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**Preliminary Background Paper on Prior Consent for Pharmaceutical Products by ANVISA in Brazil**

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In 1996, Brazil implemented a new Intellectual Property statute, adopting the standards set out by the World Trade Organization TRIPS Agreement. The new Brazilian Intellectual Property Act – statute no. 9279/96 – grants patents over pharmaceuticals, amongst other goods, which, until then, were ruled out of the patentability scope in Brazil. Between 1997 (the year that the new Brazilian statute finally came into force) and 1999, the National Institute of Intellectual Property (INPI) was the only competent body to analyze the applications for patents for pharmaceuticals. Beginning in December 14<sup>th</sup>, 1999, by means of a legal provisional measure – a temporary law edited by the President of the Federal Republic of Brazil, later converted into a federal law (law 10.196 of February 14<sup>th</sup>, 2001), the Federal Executive introduced the mechanism of the prior consent into the Brazilian Industrial Property Act, whose article 229-c provides for:

*“The grant of patents for pharmaceutical products and processes shall depend on the prior consent by the National Sanitary Supervision Agency - ANVISA”.*

The Brazilian law, due to its laconic wording, let room for unending discussions regarding the mechanism’s range of application, its functioning, goals and legality, whereby the prior consent mechanism was originally created as a temporary measure enacted by the Executive Power, therefore there are no records of hearings before the House of Representatives concerning the goals that the mechanism was meant to achieve. As a consequence of the peculiarities surrounding the approval of the prior consent mechanism, a presidential decree implementing and clarifying the wording of article 229-C is deemed a “condition sine qua non” for its survival. Some answers for those questions, in an informal way, arose from the praxis of the ANVISA<sup>1</sup>.

Nowadays, applications for pharmaceutical patents in Brazil are filed at the INPI, official body which has the duty to analyze if the applications meet the formal as well as the patentability requirements. Once the analysis is completed, the applications that meet the

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<sup>1</sup> Due to the lack of further regulation on the prior consent mechanism, ANVISA itself approved an Internal Administrative Norm implementing its competence for the concession of prior consent. ADMINISTRATIVE NORM NO 593, AUGUST 25, 2000, Art. 73-A: The Coordination of Intellectual Property, based in the state of Rio de Janeiro, is competent to: I – grant or deny prior consent by means of an analysis of the requests for patents for pharmaceutical products and processes, filed before the INPI, body bound to the Ministry of Development, Industry and International Trade, in accordance to the Law no. 10.196/2001, with the accessory of the General Management of Medications.

formal conditions and the patentability requirements are forwarded to ANVISA for a second technical report. The ANVISA, in its turn, (re)analyzes the patent requests, verifying if the patentability requirements have been met by the applicant. If there is a conflict of conclusions between the ANVISA and the INPI, a technical meeting is organized between members of the two federal bodies in order to attempt to homogenize their position. If a consensus is not achieved, the pharmaceutical patent is not granted by the INPI, and the applicants have always the possibility of filing an administrative or judicial appeal against the decision reached by the INPI, meaning that ANVISA has “veto power” over the granting of pharmaceutical patents in Brazil.

The main difference between the analysis carried out by INPI and the one carried out by ANVISA arises from the diversity of content of the patentability guidelines adopted by each body. While the INPI adopts patentability guidelines that reproduce the practice of the *European Patent Office*, the ANVISA has drafted its own guidelines, which are much stricter than the ones followed by INPI. ANVISA, by not granting “bad patents”, protects local public health and fosters access to medicines in Brazil; therefore the higher and stricter standards of patentability adopted by ANVISA are conducive to local access to medicines. However, unfortunately it is not possible to draw an accurate picture of the practice of ANVISA, provided that, unlike INPI’s, ANVISA’s guidelines are kept secret. An imperfect overall picture of the ANVISA practice has been drawn lately from its reports, technical notes and public speeches, whereby ANVISA’s patentability guidelines were not made public up to now.

From the creation of the prior consent mechanism up to the present moment, 571 cases have been brought up to ANVISA and, out of 571, only 30 had the prior consent denied. Those 30 cases, from information provided by ANVISA, refer to:

- *Patents on new pharmaceutical uses;*
- *Selection patents (Markush groups);*
- *Polymorphisms (ANVISA has not established a clear position on the subject yet);*
- *Pipeline type patent applications whose object had already been marketed elsewhere.*

From the already analyzed cases in which consent was denied by ANVISA, it is clear that ANVISA has tried, by utilizing some of the flexibilities provided for by TRIPS and by the Brazilian Industrial Property Act, to include notions of health and public interest in the analysis’ procedures of patent applications. ANVISA envisages protection only for inventions that genuinely add something new and relevant to the state of art in the pharmaceutical field.

Today, the main conflict between the ANVISA and the INPI regards the non-granting of prior consent for patents applications involving new medical uses; ANVISA bases its position on the fact that the Brazilian legislation does not explicitly regulate the patentability of new uses.

While the INPI is in favor of the protection of new pharmaceutical uses-related patents<sup>2</sup>, the ANVISA has recently published a technical note<sup>3</sup> stating that the agency would not grant prior consent for patents applications based on second medical use. The rationales underlying this technical note are, according to ANVISA:

- *Such patents are harmful to public health;*
- *Such patents are harmful to the Brazilian scientific and technological development;*
- *These patents may hinder the access to the related drugs.*

Responding to the ANVISA's note, the Brazilian Association of Intellectual Property (ABPI)<sup>4</sup> passed in October 21, 2004, a Resolution<sup>5</sup> contesting ANVISA's arguments and presenting its own arguments opposes to the maintenance of the prior consent mechanism, as well as suggesting a new interpretation to the operational concept of prior consent.

In a nutshell, the legal arguments contrary to the prior consent submitted by ABPI are:

- *The INPI is the only legitimate body, in Brazil, for granting invention patents;*
- *The provision which regulates the prior consent was inserted as a transitory provision<sup>6</sup>, which means, for the cases of pipeline patents requests;*
- *The ANVISA, as a competent body for approving the commercialization of pharmaceutical products, is competent to examine if the object of the pipeline patent request had or had not been introduced in other international markets;*
- *The ANVISA decision of not granting second use patents clashes with the spirit of the Brazilian Innovation Act<sup>7</sup>;*

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<sup>2</sup> INPI guidelines regulating the patentability of pharmaceutical and biotechnological inventions, item 2.39.2.2 - Claims such as:

- a) Pharmaceutical composition characterized by containing the product X (eventually with other components).
- b) Composition for the treatment of the disease Y characterized by containing the product X (eventually with other components).
- c) Composition characterized by containing the product X (eventually with other components) for use on the treatment of disease Y.
- d) Composition on the form of (tablet, gel, solution for injection etc.) characterized by containing the product X (eventually with other components) for use on the treatment of disease Y,

can be granted, as long as the compositions concerned are new and present inventive activity.

<sup>3</sup> "Esclarecimentos sobre pedidos de patentes dos produtos e processos farmacêuticos". <http://www.anvisa.gov.br/divulga/alertas/2004/250804.htm>.

<sup>4</sup> The ABPI is a Brazilian association that gathers members of the national and international industry; its main goal is the local defense of the interests of those industries in the field of intellectual property.

<sup>5</sup> Resolution no. 63, published on the website: <http://www.abpi.org.br/resolucoes/resolucao63.htm>

<sup>6</sup> As a matter of fact, the prior consent mechanism was inserted on the Section VIII – Transitory and **Final** Provisions.

<sup>7</sup> Law no. 10.973, of December 2nd, 2004 (Observation: It does not add to the IP Law – This is "ABPI thesis").

- *The ANVISA's decision infringes the articles 1, 2, 5, XXIX and 37 of the Federal Constitution, the articles 27, 41.2 and 62.1 of the WTO TRIPS Agreement, the articles 2, 6, 8 and 37 of the Law no 9.279/96 (see Annex 1 – Brazilian Legislation);*
- *Prior consent constitutes a forth patentability requirement, besides novelty, inventiveness and industrial application.*

Other practitioners pro-pharmaceutical industry have recently released studies which basically support that intellectual property rights, once enshrined in the Federal Constitution, acquire the feature of absolute rights, and hence, are undeniable once the patentability requirements are met.

Our understanding is that the legislature has not violated any express or implicit principle of internal law by inserting the prior consent mechanism into the Brazilian Industrial Property Act. The Federal Constitution of Brazil requires that the property shall observe its social function (article 5 XXIII) and that the economic order shall obey the principle of the social function of the property (article 170, III), as a warranty of social justice. The recognition of the supremacy of the welfare over individual rights is clearly established in our Fundamental Law (see Annex 1 – Brazilian Legislation).

No argument can resist to the logic that in the relationship between the State and the individual, the fundamental rights assume a position of pre-eminence. There is no discretion when the State, by means of its bodies, acts in defense of human fundamental rights, while not granting patents over given drugs in certain circumstances. In this sense, the text of the article 197 of the Federal Constitution is clear: *“Health is a right of all and a duty of the State and shall be guaranteed by means of social and economic policies aimed at reducing the risk of illness and other hazards and at the universal and equal access to actions and services for its promotion, protection and recovery”*.

In the same direction, our understanding is that the prior consent does not violate any principle of International Law. The intellectual property rights have been built upon the strong pillars of the International Law, having as background humanitarian principles and the protection of the rights of the human being, as it can be observed on the Cooperation Agreement between the United Nations and the World Intellectual Property Organisation.

The critics being made to the prior consent concerning the obligations Brazil has taken over before the WTO are also weak when faced with TRIPS' flexibilities and safeguards, precisely because its protection patterns shall embrace developed countries as well as developing ones.

Regardless of the clearness and the logic of TRIPS goals and principles, more recently, the Doha Declaration on TRIPS Agreement and Public Health, adopted by the Member States of the WTO in 2001, emphasizes that the Agreement shall be interpreted and implemented in such a manner as to guarantee, in Member-States, the protection for public health and the promotion of a wide access to medication.

It can be noticed that, in accordance with the Doha Declaration, the patent registration bodies, as in the current case, the INPI/ANVISA, shall not grant pharmaceutical patents contrary to public interest and that could hinder the access to essential medicine.

## **ANNEX I BRAZILIAN LEGISLATION**

### **The Constitution of the Federal Republic of Brazil**

**Article 1.** The Federative Republic of Brazil, formed by the indissoluble union of the states and municipalities and of the Federal District, is a legal democratic state and is founded on:

- I. sovereignty;
- II. citizenship;
- III. the dignity of the human person;
- IV. the social values of labour and of the free enterprise;
- V. political pluralism.

Sole paragraph - All power emanates from the people, who exercise it by means of elected representatives or directly, as provided by this Constitution.

**Article 2.** The Legislative, the Executive and the Judicial, independent and harmonious among themselves, are the powers of the Union.

**Article 5.** All persons are equal before the law, without any distinction whatsoever, Brazilians and foreigners residing in the country being ensured of inviolability of the right to life, to liberty, to equality, to security and to property, on the following terms:

(...)

XXIII - property shall observe its social function;

(...)

XXIX - the law shall ensure the authors of industrial inventions of a temporary privilege for their use, as well as protection of industrial creations, property of trademarks, names of companies and other distinctive signs, viewing the social interest and the technological and economic development of the country;

**Article 37.** The direct or indirect public administration of any of the powers of the Union, the states, the Federal District and the municipalities, as well as their foundations, shall obey the principles of lawfulness, impersonality, morality, publicity and also the following:

- I. public offices, positions and functions are accessible to all Brazilians who meet the requirements established by law;
- II. investiture in a public office or position depends on previously passing an entrance examination consisting of tests or tests and presentation of academic and professional credentials, except for appointment to a commission office declared by law as being of free appointment and discharge;
- III. the period of validity of a public entrance examination shall be up to two years, extendable once for a like period of time;
- IV. during the unextendable period established in the public call notice, a person who has passed a public entrance examination of tests, or of tests and presentation of academic and professional credentials, shall be called with priority over newly approved applicants, to take an office or position in the career;
- V. commission offices or positions of trust shall be exercised, preferentially, by civil servants holding a post in a technical or professional career, in the cases and under the conditions established in law;
- VI. the right to free union association is guaranteed to civil servants;
- VII. the right to strike shall be exercised in the manner and within the limits defined by a supplementary law;
- VIII. the law shall reserve a percentage of public offices and positions for handicapped persons and shall define the criteria for their admittance
- IX. the law shall establish the cases of hiring for a limited period of time to meet a temporary need of exceptional public interest;
- X. the general review of the remuneration of Government employees without distinction between the indices applied to civil and military servants, shall always occur on the same date;
- XI. the law shall establish the maximum limit and the proportion between the highest and the lowest remuneration of public servants, taking into account, as maximum limits and within the sphere of the respective powers, the amounts received as remuneration, in legal tender of any sort, by members of the National Congress, Ministers of State and Justices of the Supreme Federal Court and the corresponding offices in the states, the Federal District and the territories and, in the municipalities, the amount received as remuneration, in legal tender, by the Mayor;
- XII. the salaries for positions of the Legislative and Judicial Powers may not be higher than those paid by the Executive Power;

- XIII. the linkage or equalization of salaries, for purposes of the remuneration of the personnel in the public services, is forbidden, except for the provisions of the preceding item and of article 39, paragraph 1;
- XIV. the pecuniary raises received by a government employee shall not be computed or accumulated for purposes of granting subsequent raises, for the same reason or on an identical basis;
- XV. *the salaries of government employees may not be reduced, and the remuneration shall comply with the provisions of article 37, XI and XII, 150, II, 153, III, and paragraph 2, I;*
- XVI. remunerated accumulation of public offices is forbidden, except when there is compatibility of working hours:
  - a. of two teaching positions;
  - b. of one teaching position with another technical or scientific position;
  - c. of two exclusively medical positions;
- XVII. the prohibition to accumulate extends to positions and functions and includes autonomous government agencies, public companies, mixed- capital companies and foundations maintained by the Government;
- XVIII. the financial administration and its revenue officers shall, within their spheres of authority and jurisdiction, have the right to precedence over the other administrative sectors, as the law provides;
- XIX. a public company, a mixed-capital company, an autonomous Government agency or a public foundation may only be created by means of a specific law;
- XX. the creation of subsidiaries of the agencies mentioned in the preceding item depends on legislative authorization, in each case, as well as the participation by any of them in a private company;
- XXI. with the exception of the cases specified in law, public works, services, purchases and disposals shall be contracted by public bidding proceedings that ensure equal conditions to all bidders, with clauses that establish payment obligations, maintaining the effective conditions of the bid. as the law provides, which shall only allow the requirements of technical and economic qualifications indispensable to guarantee the fulfilling of the obligations.

Paragraph 1 - The publicity of the acts, programmes, public works, services and campaigns of Government agencies shall be of educational, informative or social orientation character, and shall not contain names, symbols or images that characterize personal propaganda of Government authorities or employees.

Paragraph 2 - Non-compliance with the provisions of items II and III shall result in the nullity of the act and punishment of the responsible authority, as the law provides.

Paragraph 3 - Complaints relating to the rendering of public services shall be regulated by law.

Paragraph 4 - Acts of administrative dishonesty shall result in the suspension of political rights, loss of public function, prohibition to transfer personal property and reimbursement to the Public Treasury, in the manner and grading established by law, without prejudice to the applicable criminal action.

Paragraph 5 - The law shall establish the limitations for illicit acts, performed by any agent, whether or not a Government employee, which cause losses to the Public Treasury, without prejudice to the respective claims for reimbursement.

Paragraph 6 - Public legal entities and private legal entities rendering public services shall be liable for damages that any of their agents, acting as such, cause to third parties, ensuring the right of recourse against the liable agent in cases of malice or fault.

**Article 170.** The economic order, founded on the appreciation of the value of human work and on free enterprise, is intended to ensure everyone a life with dignity, in accordance with the dictates of social justice, with due regard for the following principles:

- I. national sovereignty;
- II. private property;
- III. the social function of property;
- IV. free competition;
- V. consumer protection;
- VI. environment protection;
- VII. reduction of regional and social differences;
- VIII. pursuit of full employment;
- IX. *preferential treatment for small enterprises organized under Brazilian laws and having their head-office and management in Brazil.*

Sole paragraph - Free exercise of any economic activity is ensured to everyone, regardless of authorization from government agencies, except in the cases set forth by law.

### **Brazilian Industrial Property Act (Law no 9.279/96)**

2. The protection of industrial property rights, considering the social interest and the technological and economic development of this country, is afforded by means of:

- I. the granting of invention and utility model patents;
- II. the granting of a registration of an industrial design;

III. the granting of a registration of a trademark;

IV. the repression of false geographical indication; and

V. the repression of unf **6.** It shall be assured to the author of an invention or a utility model the right to obtain a patent that guarantees his property, under the conditions established in this Law.

(1) In the absence of proof to the contrary, the applicant is presumed to be legitimately entitled to obtain the patent.

(2) A patent may be applied for in the author's own name, by the heirs or successors of the author, by the assign or by whomever the law or the employment or services contract determines to be the owner.

(3) In the case of an invention or utility model created jointly by two or more persons, the patent may be applied for by all or any of them, by means of naming and identifying the others, to safeguard the respective rights.

(4) The inventor shall be named and identified, and may request that his name not be disclosed.

**8.** An invention is patentable if it satisfies the requirements of novelty, inventive step, and industrial application.

**10.** The following are not considered to be inventions or utility models:

I. discoveries, scientific theories, and mathematical methods;

II. purely abstract conceptions;

III. commercial, accounting, financial, educational, advertising, raffling, and inspection schemes, plans, principles or methods;

IV. literary, architectural, artistic and scientific works, or any aesthetic creation;

V. computer programs *per se*;

VI. presentation of information;

VII. rules of games;

VIII. surgical techniques and methods, as well as therapeutic or diagnostic methods, for application to human or animal body; and

IX. all or part of natural living beings and biological materials found in nature, even if isolated therefrom, including the genome or germoplasm of any natural living being, and the natural biological processes.

**11.** An invention and a utility model are considered to be new if they are not part of the state of the art.

**(1)** The state of the art consists of everything that became accessible to the public prior to the filing date of the patent application, by means of a written or oral description, by use or by any other means, in Brazil or abroad, except as provided in Articles 12, 16, and 17.

**(2)** For the purposes of determining novelty, the entire content of an application filed in Brazil, and not yet published, shall be considered to be state of the art from the date of filing or of claimed priority, provided that it comes to be published, even subsequently.

**(3)** The provisions of the preceding Paragraph shall apply to an international patent application filed according to a treaty or convention in force in Brazil, provided that there is national processing.

### Chapter III

#### Patent Applications

#### Section I

#### Filing of Application

**19.** A patent application, in accordance with the conditions established by the INPI, shall contain:

I. the request;

II. the specifications;

III. the claims;

IV. drawings, if applicable;

V. the abstract; and

VI. proof of payment of the filing fee.

**20.** Once the application has been submitted, it shall undergo a formal preliminary examination and, if found to be properly documented, shall be docketed, the date of submission shall be considered as the date of filing.

**21.** An application that does not formally satisfy the provisions of Article 19, but that contains data relating to the object, to the applicant and to the inventor, may be submitted, against dated receipt, to the INPI, which shall stipulate the requirements to be satisfied, within a period of 30 (thirty) days, under penalty of having the documentation returned or the application dismissed.

**Sole Paragraph.** Upon satisfaction of the requirements, the filing shall be considered as having occurred on the date of the receipt.

**33.** The examination of a patent application must be requested by the applicant or by some other interested party, within a period of 36 (thirty six) months of the date of filing, under penalty of having the application dismissed.

Sole Paragraph. A patent application may be reinstated, if the applicant so requests, within 60 (sixty) days of the date it was dismissed, upon payment of a specific fee, under penalty of having the application definitively dismissed.

**36.** When the opinion ascertains the non-patentability of the application or the incompatibility of the application to the nature claimed, or makes some demand, the applicant shall be notified to submit comments within a period of 90 (ninety) days.

(1) If there is no response to the demand, the application shall be definitively dismissed.

(2) If there is response to the demand, even if it has not been satisfied, or its formulation is contested, and whether or not comments on patentability or compatibility have been submitted, the examination shall be continued.

**37. Once the examination has been concluded, a decision shall be handed down, either approving or rejecting the patent application.**

"**229.** The provisions of this Law shall be applied to all pending applications, except with respect to the patentability of applications filed until December 31, 1994, whose object of protection comprises substances, matter or products obtained by chemical means or processes and alimentary and chemical-pharmaceutical substances, matter, blends or products and medicaments of any type, as well as the respective attainment or modification processes, and whose applicants have not used the right provided in Articles 230 and 231 of this Law, which shall be considered rejected for all purposes, the Brazilian Patent and Trademark Office being bound to publish the referred rejections.

Sole Paragraph. The criteria for patentability set in this Law shall be applied to applications connected with pharmaceutical and chemical products intended for agriculture, which were filed between January 1, 1995 and May 14, 1997, on the effective filing date of the application in Brazil or of the priority, wherever applicable, the protection being assured from the date when patent is granted, throughout the remaining term counted from the filing date in Brazil, limited to the term provided in the *caput* of Article 40."

"**229.-A.** The patent applications of processes filed between January 1, 1995 and May 14, 1997, to which no protection was provided by Article 9, Subparagraph "c" of Law No.5.772 of December 21, 1971, shall be considered rejected and the Brazilian Patent and Trademark Office shall provide the publication of the referred rejections."

"**229.-B.** The patent applications of products filed between January 1, 1995 and May 14, 1997, to which no protection was provided in Article 9, Subparagraphs "b" and "c" of Law No. 5.772 of December 21, 1971, and whose applicants failed to avail themselves of the right provided in Articles 230 and 231, shall be decided until December 31, 2004, pursuant to this Law."

"**229**.-C. The granting of patents on pharmaceutical products or processes shall depend on the prior consent of the National Sanitary Supervision Agency (ANVISA)."