Licks ATTORNEYS

Prepared by Otto Licks

IPR strategy in Brazil

The 4th LES ASIA Pacific Regional Conference

October 17th, 2013, Hangzhou

1. Basic facts about Brazil and its IP regime
2. Patentable subject matter
3. BRPTO – influences and back log
4. New guidelines and Resolution #93 of 2013
5. ANVISA's prior approval under 229-C
6. Patent exclusive rights
7. Patent Cooperation Treaty – PCT in Brazil
8. Data package exclusivity – Current policy

Licks ATTORNEYS

1. Basic facts about Brazil and its IP regime

Licks ATTORNEYS

The Federative Republic of
Brazil

Brazil is the 5th largest country in the world (larger than the continental U.S. and almost 23 times the size of Japan).It is the largest country in Latin America.

Brazil has been a republic since 1889 with a legislature called National Congress (Senate and House of Representatives). Democratic changes in government have impact in the IP landscape, as different political parties have diverse views and industrial policy objectives.

Brazil was a Portuguese colony from the year 1500 to 1822.

China and Brazil have a long relationship
with no problems in the far past, recent past or present.

China is Brazil's # 1 client for exports.

The Brazilian population is about 200 million (also 5th in the world).

The James Monroe's administration of the United States
was the first to recognize Brazil's independence, followed by
Portugal itself in 1825.

Host for the World Cup of 2014 and the Olympic games of 2016

Brazilian legal system
Basic facts

The Brazilian legal system has taken shape under the influence of the main European civil codes, especially those of France, Italy and Germany, influenced by the Napoleonic Code. The original Portuguese legislation has left marks upon Brazilian legal institutions, which have also been influenced by the United States.

The 1988 Constitution addresses a wide range of topics, from IP to mandatory healthcare coverage, and ensures a comprehensive list of rights and guarantees. The IP provision of the Constitution is regularly applied by courts (Article 5, XXIX).

The Brazilian legal system is based on the Constitution, federal laws and international treaties and conventions, as well as other administrative instruments, such as decrees and administrative rules.

In Brazil, only the Federal Union issues all intellectual property, trade secrets, unfair competition and antitrust laws. When there is no specific legal provision, the courts decide based on analogy, customs and general legal principles. Judicial precedents are not *stare decisis* although they do exercise a role in supporting courts' decisions.

Constitutional and administrative law allows courts to review all ministerial administrative acts, including the decisions from the BRPTO and other agencies, such as the Brazilian FDA and Customs, for example.

Brazilian legal system

Implementation of intellectual property treaties 1

The procedures to implement a treaty are found in the constitution and remain the same since the enactment of the Paris Convention in 1884, by the Imperial Decree 9.233.

After receiving the Brazilian delegate who signed a treaty, subject to ratification, the Brazilian President sends to the National Congress a message, seeking approval consent for the ratification of the treaty, as per Article 49, I, of the Constitution.

When the message reaches the Congress, a bill for a legislative decree is created, which is the instrument used to enact its decisions without the need of presidential ratification. The bill will have to be approved by specific committees in Congress. All the discussions relate to whether a legislative decree giving advice and consent will be approved or not.

If approved, the advice and consent of the Brazilian Congress is made public by the enactment of the legislative decree by the president of the Senate. The only two functions of the legislative decree are: 1. to authorize the executive branch to deposit the instrument of ratification of the treaty, finally binding the Brazil according to the treaty specific provisions; and 2. to give the executive branch the authority to incorporate the treaty provisions into Brazilian domestic law.

However, the enactment of the legislative decree does not have the legal consequence of transforming the provisions of a treaty into Brazilian domestic law.

Brazilian legal system
Implementation of intellectual property treaties 2

It is not debated that the clear and reiterated case law from Brazilian highest courts, (Supreme Court and Superior Justice Court) and the practice of the Administration require a Presidential Decree of promulgation of the Portuguese translation of the treaty.

Only the Presidential Decree of promulgation of a treaty, with the full translation in Portuguese has the power to establish the treaty as law of the land in Brazil.

The constitutionality and legality of the application of the Presidential Decree of promulgation as if it was a statute developed the notion (and rule of law) of the direct applicability or self-execution of the Portuguese translation included into to the Presidential Decrees of promulgation. Some important samples:

- Convention Establishing the WIPO, Presidential Decree #75.541 of 1975.
- Patent Cooperation Treaty - PCT, Presidential Decree #81.742, of 1978.
- Paris Convention, Stockholm Revision, Presidential Decree #1.263 of 1994.
- The WTO TRIPS Agreement, Presidential Decree #1.355, of 1994.

The Presidential Decrees of promulgation of treaties are regularly applied and enforced by Brazilian judges and the administration. WTO TRIPs EMRs and Mail Box are examples.

Brazilian legal system

Implementation of intellectual property treaties 3

Article 102, III, b of the Constitution establishes that the Supreme Court (STF) has the jurisdiction to review decision declaring a treaty unconstitutional. This article is referring to the Presidential Decree of promulgation, and not to the treaty itself, which has no relation to the Brazilian legal system.

The Presidential Decrees implementing intellectual property treaties are federal statutes and – similar to any federal law – cannot survive in the Brazilian legal system if they are declared to be unconstitutional by the Brazilian Supreme Court.

The Superior Justice Court, (the highest appellate court of the Federal Court system) has exclusive jurisdiction to review decisions that infringe a treaty, or denies its applicability, (Article 105, III, c of the Constitution).

Once again, article 105, III, c, is indisputably referring to the Presidential Decree of promulgation, and not to the treaty itself.

As an example, the Supreme Court has decided in 1999, on a en banc decision, (RO #8.279) that the Ouro Preto Protocol could not enforced, - despite acknowledging that i) the treaty was signed in December 1994; ii) the legislative decree # 192/95 has been published and iii) the instrument of ratification was indeed deposited in 1997 - for lack of a Presidential Decree of promulgation.

Last 20 years of effective patent protection

1992 Implementation of he Stockholm revision of the Paris Convention (Decree #1.263).

1994 The WTO TRIPS Agreement was implemented in Brazil (Decree 1.355).

1995 Mailbox applications started to be accepted by the BRPTO.

1996 Pipeline patents (extra time to claim priority, same novelty in addition to commercial novelty). 1198 pipeline applications were filed. Over 70% were issued.

1997 Industrial property law, Law #9.279 enter into effect ("patent law").

1999 Regulatory review exception (Article 43, VIII) and political prior approval for patents claiming pharmaceutical inventions (Article 229-C) was first issued. (PM #2.006)

2001 Law #10.196 with amendments to the Law #9.279 is approved by Congress and enacted by the President.

2002 BRPTO guidelines for pharmaceutical and biotech inventions.

2008 ANVISA establishes the procedure for examination of patent applications claiming pharmaceutical inventions under 229-C (Resolution #45 of ANVISA)

2012 Harmonized rules for BRPTO - ANVISA's prior approval under 229-C

2013 Bill to amend the Brazilian Industrial Property Law and Regulation 93/2013.

Law 9.279, of May 15, 1996, as amended
The patent application in Brazil, first to file

A patent application, in accordance with the conditions established by the BRPTO, will contain: I - a request; II - a specification; III - claims; IV- drawings, if any; V - an abstract; and VI - proof of payment of the filing fee. (Article 19).

Once presented, the application will be submitted to a preliminary formalities review and, if in due order, will be protocolled, the date of presentation being considered as the filing date. (Article 20)

An application that does not meet the formal requirements, but which contain data about the subject matter, the applicant and the inventor, may be filed against a dated receipt which will establish an office action requesting compliance to be met within a period of 30 (thirty). Filing will be considered to have been made on the date of the receipt. (Article 21)

An application for a patent of invention must refer to a single invention or to a group of inventions so interrelated as to comprise a single inventive concept. (Article 22)

If two or more authors have independently devised the same invention or utility model, the right to obtain a patent will be assured to whoever proves the earliest filing, independently of the dates of invention or creation. The withdrawal of an earlier filing without producing any effects will give priority to the first later filing. (Article 7)

Law 9.279, of May 15, 1996, as amended

Patentability requirements

To be patentable an invention must meet the requirements of novelty, inventive activity and industrial application. (Article 8)

An object, or part thereof, is patentable as a utility model, when it is susceptible of industrial application, presents a new shape or arrangement and involves an inventive act that results in a functional improvement in its use or manufacture. (Article 9)

The specification must describe the subject matter clearly and sufficiently so as to enable a person skilled in the art to carry it out and to indicate, when applicable, the best mode of execution. (Article 24)

In the case of biological material essential for the practical execution of the subject matter of the application, which cannot be described in the form of this article and which has not been accessible to the public, the specification will be supplemented by a deposit of the material in an institution authorized by INPI or indicated in an international agreement.

The claims must be based on the specification, characterizing the particularities of the application and defining clearly and precisely the subject matter to be protected. (Article 25)

Law 9.279, of May 15, 1996, as amended

Novelty

Inventions and utility models are considered to be new when not included in the state of the art. (Article 11)

The state of the art comprises everything made accessible to the public before the date of filing of a patent application, by written or oral description, by use or any other means, in Brazil or abroad, without prejudice to the provisions of articles 12, (grace period) 16 and 17 (priority claims).

For the purpose of determining novelty, the whole contents of an application filed in Brazil, but not yet published, will be considered as state of the art from the date of filing, or from the priority claimed, provided that it is published, even though subsequently.

The provisions of the previous paragraph will be applied to a PCT application filed in accordance with a treaty or convention in force in Brazil, provided that there is national processing.

Law 9.279, of May 15, 1996, as amended

Grace period

The disclosure of an invention or utility model which occurs during the twelve months preceding the date of filing or priority of the patent application will not be considered as part of the state of the art, provided such disclosure is made: (Art. 12)

- by the inventor;
- by the National Institute of Industrial Property - INPI, by means of the official publication of a patent application filed without the consent of the inventor and based on information obtained from him or as a result of his acts; or
- by third parties, on the basis of information received directly or indirectly from the inventor or as the result of his acts.

The BRPTO may require the inventor to provide a declaration relating to the disclosure, accompanied or not by proof, under the conditions established in the rules.

The BRPTO does not accept national applications claiming the grace period when applicants fail to meet the deadline for priority claims.

Law 9.279, of May 15, 1996, as amended

International priority 1

Priority rights will be guaranteed to a patent application filed in a country that maintains an agreement with Brazil or in an international organization, that produces the effect of a national filing, within the time limits established in the agreement, the filing not being invalidated nor prejudiced by facts that occur within such time limits. (Article 16)

Priority claims must be made at the time of filing, but may be supplemented within 60 (sixty) days by other priorities earlier than the date of filing in Brazil.

A priority claim must be proved by means of a suitable document of origin, containing the number, date, title, specification and, when they exist, claims and drawings, accompanied by a simple translation of the certificate of filing or equivalent document containing data identifying the application, the contents of which will be of the entire responsibility of the applicant.

If not effected at the time of filing, the proof must be presented within 180 (one hundred and eighty) days from filing.

For international applications filed in virtue of a treaty in force in Brazil, the translation must be filed within the period of 60 (sixty) days from the date of entry into national processing (Paris Convention).

Law 9.279, of May 15, 1996, as amended

International priority 2

When the application filed in Brazil is completely contained in the document of origin, a declaration by the applicant in this respect will be sufficient to substitute the translation.

When the priority is obtained by virtue of assignment, the corresponding document must be filed within 180 (one hundred and eighty) days from filing or, in the case of entry into national processing, within 60 (sixty) days from the date of such entry, consular legalization in the country of origin not being required.

Failure to file proof within the time limits established will result in loss of the priority.

In the case of an application filed with a priority claim, any request for early publication must be made with proof of the priority having been filed.

The basis for the international priority is found in Article 16 of the Law #9.279/96, but not the terms, as the article states “within the time limits established in the agreement”. “The agreement” should be understood as the Presidential Decree of promulgation. Therefore, the one year term for claiming priority under the Paris Convention is found at Presidential Decree #1.263 of 1994, which implements in Brazil the Stockholm Revision.

Law 9.279, of May 15, 1996, as amended
Inventive step, industrial applicability and unity

An invention shall be taken to involve inventive activity when, for a person skilled in the art, it does not derive in an evident or obvious manner from the state of the art. (Art. 13)

A utility model shall be taken to involve an inventive act when, for a person skilled in the art, it does not derive in a common or usual manner from the state of the art. (Art. 14)

Inventions and utility models are considered to be susceptible of industrial application when they can be made or used in any kind of industry. (Art. 15)

An application for a patent of invention must refer to a single invention or to a group of inventions so interrelated as to comprise a single inventive concept. (Art. 22)

An application for a utility model must refer to a single principal model that may include a plurality of distinct additional elements or structural or configurative variations, only if technical-functional and corporeal unity of the object is maintained. (Art. 23)

Law 9.279, of May 15, 1996, as amended

Certificates of addition to a patent

On payment of a specific fee, the applicant or patentee of a patent of invention may request a certificate of addition to protect an improvement or development introduced in the subject matter of the invention, even if lacking inventive activity, provided that it shares the same inventive concept. (Article 76)

If publication of the main application has already taken place, the application for the certificate of addition will be published immediately. Substantive examination for a certificate of addition will be follow the same rules applicable for patent application.

An application for a certificate of addition will be rejected if its subject matter does not involve the same inventive concept.

The applicant may, within the period for appeal, by payment of the corresponding fee, request the conversion of an application for a certificate of addition into a patent application benefiting from the date of filing of the application for the certificate.

A certificate of addition is accessory to the patent, has the same expiry date and accompanies it for all legal effects.

In a nullity process, the patentee may request that the subject matter contained in the certificate of addition be examined to verify the possibility of its subsistence, without prejudice to the term of protection of the patent.

Law 9.279, of May 15, 1996, as amended
Divisional and publication of applications

A patent application may, until the end of examination, be divided, ex officio or on request of the applicant, into two or more applications, provided that the divisional application:

- makes specific reference to the original application; and
- does not exceed the matter disclosed in the original application.

A request for division not in accordance with the provisions of this article will be dismissed. (Article 26) limited by Article 32, since the enactment of Regulation 93 in June 6, 2013.

Divisional applications will have the filing date of the original application and the benefit of the priority of the latter, if any. (Article 27) Each divisional application will be subject to payment of the corresponding fees. (Article 28)

A patent application will be kept secret during 18 (eighteen) months counted from the date of filing or of the earliest priority, if any, after which it will be published. Publication of the application may be anticipated on request by the applicant. (Article 30)

The publication must include data identifying the patent application, a copy of the specification, claims, abstract and drawings being made available to the public at INPI.

Law 9.279, of May 15, 1996, as amended

Substantive examination 1

Substantive examination of a patent application must be requested by the applicant or by any interested party, within 36 (thirty six) months counted from the date of filing, under penalty of dismissal of the application. (Article 33)

Examination will not be initiated prior to 60 (sixty) days from publication of the application. (Article 31)

Documents and information for aiding examination may be filed by interested parties after the publication of the application, until the end of the examination. (Article 31)

In order to better clarify or define a patent application, the applicant may effect alterations up to the request for examination, provided that they are limited to the subject matter initially disclosed in the application. (Article 32)

Once examination has been requested and whenever so requested, the following should be filed within 60 (sixty) days, under penalty of dismissal of the application:

I - objections, prior art searches and the results of examination for the grant of corresponding applications in other countries; II - documents for the substantive examination of the application; and III - a simple translation of the suitable priority document. (Article 34)

Law 9.279, of May 15, 1996, as amended

Substantive examination 2

At the time of the substantive examination, a search report and an opinion will be prepared with respect to:

I - the patentability of the application; II - the adaptation of the application to the nature of protection claimed; III - the reformulation of the application or the division thereof; or IV - technical requirements. (Article 35)

When the office action is for non-patentability or for the inadequacy of the application for the nature of protection claimed or formulates any requirement, the applicant will be notified to reply within a period of 90 (ninety) days. (Article 36)

If no reply to the office action is filed, the application will be definitively dismissed.

If a reply to the office action is filed, but the latter is not met or its formulation is reconsidered, and independently of arguments being filed regarding patentability or adequacy, examination will be continued.

Once examination is concluded, a decision will be issued, allowing or rejecting the patent application. (Article 37)

Law 9.279, of May 15, 1996, as amended

Post grant invalidity and invalidity before courts

Nullity of a patent will be declared administratively when: (Article 50)

- any of the legal requisites have not been met;
- the specification and the claims do not meet the provisions of articles 24 and 25, respectively;
- the subject of protection of the patent extends beyond the contents of the application as originally filed; or
- any of the essential formalities indispensable for grant were omitted during prosecution.

The nullity procedure may be instituted ex officio or at the request of any person having legitimate interest, within 6 (six) months counted from the grant of the patent (Article 51)

The nullity procedure will continue even if the patent is extinct.

The patentee will be notified to respond within a period of 60 (sixty) days. (Article 52)

Law 9.279, of May 15, 1996, as amended

Post grant invalidity and invalidity before courts

Independently of a reply having been filed, once the period determined in the previous article has passed, INPI will issue an opinion, notifying the patentee and the applicant to reply within a common period of 60 (sixty) days. (Article 53)

Once the period determined in the previous article has passed, even if no replies have been presented, the process will be decided by the Commissioner of INPI, terminating the administrative sphere. (Article 54)

A nullity action can be filed at any time during the term of a patent by INPI or by any legitimately interested party. (Article 56)

Nullity of a patent may be argued, at any time, as matter for defense.

The judge may, as a preventive or incidental measure, determine the suspension of the effects of a patent, provided the relevant procedural requirements are met.

Nullity actions will be adjudged in the forum of the Federal Courts, and INPI, when not plaintiff, will participate in the action. The period for the defendant to reply will be 60 (sixty) days. (Article 57)

Once the decision on a nullity action becomes final, INPI will publish a notice to notify third parties.

Law 9.279, of May 15, 1996, as amended

Annuities and restoration

The applicant and patentee are subject to the payment of annual fees, as from the beginning of the third year from the date of filing. Advance payment of the annual fees will be regulated by INPI. (Article 84)

The payment should be effected within the first 3 (three) months of each annual period, but may still be effected within the following 6 (six) months, independently of notification, by payment of an additional fee. (Article 84)

The same rules apply to international applications filed in virtue of a treaty in force in Brazil, the payment of annual fees due before the date of entry into national processing having to be effected within a period of 3 (three) months from that date. (Article 85)

Failure to pay an annual fee, under the terms of articles 84 and 85, will result in the dismissal of the application or extinction of the patent. (Article 86)

A patent application and patent may be restored, if the applicant or patentee so requests, within 3 (three) months counted from notification of dismissal of the application or extinction of the patent, on payment of a specific fee. (Article 87)

Law 9.279, of May 15, 1996, as amended

Patent term in Brazil and extinction

Licks ATTORNEYS

Patent term extensions are not codified in Brazil, which does not preclude the patent owner from seeking remedies from Brazilian federal courts in case of delay.

A patent of invention will have a term of 20 (twenty) years and a utility model patent a term of 15 (fifteen) years, counted from the filing date; (Article 40). See Article 229 for mailbox patents.

The term will not be less than 10 (ten) years for patents and inventions and 7 (seven) years for utility models, counted from grant, except when INPI is prevented from proceeding with the examination as to the merit of the application, due to a proven pendente lite or for reasons of "force majeure"..

Article 78 - A patent shall become extinct:

- I - on expiry of the term of protection;
- II - on waiver by the patentee, without prejudice to the rights of third parties;
- III - on forfeiture;
- IV - on non-payment of the annual fee, within the periods provided for in Article 84
- and in Article 87; and
- V - on non-observance of the provisions of Article 217.

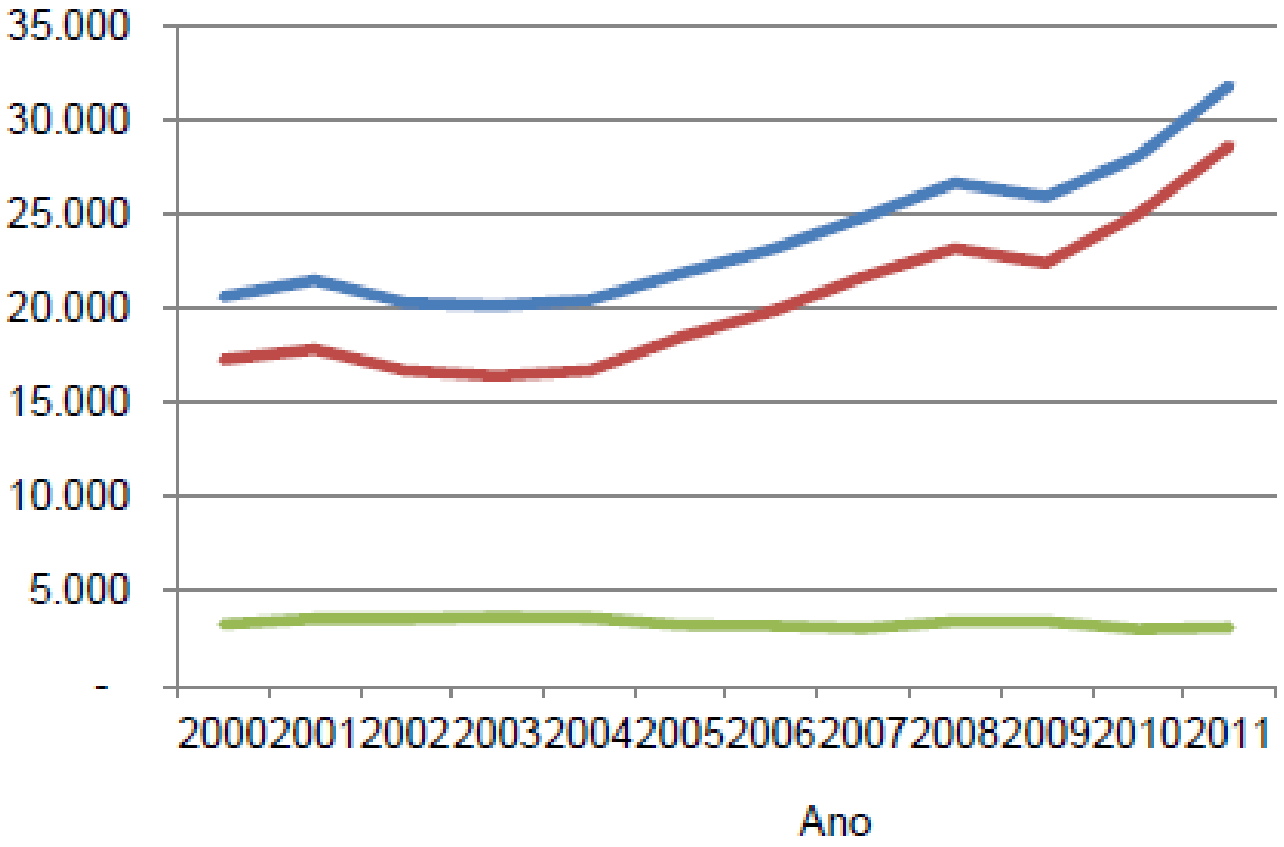
Once a patent becomes extinct, its object falls within the public domain.

Number of Patents
Filed between 2000-2011 according to the BRPTO

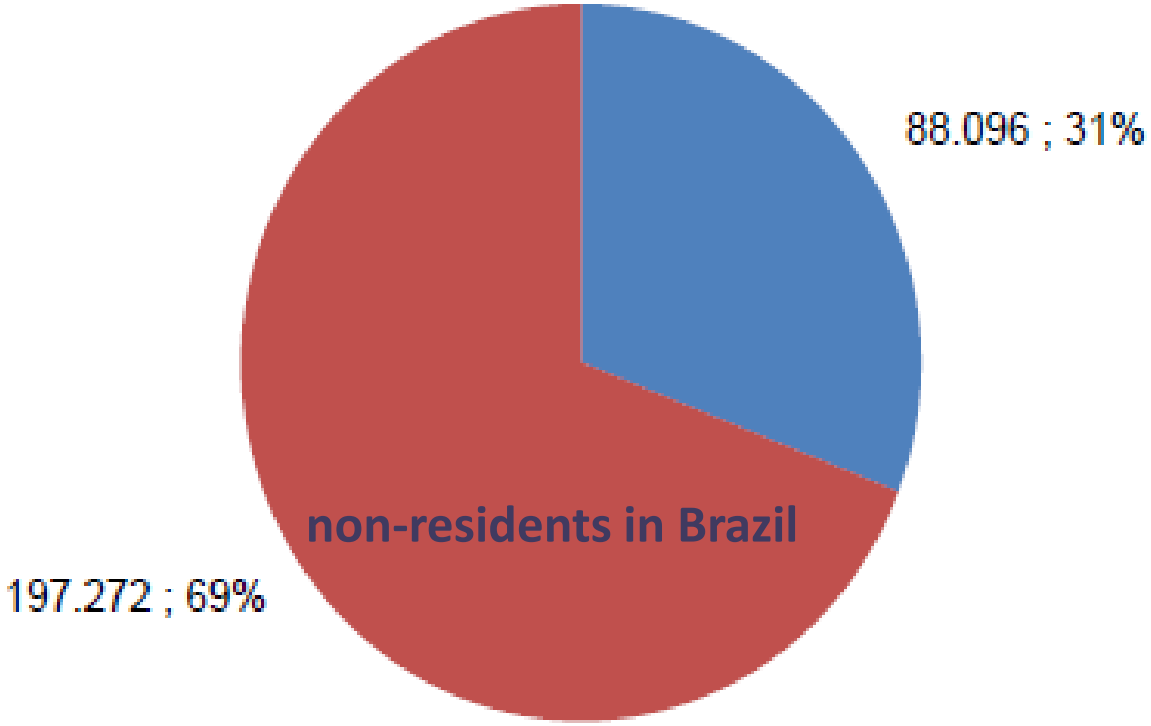
Blue line = total

Red line = patents

Green line = utility models



Number of Patents
Filed between 2000-2011 according to the BRPTO



Number of Patent applications and decisions
between Jan - June of 2013 according to the BRPTO

	Jan.	Feb.	March	April	May	June	Total
Applications filed	2.502	2.519	2.746	3.050	2.790	3.352	16.959
Patents of invention (PI)	557	562	602	727	597	614	3.659
Divisionals of PI	32	29	17	25	31	30	164
Utility Models (UM)	177	197	212	264	250	245	1.345
Divisionals of UM	1	-	1	2	-	15	19
Via PCT	1.721	1.719	1.908	2.020	1.898	2.449	11.714

	Jan.	Feb.	March	April	May	June	Total
Decisions	786	902	975	922	936	1.506	6.027
Dismissed	388	528	423	375	587	1.065	3.366
Granted	225	297	205	317	209	294	1.548
Abandoned	4	-	5	3	17	4	33
Rejected	169	77	342	227	123	143	1.081

2. Patentable subject matter

Licks ATTORNEYS

What types of patents can be obtained in Brazil

Brazil is an original signatory of the Paris Convention and its patent law dates from 1809.

Brazil is a founding member of the United Nations, OAS, GATT, WTO.

What type of patent protection was available in the recent past:

1) WTO TRIPS Exclusive Market Rights (EMRs);
2) WTO TRIPS Mailbox protection;
3) Pipeline patents (revalidation).

What type of patent protection is available today:

1) Utility patents for both **products** (product by process, etc) and **process** (methods, Swiss type claims, etc);
2) Utility Models; and
3) Certificates of Addition.

What types of patents can be obtained in Brazil

Patentable Subject Matter in Brazil

Article 18 of Patent Statute #9,279 of 1996 - The following are not patentable:

- That which is contrary to morals, good customs and public security, order and health;
- Substances, matter, mixtures, elements or products of any kind, as well as the modification of their physical-chemical properties and the respective processes of obtaining or modifying them, when they result from the transformation of the atomic nucleus; and
- Living beings, in whole or in part, except transgenic micro-organisms meeting the three patentability requirements — novelty, inventive activity and industrial application — provided for in article 8 and which are not mere discoveries.

For the purposes of patent law, transgenic micro-organisms are organisms, except the whole or part of plants or animals, that exhibit, due to direct human intervention in their genetic composition, a characteristic that cannot normally be attained by the species under natural conditions.

[*Processes for cloning human beings; processes for modifying the genetic identity of germ cells of humans; use of human embryos for industrial purpose or business; process for purification of illegal drugs, (cocaine, etc).*

What types of patents can be obtained in Brazil

Patentable Subject Matter in Brazil

Human Embryo Stem Cells	Not patentable subject matter under article 10, IX. Some process claims might be obtained. The BRPTO has more restrictive views towards human stem cells when compared to animals. A group at the BRPTO is reviewing the current policy, using EPO guidelines and Brazilian Law #11,105 of 2005.
Gene patents	Not patentable subject matter under article 10, IX. Use and process claims are allowed. A new guideline will soon replace the current one, from 2002.
Antibody	Not patentable when polyclonal, therefore, subject matter under article 10, IX. Patentable when it is monoclonal defined by the hybridoma or when it is humanized, because they are recombinant, therefore there is a change in the monoclonal chain.
Biomarkers	Not patentable when it is only the DNA sequence *per si*, subject matter under article 10, IX. Patentable if the biomarker be changed, distinct from the natural, as a group of markers or a composition, quantity defined, containing markers.
DNA sequences	Patentable if changed with human intervention. Isolation only is not allowed.

3. BRPTO – influences and back log

Licks ATTORNEYS

Brazilian Patent and Trademark Office

Influence

The USPTO and the BRPTO embarked on a cooperation in 2008, with the USPTO hosting and providing expertise in patent grant procedures related to the biotechnology area.

An internal review for quality control and audit was done in 800 issued patents at the BRPTO. The study will not be published. Two interesting information:

1)The Brazilian examiners are not doing searches. Almost 100% of all examinations in the 800 patents reviews used only the PCT search and prior art filed by third parties.

2)The BRPTO is not being able to keep young examiners, because other government agencies are offering much better salaries and career opportunities.

The BRPTO practice is indeed influenced by the EPO's in several aspects. There are some differences in pharmaceutical, chemical and software implemented inventions.

The examiners at the BRPTO will most often study the examination of the EPO family patent before making a decision on the brazilian application.

Brazilian examiners do not like to be instructed by applicants to look the result of the EPO family patent. The politically correct way is to conform the Brazilian claims and reasoning to what has been presented or allowed in EPO, without making an express statement.

BRPTO Backlog

Measures being taken to deal with the backlog

Currently, the BRPTO has less than 300 patent examiners. The actual number of patent examiners doing patent examination is less than 200.

It receives approximate 35 thousand applications a year and currently has a backlog estimated in little over 170 thousand applications.

In 2012, the BRPTO granted pharmaceutical patents filed in 2000 – 2002. Productivity in this area is low among Brazilian examiners, estimated in 1-2 decisions per month. The official backlog is 5-6 years, but users experience 9-10 years of average delay.

BRPTO claims to act to fight the backlog:

Hiring of more 400 examiners until 2014; Investments in in-house training; Establishment of the e-Patents system (developed based on the EPO model); Creation of new guidelines for patent examination (Biotechnology and pharmaceutical) as well as in general examination, software and utility model.

Implementation of fast tracks (priority examination – Resolution #14 of 2013):

Priority examination for pharmaceutical patent applications covering drugs purchased by the Brazilian Government's Unified Health System (SUS).

Priority examination for green patents.

Brazilian Patent and Trademark Office

New initiatives

Since 2012, patent applications filed in Brazil have the same search report and preliminary examination provided by the Patent Cooperation Treaty – PCT to international patent applications. This aims to give more flexibility for the Brazilian patent applicants.

Utility models will have preferential treatment, a process that is currently being discussed in a public consultation. Utility models correspond to 20% of the backlog and 50% of the patent filings by nationals.

The “Green Technology Highway”, launched on April 17, 2012, is a pilot program for green patents, in which the period of examination of patent applications related to clean technologies will fall to less than two years.

According to the BRPTO, the office will only consider technologies that "reduce the impact of climate change, withdraw or emit less CO2 from the atmosphere." Besides having to follow those precepts, the inventions should be related to waste management, alternative energy, agriculture, and transport or energy conservation.

Recently, the vice-commissioner for patents, Mr. Julio Cesar Moreira, informed that the BRPTO was implementing new rules in order to reduce the current backlog of average eight years to three years to granting patents anytime soon.

Brazilian Patent and Trademark Office

New initiatives

In Brazil, there are three BRPTO resolutions that establish the prosecution for fast-track examination of patent applications, Resolution #68/2013, Resolution #80/2013 and Resolution #83/2013. Basically, it is possible to request a fast-track examination for a patent application when at least one of the following conditions is met:

(i) the applicant is an individual over sixty (60) years old;

(ii) the subject matter of the patent application is being reproduced by an unauthorized third-party;

(iii) the grant of the patent is a condition for obtaining financial resources from official credit institutions;

(iv) the subject matter of the patent application is of public interest or if national emergency is declared;

(v) the patent application relates to the diagnosis, prophilaxis or treatment of AIDS, cancer or neglected diseases;

Brazilian Patent and Trademark Office

New initiatives

(vi) the patent application relates to products, processes, devices and/or materials used in health related to the National Policy of Pharmaceutical Assistance of the Ministry of Health and established as strategic to the Brazilian Unified Health System (SUS);

(vii) the patent application covers a “green” invention, i.e. inventions related to alternative energy, transportation, energy conservation, waste management and agriculture as defined in the green inventory of WIPO (http://www.wipo.int/classifications/ipc/en/est/); excluding inventions related to administrative, regulatory or design aspects, and nuclear power generation.

The BRPTO is accepting Electronic patent applications since March 2013.

However, it is not possible to file PCT applications nor industrial design applications, only National and Paris convention applications.

For a patent to be filed electronically it must be complete with all the necessary documents, making it impossible to later complement the application.

Most applications are still filed on paper.

4. New guidelines and Resolution #93 of 2013

Licks ATTORNEYS

Brazilian Patent and Trademark Office

New guidelines

The BRPTO is about to publish a new Examination Guideline for Inventions implemented by Computer Programs. This represents an innovative measure, since the old guidelines did not provide any regulation regarding these inventions.

This measure basically reflects the current practice of the BRPTO examiners.

The new Examination Guideline for Biotechnology and Pharmaceutical Inventions which is also undergoing the process of public consultation and is not yet in force basically reflects the current practice of the BRPTO examiners in this area and explains some points that were not covered in previous guideline or which resulted in doubt, such as: monoclonal antibody is treated as non-natural and if a cDNA is non-natural, it may be considered as liable to patentability.

The draft under public consultation is very didactic, as there are many examples of how to request the subject matter.

A Normative Instruction issued recently (Normative Instruction 1/2013) deals with Genetically modified products and regulates the statutory prohibition of patenting and licensing “genetic use restriction genetic technology”.

Brazilian Patent and Trademark Office

Resolution 93 of 2013 on claim amendment

In June, the BRPTO issued Resolution #93/2013 for the application of Articles 26 and 32 of the Brazilian Patent Statute (Law #9.279 of 1996) regarding claim amendment.

Since the Statute #9.279 of 1996 has entered into force, the BRPTO has shown some concern about claim amendment at later levels of the prosecution, mainly after the request of substantive examination.

Resolution #93/2013 establishes that voluntary amendments or amendments resulting from technical examination, after the request for examination of the application, to the claims is not acceptable if implicates on the “broadening the scope of the claims”.

Before the request any amendment on the specifications, abstract, drawings and claims is acceptable if it is limited to the disclosed subject matter.

Please note that amendments that aim to correct typos or translation issues will be accepted at any time during the process of examination. These changes, however, must be supported by the subject matter included in the priority document, specification, abstract, drawings, in international filed application.

Amendments to harmonize the claim chart with the Resolution #17/2013 (BRPTO’s Resolution for patent procedure – former Normative Act #127/98) are accepted at any time. As an example, the absence of the expression “characterized by” on the claims.

Brazilian Patent and Trademark Office

Resolution 93 of 2013 on claim amendment

Further, Resolution #93 of 2013 establishes that changing the category of a claim after the request of examination will only be acceptable in the following cases:

“i) When the original claim chart contains claims of "product characterized by the process" and the applicant amends the claims to "process characterized by the process";

ii) When the original claim chart contains "process characterized by the product" and the applicant amends the claims to “product characterized by product" and

iii) When is an evident error, in case the applicant has originally requested a claim on an incorrect category. For example, a product defined by steps of a process when the process would be a method claim.”

As an example, if the claim chart is a "product characterized by product" will not be allowed to change to the category of "process", even if the examiner understands, referring to the specification, that the invention would be a process and not a product.

Another possibility that the BRPTO does not accept is the change of claims related to therapeutic method to claims like "swiss type".

Brazilian Patent and Trademark Office

Resolution 93 of 2013 on claim amendment

The bottom line of Resolution #93 of 2013 is that in case of an amendment that the BRPTO consider to "broadening the scope of the claims" the Patent Office will reject the entire claim chart, even if the amendment occurs only in one of the claims. In this case the BRPTO will analyze the former claim chart presented by the applicant.

Divisional applications can be filed until the end of the examination of the parent case. Divisional applications may be filed in response to a non-unity rejection or on a voluntary basis and will be deemed to be in the same processing phase as the original application.

However, the BRPTO has restricted views concerning the filing of divisional applications after the request for examination. Such divisional will be examined under the provisions of Article 32 of the Patent Statute.

Therefore, the claim chart of the divisional application must be restricted to the subject claimed on the valid claim chart of the parent application.

5. ANVISA’s prior approval under 229-C

Licks ATTORNEYS

Mandatory review of pharma patent applications by Brazilian Food and Drug Agency - ANVISA

The Brazilian Patent and Trademark Office - BRPTO

National Institute of Industrial Property - INPI

Under Article 38 of Patent Statute #9,279 of 1996 the BRPTO grants patents after the application is allowed (Article 35) and the final/issuance fee is duly paid.

The Brazilian Food and Drug Agency – BRFDA

National Agency of Sanitary Surveillance – ANVISA

Under Article 229-C of Patent Statute #9,279 of 1996 the grant of a patent claiming pharmaceutical products of process is subject to the Brazilian FDA prior approval.

Under Article 12 of Statute #6,360 of 1976, ANVISA grants marketing approval for pharmaceutical products and services.

Mandatory review of pharma patent applications by Brazilian Food and Drug Agency - ANVISA

"Article 229-C - The grant of patents to pharmaceutical products and processes will depend on the previous approval of the National Health Surveillance Agency - ANVISA."

Article 229-C of Patent Statute #9,279, of May 14, 1996, implemented by Provisional Ruling #2,006, of December 15, 1999.

Adopted by National Congress and signed by the President, passing into Law #10,196, of February 14, 2001.

Changes the ministerial acts of technical examination, allowance and issuance of a patent into a discretionary one.

Imposes an additional patentability requirement for pharmaceutical patent applicants and discriminates against a specific field of technology, infringing many sections of the WTO TRIPS Agreement.

The ANVISA lacks expertise on patent law. Extrapolates BPTO's exclusive statutory authority to examine patent applications.

Mandatory review of pharma patent applications by Brazilian Food and Drug Agency - ANVISA

"Article 229-C - The grant of patents to pharmaceutical products and processes will depend on the previous approval of the National Health Surveillance Agency - ANVISA."

Article 229-C is a requirement for the grant of the letter patent, under Article 38.

- *Article 38 - A Patent will be granted after the application is allowed and, after proving payment of the corresponding fee, the respective letters-patent will be issued.*

Article 229-C It is not a requirement for the allowance of the application, after the substantive examination, under Article 37.

- *Article 37 - Once examination is concluded, a decision will be issued, allowing or rejecting the patent application.*

Article 229-C is a requirement for the grant, not a patent defeating condition, under Article 35.

- *Article 35 - At the time of the substantive examination, a search report and an opinion will be prepared with respect to: I - the patentability of the application; II - the adaptation of the application to the nature of protection claimed; III - the reformulation of the application or the division thereof or IV - technical requirements.*

Mandatory review of pharma patent applications Article 229-C – History

Licks ATTORNEYS

May 15th, 1996

Law 9.279/96 is effective as regards subject matter contained in article 230, which establishes the conditions for filing and granting "pipeline" patents: (1) it shall be filed until May 15, 1997; (2) provisions of articles 10 and 18 shall be complied with; and (3) issuance of a patent in the country of first application must be proven.

May 15th, 1997

Deadline for filing "pipeline" applications. article 230.

December 15th, 1999

Provisional Ruling nº 2.006/99 is published in the Official Gazette, including article 229-C in Law 9.279/96, which implements ANVISA's prior approval system for "pipelines" in connection with **"medicaments of any kind, and the respective process for obtaining or modifying"**. This is the authentic interpretation of article 229-C, under the provision of article 230, which does not use the same terms "product and pharmaceutical process"

June 16th, 1998

The BPTO starts to grant "pipeline" patents.

12/28/1999 until 08/08/2000

Time frame where the BPTO issued "pipeline" letters-patent for **"medicaments of any kind, and the respective process for obtaining or modifying"** without ANVISA's prior approval.

April 2nd, 2001

Opinion INPI/PROC 003/00 Revoked by the President of the BPTO. The BPTO implements official action 23.17 in the BPTO Official Gazette (RPI) for prior approval of "pipeline" through the official notice INPI/DIRPA 17/02/2001.

May 15th, 2001

The BPTO started to send "Pipeline" applications to ANVISA, as per publication in the BPTO Official Gazette 1584. Official action 23.17 is published for the first time in the Chart of Codes and Official actions of applications. Approximately 100 "pipeline" applications were sent to the ANVISA until May 2002.

May 21st, 2001

ANVISA starts its activities related to article 229-C
Rule nº 239, which alters Internal Rule of ANVISA, creating its Intellectual Property Commission, is published in the Official Gazette.

1996 | 1997 | 1998 | 1999 | 2000 | 2001

1.186 "pipeline" applications filed in the time frame of 1 year.

According to the express authorization of article 229 caput and 230, "pipeline" patent applications can claim up to four different technologies. Only one of them is mentioned in article 229-C. "Pipeline" applications for inventions in the other three technologies are excluded from the scope of article 229-C:

1- Medicaments of any kind, and the respective process for obtaining or modifying. (article 229-C, after 12/15/1999).

2- Substances, matter or products obtained by chemical means or processes, and the respective process for obtaining or modifying.

3- Substances, matter, compounds or foodstuffs and the respective process for obtaining or modifying.

4- Substances, matter, compounds or chemical-pharmaceutical substances and the respective process for obtaining or modifying.

IMPORTANT

257 "pipeline" patents were granted by the BPTO during the time frame of 12/28/1999 until 08/08/2000.

Besides the "pipeline" patents subject to ANVISA's prior approval system, in the same Official Gazettes, the BPTO also granted "pipeline" patents for the other three technologies contained in article 230 of the Law 9.279/96.

Thus, all granted "pipeline" patents, that do not have as object medicaments of any kind, and the respective process for obtaining or modifying, are not subject to article 229-C (such as the "pipelines" of EMBRAPA, or the oner that have as object inventions of chemical products). Among the 257 "pipeline" patents granted, few more than one hundred may be subject to ANVISA's prior approval system.

17 months of inactivity and indefinition of ANVISA as regards the way and manner of proceeding. Article 229-C was not implemented yet by ANVISA, which has never established any rule regarding the granting of prior approval.

February 23rd, 2000

Opinion/ INPI/ PROC nº 003/00 of the BPTOs Attorney General, Ricardo Luiz Sichel:

Summary: pipeline application, non-applicability of art. 229-C of Provisional Ruling nº 2014-2/99

1 – The Patent Commissioner poses a question about the applicability of art. 229-c, of the Provisional Ruling nº 2.014-2/99, as regards "pipeline" applications, for pharmaceutical products.....
4 – On the other hand, as regards the ANVISA's intervention in the granting of patents for pharmaceutical products and processes, it is verified the desired spirit of cooperation, which should exist in the Public Administration, in a way to reach the rules contained in art. 37 of the Federal Constitution.
*5 - However, as previously supported, I have observe that the "pipeline" applications are not subject to the examination as provided for in article 8º of the Industrial Property Law. Due to this fact, **I do not foresee the need to send such patent applications to the ANVISA**. In this context, I notice the convenience of establishing a covenant between the BPTO and the mentioned Agency, aiming at balancing the relationship bewteen the two entities, in a way to comply with the lawfulness doctrine, besides the public interest involved. To the consideration rendered by the Hon. President, suggesting the granting of normative effect to the present opinion.*
Ricardo Luiz Sichel

February 23rd, 2000

President of the BPTO, José Graça Aranha, determines the normative nature of opinion INPI/PROC nº 003/00 of the Attorney Genereal, deciding that "pipeline" patents for medicaments of any kind, and the respective process of obtaining or modifying are subject to the prior approval mentioned in article 229-C of the Law 9.279/976.

Mandatory review of pharma patent applications

Article 229-C practice by ANVISA

"ANVISA's Intellectual Property Commission (COPI), located in Rio de Janeiro, has the authority to grant prior approval to patent applications for pharmaceutical products and processes", as per Article 7.1 of the ANVISA's Rule #239 of 05/17/2001, as amended by Rule #435 of 08/01/2002.

Despite having the prior approval system established by Statute #10,196 of 2001 applying only to pipeline patent applications, ANVISA has been extrapolating the statutory authority granted by Article 229-C to include the regular non-patent applications into the prior approval system too.

ANVISA maintains that it should provide checks to the Brazilian patent system to protect the Brazilian people and the local interests of public and private pharmaceutical industries, collectively known as "public interest" in the agency's statements.

On May 25, 2012, The Ministry of Health and the Ministry of Commerce made public a report prepared by an inter-ministerial group (Health Ministry; Commerce Ministry; Attorney General's Office; BRPTO and ANVISA) about the implementation of Article 229-C.

The report was officially published as an annex of Ordinance #1,065, of May 24, 2012. The report covers the institutional relationship between the BRPTO and the ANVISA.

On April, 15, 2013, ANVISA published Resolution #21, amending Resolution #45 of 2008 regarding ANVISA's prior approval under 229-C.

Mandatory review of pharma patent applications

ANVISA's practice under new RDC #21 of 2013

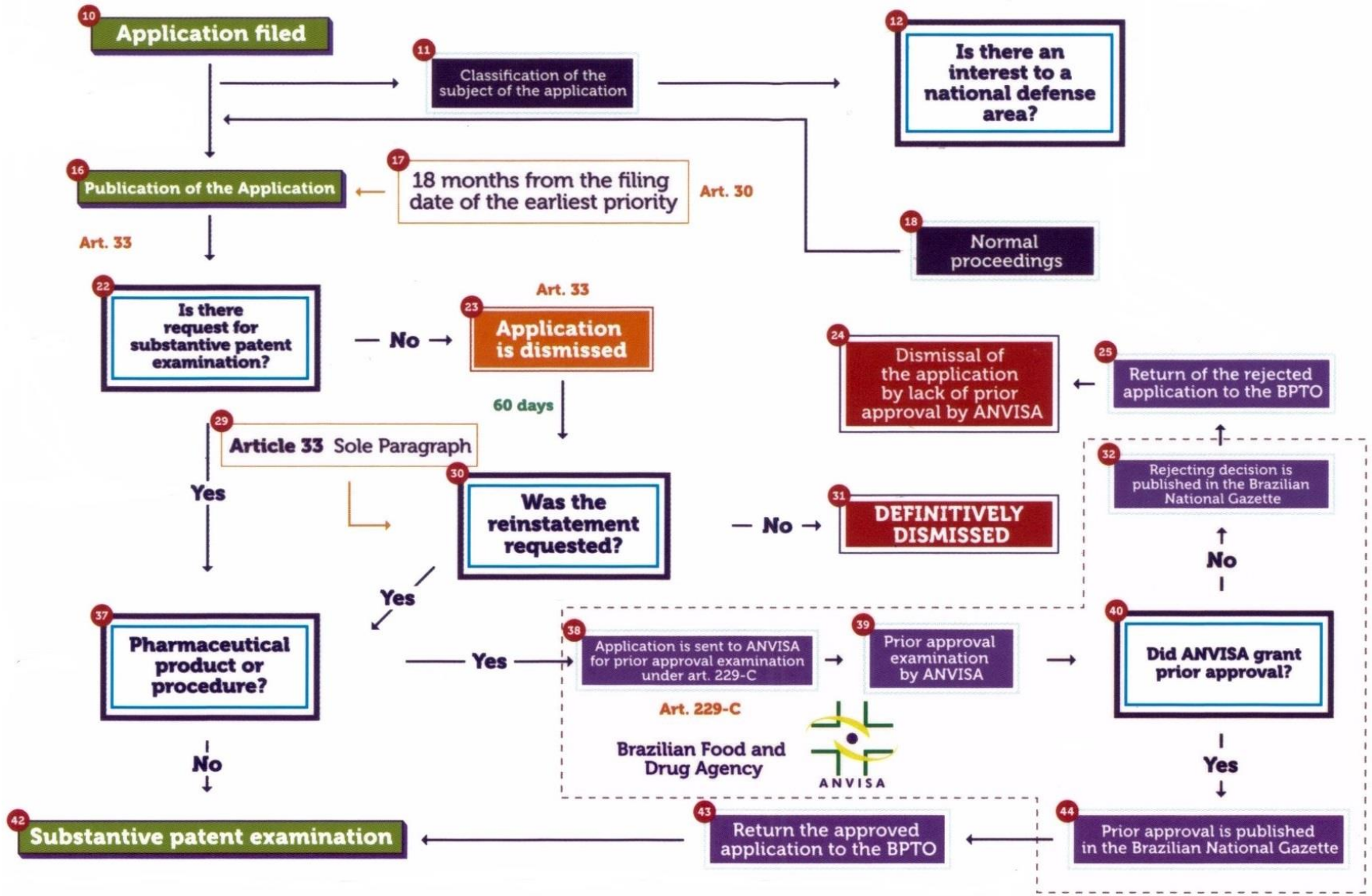
Resolution #21 of 2013, amending Resolution #45 of 2008 suggests that ANVISA can deny prior approval under article 229-C for patent applications considered of interest to the Brazilian public policies of access to medicines and pharmaceutical assistance of the Public Healthcare System and that "do not meet patentability requirements".

Public policies of access to medicines and pharmaceutical assistance include patent applications covering products and therapeutic indications listed in the ordinances with the formularies (PCDTs, PDPs, etc) published by the Ministry of Health.

The flow chart in the next slides take into consideration ANVISA's policy but places the timing of the prior approval examination of both regular and pipeline applications after the notice of allowance, seeking to increase transparency of the Brazilian patent system.

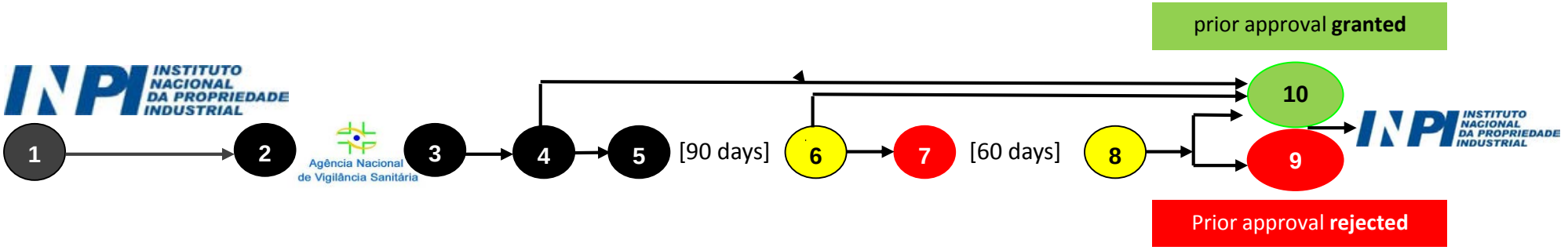
Mandatory review of pharma patent applications

Workflow between agencies and inside ANVISA



Mandatory review of pharma patent applications

ANVISA's RDC #45/2008, as amended by RDC #21/2013

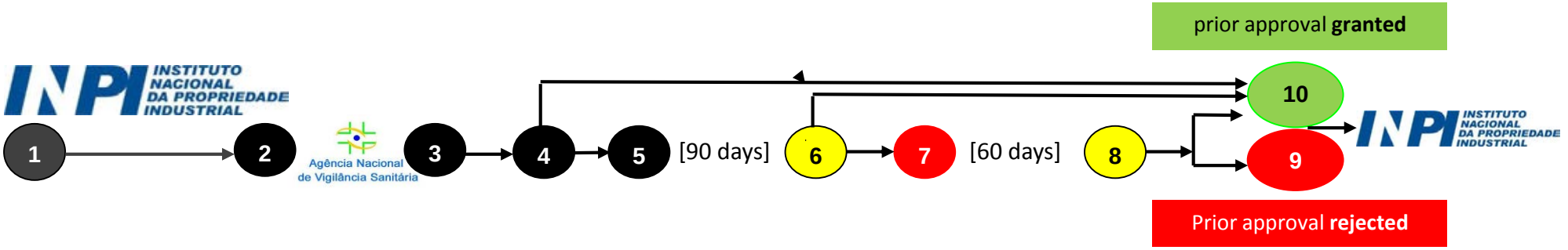


1. The INPI performs the preliminary formalities examination of the application or PCT national phase under Article 19 of Patent Statute #9,279/1996.
2. If properly filed and duly published, the INPI will look for claims for pharmaceutical product or process, after examination is requested, under article 33 (36 months). The INPI will send the patent application to the ANVISA if a claim for pharmaceutical product or process is found.
3. ANVISA will perform its examination in light of public health (as per Article 4 of RDC #45 of 2008 of June 24, 2008, as amended by RDC #21 of 2013).The patent application shall be considered against public health when (Article 4, Paragraph 1st):

   The pharmaceutical product or process in the patent application presents risk to health;
   The patent application of pharmaceutical product or process is of interest to the public policies of access to medicines and pharmaceutical assistance of the Public Healthcare System (SUS) and does not meet patentability requirements and further criteria established by Patent Statute #9,279 of 1996.

Mandatory review of pharma patent applications

ANVISA's RDC #45/2008, as amended by RDC #21/2013



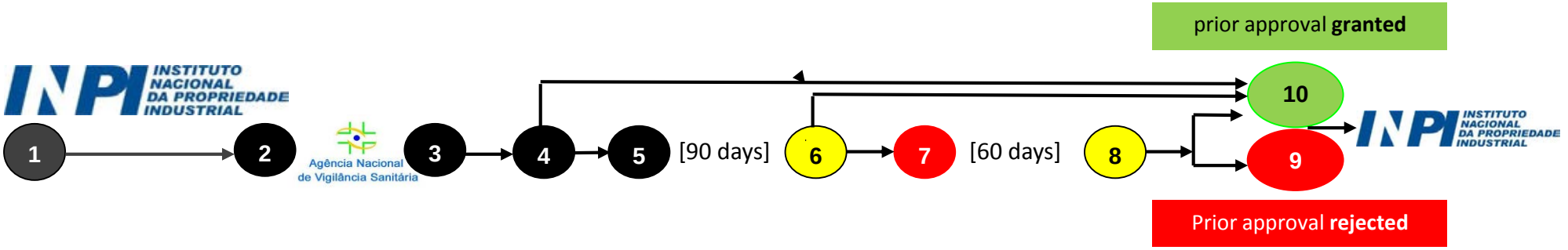
4. ANVISA's IP Commission (COOPI) might grant prior approval (#10), issues an office action for amendments or an opinion of preliminary rejection (#5). Until the end of the examination, interested parties can present documents and other information to assist ANVISA's examination (Article 4, paragraph 6th of RDC #45 of 2008 of June 24, 2008, as amended by RDC #21 of 2013).

5. Summon of patentee to comply within 90 days (Article 5 of RDC #45 of 2008 of June 24, 2008, as amended by RDC #21 of 2013).

6. Reply or compliance with office actions. ANVISA's analysis continues (Article 5, Paragraph 1 of RDC #45 of 2008 of June 24, 2008, as amended by RDC #21 of 2013). In case of lack of reply to the summons of the office action, the prior approval is rejected, according to Article 5, Paragraph 2ndof RDC #45 of 2008 of June 24, 2008, as amended by RDC #21 of 2013 (#7).

Mandatory review of pharma patent applications

ANVISA's RDC #45/2008, as amended by RDC #21/2013



7. Rejection (Article 5, Paragraph 2ndRDC #45 of 2008 of June 24, 2008, as amended by RDC #21 of 2013).

8. Appeal to the Board of Directors within 60 days (Article 7, Paragraph 1stof RDC #45 of 2008 of June 24, 2008, as amended by RDC #21 of 2013).

9. Final rejection by the ANVISA. After the publication of the final rejection, ANVISA sends the application to the INPI (Article 7, paragraph 2ndof RDC #45 of 2008 of June 24, 2008, as amended by RDC #21 of 2013).

PS: The INPI will likely publish the shelving of the application, without no further administrative appeal and no substantive examination, despite the lack of statutory authority.

10. Prior approval granted. Application will be sent to the INPI for substantive examination.

Mandatory review of pharma patent applications

What would be “risk to health”?

Licks ATTORNEYS

Second ANVISA and RDC #45 of 2008, as amended by RDC #21 of 2013, risk to health would be:

The risk to health will be characterized when the pharmaceutical product comprises, or the pharmaceutical process results in, substance which the use may have been prohibited in the country. (Paragraph 2nd of Article 4 of RDC #45 of 2008 as amended)

Further, the same Resolution established which products or process would be of interest of public policies:

The patent application for pharmaceutical product or process will be deemed as interest to the public policies of access to medicines and pharmaceutical assistance of the Public Healthcare System (SUS) when comprises, or results in, substance established in the Ordinances published by the Ministry of Health establishing the strategic products, for SUS, and your regular updates, as well as comprises, or results in, substance established to the therapeutic purpose listed in the mentioned Ordinances. (Paragraph 3rd of Article 4 of RDC #45 of 2008 as amended)

ANVISA states that under Resolution #45 2008, as amended, and under Report #1,065 of 2012, in case of the denial of prior approval, the BPTO would have to dismiss the application without any substantive examination.

Until the moment there is no official act by the BPTO regarding such statement.

Mandatory review of pharma patent applications
Statistical report

ANVISA's prior approval between June, 2001 and July, 2010, as published at ANVISA's website

Status of the applications	Quantity of applications
Prior approval granted	**1100**
Prior approval denied	**143**
Pending final decision (appeal)	**158**

ANVISA's prior approval between March, 2011 and March, 2013

Status of the applications	Quantity of applications
Prior approval granted	**230**
Prior approval denied	**62**
Pending final decision (appeal)	**09**

Mandatory review of pharma patent applications

Article 229-C – Leading Case Takeda v. ANVISA

Brazilian court decisions are constantly restricting ANVISA's examination under 229-C. Most of the decisions limited ANVISA's examination to patentable subject matter, under article 18, I, of Statute #9.279/96. Some leading cases in such regard are:

Leading case - Takeda v. ANVISA:

"*This provision only restricts the patenting of those inventions that, by its nature or purpose, are contrary to public health. For example, the European Directive on Biotechnology, in its 23d rule prevents the patenting, among others, of processes for cloning human beings ("a") and the use of human embryos for industrial and commercial purposes ("c").*

It is quite obvious, being the agency's field of knowledge that the authority knows quite well how to distinguish the patentability exam, the sanitary registration and each of their requirements. That is the reason why I believe that this court does not need to teach the agency how to proceed." Hon. José Márcio, Federal Judge of the 7th Federal Court.

The Federal Court ordered ANVISA to grant prior approval to a pipeline application within 72 hours and to send the application file wrappers to the BRPTO for immediate issuance of the letter patent. Also established a daily fine of approximately $12,000 and one-off fine against ANVISA of approximately $120,000.

Mandatory review of pharma patent applications

Article 229-C – Leading Case Merck v. ANVISA

Federal Court of Appeals for the 1st Circuit ordered ANVISA to grant the prior approval to Merck's patent based only on the analyses of possible risks to public health under Article 18, I of Statute #9.279/96. The Federal Court established that ANVISA should limit its "prior approval" to assessing possible risks to public health. According to Judge Megueriam, the scope of ANVISA's prior approval is confined to the legal ban on patenting inventions harmful to public health, as provided by Patent Statute #9,279/96.

The decision establishes that Article 18, I, does not require applicants to present a full new drug application when filling their patent applications and that drug safety and efficacy are to be proven in the marketing approval proceeding, but not in the patent examination proceeding.

The decision also makes a clear-cut distinction between the limitation of patentable subject matter (inventions against public order and public health) and requirements for marketing approval of a new drug, severely diminishing ANVISA's role in the Brazilian pharmaceutical patent system.

Mandatory review of pharma patent applications

Article 229-C – Other cases

Case Schering Corp v. ANVISA, BPTO

The Federal Court of Appeals for the Second Circuit rendered granted Schering's Interlocutory Appeal to nullify ANVISA's denial of its prior approval and order the agency to make a new analysis of Schering's patent application PP1100138 limited to aspects of public health, that is, foreclosing the re-examination of patentability requirements. The decision ordered ANVISA to present such analysis in a 30 days-term.

Case Abbott GMBH v. ANVISA, BPTO

Federal Court of Appeals for the 1st Circuit ordered ANVISA to grant the prior approval to Abbot's patent based only on the analyses of possible risks to public health under Article 18, I of Statute #9.279/96.

Civil Class Action brought by the Federal Prosecutor

Federal District Court of Brasilia rejected the Civil Class Action holding the Federal Attorney General's opinion (#210/PGF/AE/2009) regarding the prior approval review conducted by ANVISA under Article 229-C.

6. Patent exclusive rights

Licks ATTORNEYS

Patent Statute #9,279 of 1996, as amended

Scope of protection and exclusive rights

The extension of the protection conferred by a patent will be determined by the content of the claims, interpreted in light of the specification and drawings. (Article 41)

The right to obtain compensation for unauthorized exploitation, including with respect to the period prior to grant of the patent, is limited to the contents of the subject matter of the patent, under the terms of Article 41.

According to Article 42, a patent grants to its proprietor the right to prevent third parties from manufacturing, using, offering for sale, selling or importing for such purposes without his consent:

- a product that is the subject of a patent;
- a process, or product directly obtained by a patented process.

The patentee is further guaranteed the right to prevent third parties from contributing to the practice by other parties of the acts.

The rights in a process patent will be violated when the holder or owner of a product fails to prove, through specific judicial ruling, that it was obtained by a manufacturing process different from that protected by the patent.

Patent Statute #9,279 of 1996, as amended

Patent exclusive rights and limitations

Patent exclusive rights

The author of an invention or of an utility model will be assured the right to obtain a patent that guarantees to him the property, under the terms established by the law. (Article 6)

A patent grants to its owner the right to prevent third parties from manufacturing, using, offering for sale, selling or importing for such purposes without his consent: A product that is the subject of a patent; A process, or product directly obtained by a patented process. (Article 42, I and II)

The patentee is further guaranteed the right to prevent third parties from contributing to the practice by other parties of the acts. (Article 42, § 1)

Patent limitations - the right to exclude others does not apply to acts carried

1) By unauthorized third parties relating to the patented invention exclusively to produce information, data and test results to seek market approval in Brazil or abroad, in order to exploit or commercialize the patented product after the term has expired. (Article 43, VII – regulatory review exception, or "*Bolar*" Exemption)

2) To the preparation of a medicine according to a medical prescription for individual cases, executed by a qualified professional, as well as to a medicine thus prepared; (Article 43, III)

Infringement of patent by third generic companies
what extent is there patent linkage?

There is no specific law on patent linkage in Brazil. There is no legislation requiring patent listing, and no public database listing patents covering a specific product, such as the U.S. Orange Book. In addition, no certification requirement exists, i.e. generic applicants are not required to notify patent owners informing that patents are either not being infringed or are invalid, such as a U.S. "paragraph IV" certification. Therefore, ANVISA does not prevent or delay the granting of marketing approval to new drug applications (ANDAs) because of existing patent rights.

The only circumstance when patent owners may link a patent to a specific product is during the price approval procedure before the Brazilian cabinet ministers ("Câmara de Regulação do Mercado de Medicamentos" – CMED), the responsible chamber for approving drug prices within ANVISA. Information on both granted patents and pending applications may be provided by the patent owners but this information is not checked by the CMED. Further, it is not mandatory.

The ANVISA does not consider itself required by law to enforce third parties patent rights (Memo 197/GGMED/ANVISA of December 2nd, 2003).

Brazilian case law supports the invalidity of marketing approvals for agrochemicals since 80's

7. Patent Cooperation Treaty – PCT in Brazil

Licks ATTORNEYS

Paradoxal Patent Law:
Patent Cooperation Treaty – PCT in Brazil

The current regulation for PCT is the BRPTO Resolution #291 of August 24, 2012 (now Resolution PR #77 of 2013), published in the Intellectual Property Gazette #2,174. The hierarchy in the laws of the new Resolution will be the same as the Normative Acts.

Resolution PR #77 revoked NA#128/97. Article 5 establishes the 30-months term from the priority date to enter the national phase with a translation of the request as initially filed (descriptive report, claims, abstract and, if any, listing sequence and biological drawings); identification with the essential data of the international application (Form FQ 003); guide and proof of payment of the government fees.

Article 6 of said resolution established an important **change**: the request for the PCT national phase has to be filed at least with the translation of the claims. The revoked NA allowed the possibility of the request for the PCT national phase to be filed only with the claims (9.2). Fail to comply with article 6 will cause the withdrawal of the application.

The power of attorney needs to be filed in 60 days after the date of receipt of the brief of application for entry into the national phase (Article 31 of Resolution #77/13).

The BRPTO is currently reviewing formal document of applications filed in 2008. When the application enter in the national phase in Brazil, the first office action takes about 3 or 4 years to be published.

Paradoxal Patent Law

The term for the national phase under 22(1) of PCT

Under Resolution #77/2013,substantive examination needs to be requested in 36 months from the international filing date, under penalty of dismissing of the application. (Art. 24)

Legislative Decree #110 of 11/30/1977, gave the Brazilian Congress' advice and consent to the ratification of the PCT Treaty, signed in 1970. The ratification (18th) was deposited in January 9, 1978, making Brazil officially bound after 3 months, on April 9, 1978.

The Brazilian law implementing the PCT Treaty into domestic law is the Presidential Decree of promulgation of the PCT, Decree #81,742 of 1978, which was, and still is, the only law applicable to the Brazilian administration and to the national courts. Article 1 of the Decree #81,742 of 1978, states that the treaty should be implemented as per the text of the Portuguese translation, part of the Presidential Decree of Promulgation.

Decree #81,742 of 1978 is still enforceable. Despite important modifications made in the PCT Treaty in 1984 and 2001, Decree #81,742 was never amended.

Article 22(1) of Decree #81,742, of 1978, establishes a 20 months term from the priority date to enter the national phase, for applicants that have not filed a demand for an international preliminary examination within 19 months from the priority date.

Resolution #271/2012 does not change Decree #81,742 of 1978. Therefore, the 20 month-term is still the term established by the Brazilian Law.

Paradoxal Patent Law

The term for the national phase under 22(1) of PCT

Licks ATTORNEYS

However, article 5 of the new BRPTO's resolution, establishes a 30-months term from the priority date to enter the national phase, for applicants that have not filed a demand for an international preliminary examination.

Failure to comply with the term provided in article 22(1) of the Decree #81,742 of 1978 is not fatal under Article 12 of the BRPTO Resolution #77/2013.

The problem originated in October 3, 2001, during the 13th PCT Assembly, is that the 20 months term under article 22(1) was modified to 30 months, to be harmonized with the term of Article 39(1)(a). Brazil participated in the Assembly and accepted the changes.

Despite agreeing to the modification of the term of Article 22(1) to 30 months, the Brazilian government notified the International Bureau at WIPO that the 30-months time limit, as in force since April 1, 2002, would not apply in respect to the BRPTO, due to an incompatibility with the national law (the Presidential Decree #81,742 of 1978).

In 2004, Brazil notified the WIPO that it had withdrawn, with effect from 04/30/2004, its notification of the incompatibility of Article 22(1) (PCT Newsletter 05/2004). But no changes in article 22(1) of Presidential Decree #81,742 of 1978 were ever made.

WIPO's information on the "*Effects of modification of PCT Article 22(1) time limit*" states suggests that a change in the domestic legislation is needed as follows:

Paradoxal Patent Law

The term for the national phase under 22(1) of PCT

> *"When will all PCT Contracting States have withdrawn their notifications concerning the incompatibility of this change with their national laws?*
>
> *Unfortunately, that is impossible to predict. The PCT Assembly has recommended that any Contracting State in relation to which the modification to Article 22 is not compatible with the national law* ***take urgent action to amend its law in order to make it compatible so that such notifications can be withdrawn as soon as possible****."*
> [http://www.wipo.int/pct/en/faqs/article22_faq.htm]

The BRPTO oscillating policy offered no reasoning for the differences between the 2001 and the 2004 notifications to the WIPO.

For the PCT applications that have entered the national phase before 04/30/2004 with more than 20 months from the priority, the BRPTO issued office actions requiring the applicant to show that it qualified under Article 39(1)(a).

However, the situation is also similar with Article 39(1)(a) of the Decree #81,742 of 1978, never amended and duly enforceable, which still establishes a 25 months term from the priority date for the applicant to enter the national phase if a demand for an international preliminary examination within 19 months from the priority date has been filed.

The problem originated on February 3, 1984, when during the 7th PCT Extraordinary Assembly, the 25 months term under article 39(1)(a) was extended to 30 months.

Paradoxal Patent Law

The term for the national phase under 39(1)(a) PCT

No changes to article 29(1) (a) of Presidential Decree #81,742 of 1978 were ever made.

Article 9 of the BRPTO Resolution #271, granting 30 months to PCT applications entering the national phase for applicants that have filed a demand for an international preliminary examination within 22 months from the priority date is in accordance with Article 39(1)(a) of the 1978 Presidential Decree.

The current BRPTO policy is pro-patent, but it might change in the future. A policy that is not supported by the law might be challenged.

A recent example is the applicability of Article 229-C to pipeline patents. A change in policy at the BRPTO led to attacks to pipeline patents granted after December 1999 without ANVISA's prior approval. The BRPTO had issued two official decisions in February 23, 2000, determining that pipeline applications were not subject to 229-C, but made a strong chance in policy and interpretation on April 2, 2001.

Pipeline patents issued by the BRPTO between Dec. 2009 and April 2, 2001 without the 229-C prior approval are now being challenged in court for invalidity.

The national law might not be compatible with the BRPTO current policy, creating additional risks to PCT applicants entering the national phase in Brazil.

Paradoxal Patent Law

Conflicts of law regarding terms for national phase

Licks ATTORNEYS

International legal system

Patent Cooperation Treaty, done at Washington on June 19, 1970, amended on September 28, 1979, modified on February 3, 1984, and on October 3, 2001, 28 UST 7645; TIAS 8733.

Brazilian domestic legal system (municipal law)

- Legislative Decree #110 of 1977 [*20 months in article 22(1) and 25 months in 39(1)(a)*]
- Presidential Decree #81,742 of 1978 [*20 months in article 22(1) and 25 months in 39(1)(a)*]
- Patent Statute #9,279 of 1996 [*no changes made, PCT implementation maintained*]
- BRPTO's Resolution #77/2013 [30 months in article 22(1)]

8. Data package exclusivity – Current policy

Licks ATTORNEYS

Current policy and case law

Data package exclusivity – Astellas v. ANVISA

The availability for the research based pharmaceutical industry is still subject to much debate and litigation. However, the trend is positive. Despite the fact that the ANVISA still denies enforcement of the statutes, the Brazilian courts have started to enforce data package exclusivity, creating a judicial linkage which is an effective bar to all candidates seeking market approval by an abbreviated procedure.

DPE protection was further supported by the current Brazilian Industrial Property Statute #9,279 of 1996, which defines as a statutory felony the unauthorized use of "the results of tests or other undisclosed data presented to government entities as a condition for approving the marketing of products". However, article 195, XIV of said Law foresees DPE without a limited-term, as a matter of unfair competition.

The 2012 decision on Astellas and Janssen v. ANVISA *et al* represents the very first case where ANVISA supported the enforcement of data package exclusivity, making it a landmark decision that might prove beneficial in the short future. Furthermore, in the lawsuit filed by Astellas, ANVISA highlighted the importance on the application of Article 195, XIV of Patent Statute #9,279/96 and Article 39.3 of TRIPS in order to protect IP rights.

Current policy and case law

Data package exclusivity – Lundbeck v. ANVISA

The leading case enforcing DPE in Brazil was the decision rendered by the Federal Court of Brasilia in favor of Lundbeck. Said decision applied the 10-year term set forth in Federal Law #10,603/02 for data package of agrochemicals and veterinary drugs to the protection of drugs for human use, in order to limit the otherwise eternal protection provided by Article 195, XIV of the Brazilian Industrial Property Statute.

Federal Court enjoined ANVISA from granting MA to a third party based on the test results and data contained in the dossier submitted by Lundbeck.

The decision also pointed that the data package of the reference drug is an indivisible part of the system that allows the waiving of the presentation of tests by the producers of generic and similar drugs.

ANVISA was denying such argument defending that the Agency does not use the data of the reference drug to grant a MA to a copy drug.

The Judge also stated that the use of the dossier presented by Lundbeck, containing the information that show the effort, the scientific research, and the necessary tests to guarantee the safety and effectiveness of the reference drug, for the purpose of granting the market approval for generic and similar drugs, constitutes an act of unfair competition.

Current policy and case law
Data package exclusivity

The fact that such recent decisions upholding a term of protection of ten years for DPE over new chemical entities and five years to second pharmaceutical use suggest that due diligence in the registration of new drugs (NDAs) should be implemented in Brazil, in order to maintain the future options for enforcement of data package exclusivity. If the next years maintain the positive trend, DPE might become relevant to the research based industry. The biosimilars / biogenerics will probably place DPE into the limelight of IP enforcement in Brazil in the next years.

Currently, ANVISA explicitly infringes DPE rights in order to protect the Brazilian generic industries. Therefore, the situation is of total DPE infringement disregarding the protection provided by the legislation. Even so, the enforcement of such protection always requires litigation.

Thank you!

Otto Licks
otto.licks@lickslegal.com
T +55-21-3550-3702 | M +55-21-9792-5232