text{N} \text{O} \text{C} \text{H} \text{X}_1 \text{-R} \\
(X_2)_n \text{O} \text{N} \text{C} \text{H} \text{X}_1 \text{-R} \\
\]

Amended claim 1: A **veterinary** compound of formula

\[
\text{(NC)}_m \text{O} \text{N} \text{H} \text{N} \text{O} \text{C} \text{H} \text{X}_1 \text{-R} \\
(X_2)_n \text{O} \text{N} \text{C} \text{H} \text{X}_1 \text{-R} \\
\]
Mailbox Patents

- Name for patents filed after the coming into force of the TRIPS agreement (January 1, 1995) and before the Brazilian IP Law was in effect (May 14, 1997), for inventions covering pharmaceutical products and chemical products for agriculture.

- On September 11, 2013 PTO filed 37 lawsuits in order to obtain the nullity of mailbox patents.

- 247 patents covering drugs used to treat diseases such as: cancer, AIDS, erectile dysfunction, migraine, candidiasis, multiple scleroses, rheumatoid arthritis and psoriasis.

- The “sub judice” status was published in the Official Bulletin of October 8, 2013.

- According to the TRIPS Agreement, the term of any mailbox patent is 20 (twenty) years from its filing date. In Brazil the term of a mailbox patent is set forth in the sole paragraph of Article 229 of the Brazilian Industrial Property Law.
Current status of the pending lawsuits:

- The PTO and most patent owners are settling agreements in order to stop the lawsuits. Patent owners are renouncing non exploited patents and the PTO agrees not to continue the lawsuit against those patents.

- According to the firsts issued decisions, Brazilian judges understand that those patents are valid and the patent expiry dates should not be changed.
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 WISSENSCHAFTEN 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 conceptuals, 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).