

Newsletter

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ANVISA'S NEW RESOLUTION – RDC No. 45, OF 23rd JUNE 2008 SETS OUT THE ADMINISTRATIVE PROCEEDINGS FOR THE PRIOR CONSENT TO PATENTS FOR PHARMACEUTICAL PRODUCTS AND PROCESSES

Resolution RDC No. 45, issued by the Full Board of Directors of ANVISA (National Sanitary Surveillance Agency) on 23rd June 2008, entered into force in the country on 24th June 2008, date of its publication in the Federal Official Gazette.

It sets out the administrative proceedings for ANVISA to grant prior consent to patent applications for pharmaceutical products and processes pending on or filed after 15th December 1999.

This new resolution has apparently been passed to try to fill a gap in the Brazilian legislation, inasmuch as there have been no attempts to set forth clear rules on the administrative examination of pharmaceutical applications by ANVISA since the publication of Provisional Ruling No. 2,006, of 14th December 1999, which amended the Brazilian Industrial Property Law No. 9,279/96 to include a fourth patentability requirement as set out below:

Art. 229-C: "The granting of patents in connection with pharmaceutical products or processes shall be dependent on prior consent from ANVISA."

Provisional Rulings are *de facto* laws enacted by the President and subject to subsequent ratification by the Congress, when a law is enacted to substitute the Provisional Ruling. In the case of Provisional Ruling 2,006, it was subsequently renumbered as 2,014 (with several re-editions), and then 2,015, before turning into Law No. 10,196, on 14th February 2001.

Despite the lack of both administrative rules on how ANVISA should conduct their examination and clear criteria that should be met for the grant of consent, many patent applications were forwarded to ANVISA, in compliance with Article 229-C cited above. This, however, left much room for discussion and criticism, since the grant of prior consent could be considered a discretionary act.

Further, although all pharmaceutical applications pending on or filed after 15th December 1999 have been sent to ANVISA since the introduction of Article 229-C in the Brazilian legislation, it is our understanding that only pipeline patent applications should be subject to ANVISA's prior consent proceedings. In fact, due to the transient nature of the provision set out in Article 229-C, only special or transitory situations, such as pipelines, should be governed by such rule.

Briefly, the examination proceedings now to be followed by ANVISA are a reflection of those governing the examination of any patent application by the National Institute of Industrial Property (INPI), as set forth in the Industrial Property Law No. 9,279/96.

Indeed, Resolution No. 45 establishes that ANVISA shall look at whether the patentability requirements and other criteria set out by the legislation in force have been duly met.

During the examination, the applicant may be invited to provide documents, prior art search and examination reports issued abroad (in case the application claims foreign priority) or other documents deemed necessary to clarify a particular matter arising from the examination.

Also, until the end of the examination, any interested third party may provide ANVISA with documents and information that may aid the examination of patent applications. This means that third parties may also file "oppositions" while ANVISA is examining pharmaceutical applications. However, according to the new resolution, there will be no publication of said "oppositions"; the Applicant shall only be acquainted therewith when receiving the notice of an action or a contrary report from ANVISA or checking on the file wrapper of the case after consent has been granted or refused.

A decision will be rendered, with grounds for either granting or suggesting the refusal to grant consent. Moreover, actions may be issued during the examination. In case an action or a contrary report is issued, the Applicant or its representative shall be notified and shall have up to 90 (ninety) days as from when the notification was received to submit a response thereto. Again, it is critical to point out that no publication will take place in this regard. The notification will be sent to the Applicant or its representative by registered mail only. If no timely response is submitted whatsoever, the consent shall not be granted by ANVISA.

ANVISA's decision concluding the examination for prior consent shall be published in the Federal Official Gazette.

If the grant of the application is consented to, it shall be forwarded back to the National Institute of Industrial Property for the conclusion of the patent issuance proceedings.

If, however, ANVISA refuse to consent to the application, an appeal may be lodged to the Full Board of Directors of ANVISA within up to 60 days. After the judgment of the appeal has been laid down, the application shall be forwarded back to the National Institute of Industrial Property for the conclusion of the patent issuance proceedings.

Our comments reflect a possible interpretation to be given to Resolution – RDC No. 45. However, no official statement was issued by ANVISA before this newsletter was sent to print.

Please find enclosed an English Language text of Resolution - RDC No. 45

Should you need further information, please contact any of our attorneys or e-mail us at momsen@leonardos.com.

RESOLUTION-RDC # 45, OF 06/23/08
OFFICIAL GAZETTE 06/24/08

Regulates the administrative proceedings relative to Anvisa's prior approval 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 art.11 of the Regulation approved by Decree # 3,029, of April 16, 1999, and given the provisions of item II and paragraphs 1 and 3 of art. 54 of the Internal Guide Rule approved in the terms of Annex I of ANVISA's Ordinance # 354, of August 11, 2006, republished in the Official Gazette of August 21, 2006, in 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 art. 37 of the 1988 Federal Constitution;

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 art. 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, pursuant to art. 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 the part that it refers to 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 the population's health and its legal attributions established in Law # 9,782, of January 26, 1999;

considering that the granting of patents of pharmaceutical products and processes by the Brazilian PTO – INPI depends on prior approval 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 prior approval of Anvisa for the granting of patents for pharmaceutical products and processes, decides:

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

Art. 1st 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 in course or were deposited from that date on before the Brazilian PTO – INPI.

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

I – prior approval: Anvisa's deliberative act issued in order to comply with art. 229-C of Law # 9,279, of 1996;

II – interested party: any person, individual or company, that holds interest, pursuant to Law # 9,784, of 1999, or that possesses relevant information for the assessment of a patent application.

Art. 3rd The prior approval procedure will take place with the submission by INPI of the proceedings to Anvisa for acknowledgement and reply, and the Agency being able to conclude with approval or disapproval, through motivated decision.

Art. 4th After receiving the patent applications forwarded by INPI, Anvisa will perform its assessment regarding the approval checking the fulfillment of the patentability requirements and the other criteria established by the legislation in force, through decision consistent in a technical report issued by the competent organizational unit within the Agency.

Paragraph 1st During the assessment, the petitioner should present to Anvisa, whenever requested, as a requirement:

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

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

III – other documents necessary to clarify doubts aroused during the assessment.

Paragraph 2nd Until the conclusion of the assessment treated in this Resolution, the presentation by the interested parties of documents and information that support Anvisa's assessment will be permitted.

Art. 5th When the technical report opines, preliminarily, for the disapproval or formulates any requirement, the petitioner or his legal representative will be notified through registered letter, to reply, within ninety days, starting from the date of the official notification or the notice given to the interested party in the proceeding.

Paragraph 1st If a reply to the requirement is filed, even if it is not fulfilled, or if there is an objection to its formulation, and regardless of any manifestation about the patentability or the adequacy, Anvisa will continue the assessment.

Paragraph 2nd Approval will not be given to patent applications that have unanswered requirement notices.

Art. 6th When the assessment performed within Anvisa concludes for approval, the application will return to INPI for the conclusion of the patent granting proceeding.

Art. 7th The decisions concerning the conclusion of the prior approval assessment will be publicized in the Federal Official Gazette.

Paragraph 1st An appeal to the Full Board of Directors of Anvisa can be filed within sixty days against the decision that denies approval to the application, pursuant to art. 15, paragraph 2nd, of Law # 9,782, of 1999, art. 11, paragraph 1st, of Decree # 3,029, of April 16, 1999, art. 212 of Law # 9,279, of 1996, paying attention to the specific regulation that regulates the proceedings of administrative appeals within Anvisa.

Paragraph 2nd After the appeal is decided, the application will return to INPI for the conclusion of the patent granting proceeding.

Art. 8th The petitions and documents that this Resolution regulates will be directed to the Intellectual Property Coordination at Anvisa and received in the protocol service located at Avenue Graça Aranha, # 206, 1st mezzanine, Downtown, Rio de Janeiro, Zipcode 20.030-001.

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

DIRCEU RAPOSO DE MELLO

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