Patenting in the Emerging Markets - Brazil - Order and Progress?

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Brazil is the world's fifth largest country, both by area and population, and has the seventh largest economy measured by GDP. The country excels in the production and exportation of commodities like coffee, iron ore, soya, orange juice, tobacco, and cattle; and produces steel, automobiles & aircrafts, computers and petrochemicals. In the last decade a great portion of the population has become prosperous, and in a time where inflation rates are under control, this makes the Brazilian market attractive to foreign investments. In this article we describe peculiarities of the Brazilian patent system, which are of particular relevance for those who wish to enter the market.

The IP system in Brazil

The national motto written on the Brazilian flag is "order and progress" and Brazil historically stands as a country that enforces international IP conventions, being one of the original signatories of the Paris Convention in 1883 and of the Patent Cooperation Treaty (PCT) in 1970. The Industrial Property Law (IPL) currently in force was fully implemented in 1997 and stands in full compliance with the TRIPS agreement, bringing the legislative framework for patent protection to a standard comparable with the most developed countries in the world. The Brazilian Patent and Trademark Office (BPTO), decides upon the granting on patents of invention and utility models, besides other industrial property assets. In view of the good legislative order, progression should be guaranteed, however the reality of the Brazilian prosecution system is somewhat different, as will be apparent from the below.

Patentable subject-matter

The overall patentability criteria of novelty, inventive step and industrial applicability in Brazil correspond to the European criteria as do the exceptions from patentability. Excluded is software programs per se, methods of treatment and diagnostic methods applied to the animal or human body, all or part of natural living organisms except transgenic microorganisms, biological material found in nature or isolated therefrom, including the genome or germplasm of any living being, and natural biological processes. Also excluded from patentability is patentable subject-matter which is contrary to morality, public security, public order or health and atomic nucleus transformations.

Software inventions

Some 2 years ago a set of Guidelines for the examination of biotechnology inventions, software inventions and business methods were drafted. Although yet to be officially confirmed, these guidelines are internally approved by the BPTO's personnel and have been applied in practice. Software protection is also provided via a declaratory registration filed before the BPTO, although such registration in itself does not guarantee protection.

The guidelines for software-related inventions and business methods will provide the necessary harmonization and make clear that only software *per se* is to be excluded from patentability, much like the

current practice in Europe. If a technical effect is attainable, a patent may be granted even if the subject-matter relates to software and business methods. The guidelines will also provide a basis for the acceptance of functional language in the claims.

Biotechnology inventions
Within the field of biotechnology a very restrictive pattern has been applied by the BPTO and consequently the scope of what is allowed is usually narrow. Generally, the scope of a claim that is accepted is based on the examples and tests made. For example, an invention based on a gene or protein sequence is commonly restricted to the sequences used and described in the examples. Likewise "Markush" style claims covering chemical compounds are usually restricted to cite the one or more compounds used in the examples and definitions of gene or protein sequences by homology or identity are usually rejected.

If an invention is directed to a portion of a natural product, even if said portion is not found in nature *per se* (e.g. a fragment of a gene or protein) the claims will be rejected. During prosecution it is a major issue whether a natural counterpart to the claimed product exists, if it does, the claimed product is not patentable. The BPTO's interpretation of what is a "part" of a living being is broadly interpreted to include major organs, tissues, cells (host cells, plant cells – although not transgenic microorganisms (!)), components of such cells, organelles or structural portions of these cells, including proteins, polypeptides, etc. This interpretation applies to all types of biological material which has a natural equivalent and cannot be distinguished therefrom.

Pharmaceutical inventions
While medical treatments of the human body per se are exempt from patentability, as in Europe and many other jurisdictions, second medical use claims are acceptable. They must however be drafted in a specific Swiss type format, must target a new condition and a different mechanism of action must be shown. Preferably, *in vivo* testing should be exemplified in the specification. It is important to have the claims in the proper format at the time of filing a request for examination; otherwise the relevant claim amendments will not be accepted at a later stage or even in a divisional application.

Selection inventions usually face difficulties in arguing novelty and inventive activity.

The Brazilian FDA (ANVISA) revision of pharma applications
On the bumpy road towards obtaining a Brazilian patent directed to pharmaceutical inventions another factor comes into play; the interference of the Brazilian counterpart to the FDA, the National Health Surveillance Agency, ANVISA, in the examination of pharmaceutical related inventions. All patent applications claiming pharmaceutical products and/or processes must have what is known as "prior approval" by ANVISA.

The legitimacy of ANVISA's role in the examination of pharma patent applications has been extensively contested, both within the administrative sphere and before the Courts. The issue is far from settled and significant additional discussions before the Courts are anticipated until a final position may be established as to the boundaries of ANVISA.

ANVISA has in the meantime examined the patentability of some pharma inventions, in some instances denying a prior consent, and, moreover, determining that the BPTO – who receives the application for substantive analysis after ANVISAs analysis – ought to shelve the case away. This causes great discrepancy and legal uncertainty, for one because the BPTO's Examiners tend to have contrary views to those of ANVISA, and since the applicant has already paid the patent examination fees.

BPTO and ANVISA on occasion are in agreement, and pharma inventions which face difficulties during examination by the BPTO (such as the polymorphs, selection invention patents, second medical uses and Markush claims listed above) usually are also denied by ANVISA Examiners based on lack of novelty, inventive step, and sufficiency of disclosure.

The current reality of the BPTO

The BPTO is struggling with a massive backlog of patent applications awaiting a decision at the Examination stage: about 35.000 applications are filed each year while the BPTO finalizes less than 15.000 annually thus the backlog increases every year. The BPTO prosecution time has an average of 10 years and 109 days, for some technical fields the average prosecution time is 13 – 14 years (biotech & telecom).

Patent Term
To compensate for, or retain the incentive to file patent applications in Brazil despite the extreme backlog, a patent once issued will be in force for 20 years from its filing or 10 years from the date of grant, whichever term is more beneficial to the patentee. This guarantees a patent life term of 10 years from grant, which term is automatically granted by the BPTO whenever the examination exceeds 10 years.

Accelerated Examination possibilities
A priorization in the initiation of the examination procedures can be requested in the following situations:

a) If the invention as claimed in the application is being infringed or likely to be;
b) If the applicant is an individual of 60 years of age or more;
c) If the granting of the patent is required in order to obtain funding for exploiting the invention in Brazil; and
d) by any party if the invention concerns products, processes, equipment or materials with the objective of treating particular conditions, including cancer, HIV, malaria and neglected diseases.
   Moreover, upon request of the Ministry of Health, patent applications that refer to inventions conveying products, processes, equipment or materials for treatment of diseases listed in the Public National Health System (SUS) can be also prioritized.

The BPTO also has a "green patents" pilot program allowing accelerated examination procedures for some "green technology"-related patent applications.

Enforcement of Patent Rights in Brazil

In Brazil, when it comes to enforcement, only two categories of patents exist: process and product patents. On the other hand, the status of the patent right in enforcement procedures can only be an issued patent, although there are some debates around the rights arising from a pending application, particularly in view of the Brazilian Patent Office's backlog.

When a patent application remains pending there are some limitations concerning its enforcement. On one hand, the IPL establishes that a patentee has the right to prevent third parties from using the object of a patent only if the same was already issued, while on the other hand it also provides that the patentee shall be indemnified for damages relating to undue use even if it occurred before the issuance of the infringed patent.

In the opinion of many Brazilian scholars and forming part of Brazilian jurisprudence, a patent *application* is a mere expectant right and the applicant's sole remedy is use of a cease-and-desist letter to presumed infringers informing of the application and of payment of damages upon issuance of a patent. A cease-and-desist letter also has the effect of preventing the statute of limitations which sets a five-year time limit to claim damages due to the infringement of industrial property rights. In this sense, some State Courts refuse to analyze the merits of infringement actions that refer to pending applications.

The question has also been addressed before the Federal Court of Appeals for the Second Circuit, which determined that it is not reasonable for the BPTO to spend more than a decade to examine patent applications, even more so in view of the Brazilian Constitution that guarantees a reasonable length of administrative proceedings.

For *issued* patents the patentee has the right to prevent third parties from using the object of the patent (exceptions applies, such as non-commercial use, research use etc.). In the case of process patents the alleged infringer has the burden of proof.

Working of patents and compulsory licenses
A patent must be worked within three years from its granting; otherwise, it can be subjected to a request for compulsory license. Working of a patent means the actual working of each independent claim contained in the patent. Offering a patent for a voluntary license, in itself, is not a sufficient measure to avoid the possible request for a compulsory license.

To date only two cases in which patents were compulsorily licensed are identified. The most well-known is those concerning Merck patents directed to the anti-HIV drug Efavirenz which was compulsory licensed in 2007 with allegations focused on reasons of "public interest". The government issued a Presidential Decree determining Health emergency and abusive pricing of the medicament.

In summary, the framework of the Brazilian patent system is in order – the progression through the system leaves something to be desired, however steps have been taken to improve the situation for those who wish to obtain patent protection and enforce their rights in Brazil. So go ahead – protect your inventions in Brazil.

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