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INTELLECTUAL PROPERTY BRAZIL

04/13

#2

Recent developments regarding examination of pharma patent applications

By João Luis D. F. Vianna, Alice Rayol R. Sandes and Maria Claudia B. A. Souza

Brazilian PTO's new Resolution No. 80 of March 19, 2013 sets forth rules for granting priority examination for patent applications related to pharmaceutical products and processes, and equipments and materials related to public health

The Brazilian PTO published Resolution No. 80, on March 19, 2013 in the Official Gazette, which establishes the proceedings for requesting priority examination of patent applications related to pharmaceutical products and processes, and equipments and materials related to public health. We are pleased to hereby enclose a complete English language version of the resolution for your review.

According to the new resolution, now in full force, priority for the examination of patent applications related to public health may be requested by:

(I) The Ministry of Health when the object of the patent is considered strategic to the policies within the National Public Health System (the SUS) — the possibility of having applications examined in a priority regimen at the request of the Ministry of Health had been already foreseen in Section 4 of Resolution 68 (old Resolution 191 of October 10, 2008), though the proceedings are more detailed in this new Resolution; or

(ii) Any interested party (interested party being understood as the Applicant itself or any other third party) whenever the object of the patent application refers to the diagnosis, prophylaxis and treatment of Acquired Human Immunodefficiency Syndrome (AIDS), Cancer or neglected diseases (as listed in Annex I of the Resolution). This is a new possibility introduced by the instant Resolution, though limited to patent applications directed to a limited number diseases.

Pursuant to Resolution No. 80/13, the list of patent applications which shall benefit from priority examination, as per the request of the Ministry of Health, will be established by a specific commitee composed of members designated by the Patent Director of the PTO. The Ministry may request priority for specific applications or for sets of applications, the compoents of which will be defined by names or references to products, equipments and/or materials for use in public health. In the latter case., the committee will be responsible for properly idenytifying the applications.

The Resolution establishes that priority examinations will only be available for patent applications for which examination requests have already been filed; additiionally, in the case of a request filed by an interested party, the publication in the Official Gazette disclosing the application to the public must have already occurred. This publicaiton may be anticipated at the request of the Applicant.

The notification of grant or denial of the requests for priority examination will be made by means of specific publications to be made in the Official Gazette. We shall closely monitor the publications related to cases under our care for and shall immediately notify clients in case anything is published.

In the meantime, we shall continue to follow further developments of this matter, and will keep you updated in this respect.

André Venturini | Antonio Carlos Ramos | Cláudio Roberto Barbosa | Denise Dale | Eduardo Colonna Rosman | Elisabeth Kasznar Fekete | Fabiano de Bem da Rocha | Filipe Leonardos | Gabriel Leonardos | Gustavo Barbosa João Luis Vianna | Liz Starling | Marcelo Leite | Nancy Caigawa | Rafael Lacaz Amaral | Ricardo Boclin | Ronaldo Varella Gomes | Sonis Souza | Tatiana Silveira

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#2

New resolution ruling on prior consent analysis by the Brazilian FDA (ANVISA) published in the Official Federal Gazette No. 71 on April 15, 2013

ANVISA's Resolution RDC # 21, of April 10, 2013 comes to replace several dispositions of Resolution RDC # 45 dated 2008, and is now the rule in force as regards the administrative proceedings within ANVISA for the prior consent analysis, mandatory for patent applications covering pharmaceutical products and processes, in compliance with Section 229-C of the Brazilian IP Law.

After being the subject of a public consultation, during a 60-day term that ended on December 22, 2012 (Public Consultation # 66, published the Official Federal Gazette on October 16, 2012, subject of our Newsletter #10), this resolution was put in force and introduces a new concept of prior consent analysis, which will be in light of public health.

According to the text of the new resolution, such analysis will be limited to those applications considered to be "contrary to public health", i.e. when

I - the pharmaceutical product or process encompassed by the application poses a health risk, which is understood as the product itself being a substance of which the use was banned in our country, or a pharmaceutical process resulting in one such substance; or

II - the pharmaceutical product or process is of interest to the policies on medicines or pharmaceutical assistance within the National Public Health System (the "SUS") and does not meet the patentability requirements or other criteria set forth in Law 9279/1996 (the Brazilian Intellectual Property Law). This scomprises substances that are either listed as one of the strategic products according to Ordinances of the Ministry of Health, or that pertain to any therapeutic indication recited in such Ordinances.

The Ordinances of the Ministry of Health currently in force are Ordinance # 978/2008 and its update version, Ordinance # 1,284/2010.

For the applications not falling within one of the two criteria above, prior consent will, in theory, be granted by ANVISA.

The English version of RDC # 21/2013 is attached hereto, as well as a marked-up version of the former RDC # 45/2008, highlighting the changes introduced by the newly published resolution.

Please rest assured that we will keep you apprised of developments on this matter as they arise. In the meantime, please do not hesitate to contact us should you have any queries or concerns in this regard.

André Venturini | Antonio Carlos Ramos | Cláudio Roberto Barbosa | Denise Dale | Eduardo Colonna Rosman | Elisabeth Kasznar Fekete | Fabiano de Bem da Rocha | Filipe Leonardos | Gabriel Leonardos | Gustavo Barbosa João Luis Vianna | Liz Starling | Marcelo Leite | Nancy Caigawa | Rafael Lacaz Amaral | Ricardo Boclin | Ronaldo Varella Gomes | Sonis Souza | Tatiana Silveira |

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	FEDERAL PUBLIC SERVICE MINISTRY OF DEVELOPMENT, INDUSTRY AND FOREIGN TRADE NATIONAL INSTITUTE OF INDUSTRIAL PROPERTY

PRESIDENCY	March 19, 2013

RESOLUTION	**No. 80/2013**

Subject: Regulates the prioritized examination of patent applications for pharmaceutical products and processes, as well as equipment and materials related to public health.

The VICE PRESIDENT OF THE NATIONAL INSTITUTE OF INDUSTRIAL PROPERTY – INPI and the DIRECTOR OF THE PATENT BOARD, in the use of their legal attributions,

Whereas the provisions of Law no. 9,279, of May 14, 1996 establish that the protection of industrial property rights should reflect the social interest and the technological and economic development of the country;

Whereas this Institute is aligned with the Greater Brazil Plan (*"Plano Brasil Maior*"), with the public policies of healthcare of the Ministry of Health and with the development of the Brazilian Industrial Health Complex;

Whereas there is a need to expedite examination of patent applications related to products, processes, equipment and materials for use in healthcare, particularly those considered strategic under the Brazilian Unified Health System (SUS);

Whereas the purpose of the Priority Program of the INPI - Solution to Patent Backlog is to reduce the delay in the examination of patent applications to levels consistent with the international best practices;

Whereas there is a need to optimize procedures for prosecution of patent

applications in order to increase efficiency and assure quality;

RESOLVE:

Section 1 – This Resolution regulates the prioritized examination of patent applications for pharmaceutical products and processes, as well as equipment and materials related to public health.

§ 1 - Prioritized examination of patent applications referred to in the heading of this Section may be requested by the Ministry of Health, according to the details provided for in Section I of the present Resolution;

§ 2 - Prioritized examination of patent applications referred to in the heading of this Section may be requested by any interested party when they refer to the diagnosis, prophylaxis and treatment of Acquired Immunodeficiency Syndrome (AIDS), Cancer or neglected diseases, according to the details provided for in Section II of the present Resolution.

Section 2 - Patent applications submitted to analysis for prioritized examination under the scope of the present Resolution will be under the responsibility of the Patent Board - DIRPA.

Sole Paragraph - The Committee for Prioritized Examination, appointed by the Patent Board will be in charge of the analysis of prioritized examination of related patent applications.

SECTION I
PRIORITIZED EXAMINATION OF PATENT APPLICATIONS BY REQUEST OF THE MINISTRY OF HEALTH

Section 3 – Examination of patent applications filed with the INPI related to products, processes, equipment and/or materials for use in healthcare, which are related to healthcare policies of the Ministry of Health and considered strategic under the Brazilian Unified Health System – SUS will be prioritized.

§ 1 – Patent applications are not limited to the diagnosis, prophylaxis and treatment of the diseases listed in Annex 1 of the present Resolution;

§ 2 – Patent applications must have had technical examination requested, as set forth in Section 33[1] of the IP Law.

[1] Section **33** - 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 pain of shelving of the application.

Section 4 - The list of patent applications submitted to prioritized examination by Request of the Ministry of Health will be established by the Committee for Prioritized Examination.

§ 1 – The Director of the Patent Board is responsible for granting prioritized examination of related patent applications;

§ 2 – The list mentioned in the heading of this Section may be established based on the numbers of patent applications or names or references to products, processes, equipment and/or materials for use in healthcare related to requests made by the Ministry of Health;

§ 3 - In the case of names or references to products, equipment and/or materials for use in healthcare, the INPI will identify the respective related patent applications.

SECTION II
PRIORITIZED EXAMINATION OF PATENT APPLICATIONS BY REQUEST OF THE APPLICANT OR INTERESTED PARTIES

Section 5 – Examination of patent applications filed with the INPI related to products, processes, equipment and/or materials for use in healthcare, which are directly related to the diagnosis, prophylaxis and treatment of the Acquired Immunodeficiency Syndrome (AIDS), Cancer or neglected diseases will be prioritized.

Sole Paragraph - Based on a compendium of diseases listed by the Ministry of Health and the World Health Organization (WHO), neglected diseases are understood as those listed in Annex 1 of the present Resolution.

Section 6 - Prioritized examination of patent applications by Request of the applicant or any interested parties will be evaluated by the Committee for Prioritized Examination.

Sole Paragraph – The Patent Board Director is responsible for granting prioritized examination of related patent applications.

Section 7 - For prioritized examination of a patent application to be granted, the patent application must have been published in the Brazilian Official Gazette – RPI, as established in Section 30 of the IP Law.

Sole Paragraph - Publication of the patent application can be brought forward at

the request of the applicant, pursuant to paragraph 1 of Section 30[2] of the IP Law.

Section 8 - For prioritized examination of a patent application to be granted, the technical examination must have been requested, pursuant to Section 33 of the IP Law.

Section 9 - Request for prioritized examination for patent applications referred to in Section 5 can be made by any interested party and by means of a proper form. The proper form (FQ009 - REQUEST FOR PRIORITIZED EXAMINATION) can be found in Resolution PR No. 063/2013.

Section 10 – The acts referred to in the present Resolution, when not practiced by the interested party himself/herself, shall be accompanied by a power of attorney, pursuant to § 1 of Section 216 of the IP Law.

SECTION III
PRIORITIZED EXAMINATION - PROCEDURAL FLOW

Section 11 – The Committee for Prioritized examination shall verify whether the related patent applications meet the following mandatory requirements for prioritized examination to be granted:

I. It does not refer to a patent application whose examination is suspended for compliance with a formal requirement previously formulated by the Patent Board - DIRPA;

II. It does not refer to a patent application for which prioritized examination has already been granted;

III. It relates to a patent application for which the annuities fees referred in Section 84 of the IP Law have been paid.

Section 12 - The Patent Board will notify, in a specific publication in the Brazilian Official Gazette - RPI, when prioritized examination of the patent application has been granted.

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[2] Section 30 - 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, with the exception of the case provided for in article 75.

§ 1 - Publication of the application may be anticipated on request by the applicant.

§ 2 - 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.

§ 3 - In the case provided for in the sole paragraph of article 24, the biological material will be made available to the public at the time of the publication to which this article refers.

Section 13 - The Patent Board will notify, in a specific publication in the Official Gazette - RPI, when prioritized examination of the patent application has not been granted.

SECTION V
GENERAL PROVISIONS

Section 14 – Section 4 of Resolution No. 68 of March 18, 2013 is hereby revoked.

Section 15 - Prioritized examination provided for in the present Resolution is at no cost to the interested party.

Section 16 – The present Resolution shall come into force on the date of its publication in the Brazilian Official Gazette.

Júlio César Castelo Branco Reis Moreira
Director of the Patent Board

Ademir Tardelli
Vice President

ANNEX 1 – LIST OF NEGLECTED DISEASES

- **Chagas Disease**
- **Dengue fever / hemorrhagic dengue fever**
- **Schistosomiasis**
- **Hansen's Disease**
- **Leishmaniasis**
- **Malaria**
- **Tuberculosis**
- **Buruli ulcer**
- **Neurocysticercosis**
- **Echinococcosis**
- **Yaws**
- **Fascioliasis**
- **Paragonimiasis**
- **Filariasis**
- **Rabies**
- **Helminthiasis**
- **Manifestations arising from intoxication or poisoning caused by venomous or poisonous animals.**

Resolution RDC #21 of April 10, 2013

Alters Resolution RDC #45, of June 23, 2008, regulating the administrative proceedings relative to Anvisa's prior consent for the granting of patents for pharmaceutical products and processes.

The Full Board of Directors of the National Sanitary Surveillance Agency, by the power invested in them by items III and IV of article 15 of Law # 9,782, of January 26, 1999, by item II, and 1st and 3rd paragraphs of article 54 of the Bylaw approved in the terms of Annex I of ANVISA's Ordinance No. 354, of August 11, 2006, republished in the Official Federal Gazette of August 21, 2006, and its updates, given the provisions of item III of article 2, items III and IV of article 7 of Law # 9,782 dated 1999, article 35 of Decree # 3,029, of April 16, 2009, and Program of Improvement of the Agency's Regulatory Process, established by Administrative Ruling # 422, of April 16, 2008, at a meeting held on April 8, 2013, adopts the following Resolution of the Board of Directors, and I, the Director-President, determine its publication.

Article 1. Articles 2, 4, 5, 7 and 8 of Resolution-RDC. 45, of June 23, 2008, become effective with the following wording:

"Article 2. For the purposes of this Resolution the following definitions are adopted:

I - prior consent: Anvisa's deliberative act issued in order to comply with article 229-C of Law # 9,279, of 1996, in which the Agency examines the subject matter of the patent application in light of public health;

II - .....

III - ....."

"Article 4. After receiving the patent applications forwarded by the INPI [*Brazilian Patent Office*], Anvisa will analyze such applications in light of public health, through decision consistent in a technical report issued by the competent organizational unit within the Agency.

1st paragraph. It is considered that the patent application is contrary to public health when:

I - The pharmaceutical product or process encompassed by the patent application poses health risk; or

II – The patent application of pharmaceutical product or process is of interest to the policies on medicines or pharmaceutical assistance within the SUS [*National Public Health System*] and do not meet the patentability requirements and other criteria set forth in Law No. 9,279 of 1996 [*Brazilian IP Law*].

2nd paragraph. The health risk will be characterized when the product comprises, or the pharmaceutical process results in, substance of which use has been banned in the country.

3rd paragraph. The patent application of pharmaceutical product or process will be considered of interest to the policies on medicines or pharmaceutical assistance within the SUS when comprising, or resulting in, substance set out in Ordinances of the Ministry of Health on lists of strategic products, within the SUS, and their updates, as well as comprising, or resulting in, substance pertaining to the therapeutic indication listed in said Ordinances.

4th paragraph. The parameters for analysis on health risk and interest to the policies on medicines or pharmaceutical assistance within the SUS will be detailed in a separate normative act.

5th paragraph. The applicant shall submit to Anvisa, whenever requested, by means of an official action, all documents necessary to clarify doubts arisen during the examination.

6th paragraph. Until the conclusion of the analysis dealt with in this Resolution, the presentation, by interested parties, of documents and information subsidizing same shall be permitted. (new wording)".

"Art 5: .....

1st paragraph. If the official action is replied to, even if it is not fulfilled, or if its formulation is contended, and regardless of any manifestation on its merits, Anvisa will continue the analysis.

2nd paragraph. ....."

"Article 7. .....

1st paragraph. .....

2nd paragraph. After final decision from Anvisa, the application will be sent back to the INPI for the conclusion of the administrative proceedings".

"Article 8. Petitions and documents referred to in this Resolution shall be received according to specific regulation on Anvisa's protocol".

Article 2. Article 6 of Resolution-RDC. 45, of June 23, 2008 is hereby revoked.

Article 3. This Resolution will enter into force on the date of its publication.

DIRCEU BRÁS APARECIDO BARBANO

Marked-up version of Resolution RDC # 45/2008 altered by Resolution RDC #21/2013

Regulates the administrative proceedings relative to Anvisa's prior consent for the granting of patents for pharmaceutical products and processes.

The Full Board of Directors of the National Sanitary Surveillance Agency, by the power invested in them by item IV of article 11 of the Regulation approved by Decree # 3,029, of April 16, 1999, and given the provisions of item II and 1st and 3rd paragraphs of article 54 of the Bylaw approved in the terms of Annex I of ANVISA's Ordinance # 354, of August 11, 2006, republished in the Official Federal Gazette of August 21, 2006, at the meeting held on June 17, 2008, and

considering that the direct and indirect public administration of any of the branches of the Union, States, Federal District and Municipalities will obey the principles of legality, impersonality, morality, publicity and efficiency, pursuant to article 37 of the Federal Constitution dated 1988;

considering that the public administration will also obey, amongst others, the principles of purpose, motivation, reasonability, proportionality, full-defense, adversary system, vested rights and public interest, pursuant to article 2, of Law # 9,784, of January 29, 1999, that regulates the administrative proceedings within the Federal Government, seeking, especially, the protection of the rights of the administered and the better execution of the Administration's purposes;

considering that Anvisa's activity must be judicially conditioned by the principles of validity, celerity, finality, reasonability, impersonality, impartiality, publicity, morality and economical proceedings, under the terms of article 29 of its Regulation approved by Decree # 3,029, of April 16, 1999;

considering the dispositions of the Agreement on Trade-Related Aspects of Intellectual Property Rights – TRIPS – of the World Trade Organization, especially in what concerns the right of the members of organizing themselves administratively in their best judgment for the execution of the Agreement;

considering Anvisa's institutional purpose of promoting the protection of population's health and its legal attributions established in Law # 9,782, of January 26, 1999;

considering that the granting of patents for pharmaceutical products and processes by the Brazilian PTO – INPI – depends on prior consent from Anvisa, pursuant to article 229-C of Law # 9,279, of May 14, 1996, that regulates rights and obligations in industrial property, included by Law # 10,196, of February 14, 2001;

considering the guidelines, the priorities and the responsibilities established in the National Medicine Policy established by the Ordinance # 3,916/MS/GM, of October 30, 1998, that seeks to guarantee conditions for the safety and quality of the medicines consumed in the country, promote the reasonable use and the population's access to those considered essential;

considering the dispositions of Resolution # 338, of May 6, 2004, of the National Counsel for Health, that approves the National Policy of Pharmaceutical Assistance of the Ministry of Health; and

considering the need to improve the procedure of Anvisa's prior consent for the granting of patents for pharmaceutical products and processes, decides:

to adopt the following Resolution of the Full Board of Directors and I, Director-President, determine its publication:

Article 1. Anvisa's prior approval for the granting of patents for pharmaceutical products and processes is subject to the rules and procedures established in this Resolution and other rules in force.

Sole paragraph. The disposition established in this article applies to the applications for patents of invention of pharmaceutical products and processes that on December 15, 1999, were pending or were filed from that date on before the Brazilian Patent Office – INPI.

Article 2. For the purposes of this Resolution the following definitions are adopted:

I – prior consent: Anvisa's deliberative act issued in order to comply with article 229-C of Law # 9,279, of 1996, in which the Agency examines the subject matter of the patent application in light of public health;

II - applicant: natural or legal person of the patent application at the PTO;

III – interested party: any natural or legal person that holds interest, pursuant to Law # 9,784, of 1999, or that possesses relevant information for the examination of a patent application.

Article 3. The prior consent procedure will take place with the submission of the official file wrappers by the INPI to Anvisa for acknowledgement and reply, and the Agency being allowed to decide whether or not consent is to be granted, based on a reasoned decision.

Article 4. After receiving the patent applications forwarded by the INPI, Anvisa will analyze such applications in light of public health ~~perform its assessment regarding the consent checking the fulfillment of patentability requirements and other criteria established by the legislation in force~~, through decision consistent in a technical report issued by the competent organizational unit within the Agency.

1st paragraph. It is considered that the patent application is contrary to public health when:

I - The pharmaceutical product or process encompassed by the patent application poses health risk; or

II – The patent application of pharmaceutical product or process is of interest to the policies on medicines or pharmaceutical assistance within the SUS [*National Public Health System*] and do not meet the patentability requirements and other criteria set forth in Law No. 9,279 of 1996 [*Brazilian IP Law*].

2nd paragraph. The health risk will be characterized when the product comprises, or the pharmaceutical process results in, substance of which use has been banned in the country.

3rd paragraph. The patent application of pharmaceutical product or process will be considered of interest to the policies on medicines or pharmaceutical assistance within the SUS when comprising, or resulting in, substance set out in Ordinances of the Ministry of Health on lists of strategic products, within the SUS, and their updates, as well as comprising, or resulting in, substance pertaining to the therapeutic indication listed in said Ordinances.

4th paragraph. The parameters for analysis on health risk and interest to the policies on medicines or pharmaceutical assistance within the SUS will be detailed in a separate normative act.

~~1st~~ 5th paragraph. ~~During the assessment, t~~The applicant shall submit to Anvisa, whenever requested, by means of an official action~~:~~

~~I – documents necessary for the regularization of the proceedings and assessment of the application;~~

~~II – objections, prior art searches, and results of examination for the granting of corresponding application in other countries, when there is a priority claim; and~~

~~III – other~~ all documents necessary to clarify doubts arisen during the examination.

~~2nd~~6th paragraph. Until the conclusion of the analysis dealt with in this Resolution, the presentation, by interested parties, of documents and information ~~that support Anvisa's assessment~~subsidizing same shall be permitted.

Article 5. When the technical report opines, preliminarily, for the denial of consent or formulates any requirement, the applicant or his legal representative will be notified through registered letter, to reply, within a ninety-day term, counted as from the date of the official notification or the notice given to the interested party in the proceedings.

1st paragraph. If the official action is replied to, even if it is not fulfilled, or if its formulation is contended, and regardless of any manifestation on its merits~~the patentability or the adequacy~~, Anvisa will continue the analysis.

2nd paragraph. Consent will not be given to patent applications whose official action is not replied to.

~~Article 6. When the assessment performed within Anvisa decides for consent, the application will sent back to INPI for the conclusion of the patent granting proceedings.~~

Article 7. Decisions concerning the conclusion of prior consent analysis will be published in the Official Federal Gazette.

1st paragraph. An appeal to the Full Board of Directors of Anvisa can be filed, within a sixty-day term, against the decision that denies consent to the application, pursuant to article 15, 2nd paragraph, of Law # 9,782, of 1999, article 11, 1st paragraph of Decree #3,029, of April 16, 1999, article 212 of Law # 9,279, of 1996, upon observing the specific regulation regulating the proceedings of administrative appeals within Anvisa.

2nd paragraph. After final decision from Anvisa~~the appeal is decided~~, the application will be sent back to the INPI [*Brazilian Patent Office*] for the conclusion of the administrative ~~patent granting~~ proceedings.

Article 8. Petitions and documents referred to in this Resolution shall be received according to specific regulation on Anvisa's protocol~~sent to the Intellectual Property Coordination at Anvisa and received in the protocol service located at Avenida Graça Aranha, # 206, Sobreloja, Centro, Rio de Janeiro, Zipcode 20.030-001~~.

Article 9. This Resolution will enter into force on the date of its publication.

DIRCEU RAPOSO DE MELLO