INTERAGENCY ORDINANCE #1, OF APRIL 12th, 2017

Establishes the procedures for the enforcement of article 229-C of Brazilian IP Law # 9.279, of May 14th, 1996, as amended by Statute # 10.196, of February 14th, 2001.

THE ANVISA's PRESIDENT-DIRECTOR AND THE BRPTO's PRESIDENT, by the power invested in them, respectively, by item IV of article 12, of the ANVISA'S rule, appendix of the Decree # 3.029, of April 16th, 1999, and item XII of article 152 of the BRPTO's Internal By-Laws, appendix of Ordinance GM/MDIC # 11, of January 17, 2017, of the Industry, Foreign Trade and Services Minister.

Considering the provisions of the Law # 9.279, of May 14th, 1996, which regulates industrial property rights and obligations;

Considering the provisions of the Law # 10.196, of February 14th, 2001, which establishes the ANVISA's prior approval;

Considering the Inter-Ministerial Ordinance # 1.065, of May 24th, 2012, which makes public the Final Report presented by the Inter-Ministerial Working Group, constituted by the Inter-Ministerial Ordinance # 1.956/MS/MDIC/AGU, of August 16, 2011;

Considering the Opinion # 337/PGF/EA/2010, approved by the Brazilian Attorney General on January 7th, 2011, state:

Article 1. For the purposes of the provisions of article 229-C, of Law # 9.279, of 1996, included by article 1 of Law # 10.196, of 2001, the granting of patents for pharmaceutical products and processes will depend on the ANVISA's prior approval, in the terms of this Ordinance.

Article 2. Once the BRPTO's formal examination has been completed, according to Law 9.279, from 1996, the procedure for the granting of prior approval shall begin after the filing of the request for examination, according to section 33 of the aforementioned Law.

¶1. The BRPTO will publish the notification informing that the patent application is being forwarded to the ANVISA on the BRPTO' Official Gazette, and, when applicable, the fast-track examination decisions.

¶2. The BRPTO will provide, with the publication informing that the application is being forwarded to the ANVISA, full information of the patent application, including interlocutory briefs with that matter related and received by the BRPTO, during the administrative process flow, through the File Transfer Protocol or similar system.

¶3. The BRPTO will officially submit to the ANVISA a listing of the patent applications included in the Article 2, ¶1, simultaneously to publication informing that the application is being forwarded to the ANVISA, or the granting of fast-track examination, on the BRPTO' Official Gazette.

Article 3. The BRPTO will provide the information of its database, through a proper mechanism for ANVISA's access, in order to bring agility to the ANVISA's analysis procedure, considering the provisions of Article 30 of Law #9.279, of 1996.

Article 4. After receiving the patent applications forwarded by the BRPTO, the ANVISA will analyze them in light of the public health, and issue a decision grounded on the technical opinion issued by the competent organizational unit, within the Agency.

¶1. It is considered that the patent application will be contrary to the public health when the product or the pharmaceutical process contained therein, presents health risk.
¶2. The health risk will be characterized when the pharmaceutical product comprises, or the pharmaceutical process results in a substance that has been prohibited in the country.

¶3. If ANVISA denies the prior approval, the application will be sent to BRPTO, which will publish on its Official Gazette the denial decision and the definitive dismissal of the application.

Article 5. On the patent applications encompassing pharmaceutical products and processes of interest to the drug policies and pharmaceutical assistance of the National Healthcare System (SUS), the ANVISA may issue a technical opinion, based on patentability requirements, that will correspond to third party observations, during the BRPTO's substantive examination, as provided for in article 31 of Law #9.279, of 1996.

¶1. The ANVISA will define the pharmaceutical products or processes that shall be included in the main section of this article.

¶2 The ANVISA will send the above-mentioned technical opinions to the BRPTO, for the conclusion of the examination according to articles 35 to 37 of Law # 9.279, of 1996, after publication in the Federal Official Gazette (DOU).

¶3 The BRPTO will publish a notification informing that a technical opinion has been issued by the ANVISA, as provided for in article 31 of Law #9.279, of 1996, on the BRPTO's Official Gazette, before initiating its examination procedure, and will make the mentioned technical opinion available together with the other documents of the patent application's electronic processing.

Article 6. When in disagreement with the technical opinion issued by the ANVISA, the BRPTO must manifest its opinion with technical grounds, pointing the reasons of such disagreement.

Sole ¶. The BRPTO will send ex officio to the ANVISA a list of the patent applications included on the main section of this article, concomitantly to be published on the BRPTO Official Gazette.

Article 7. By the end of the BRPTO's examination of the patent applications granted by the ANVISA, the BRPTO must send to the agency, officially, a list of the patent applications granted and published on the BRPTO Official Gazette.

Sole ¶. The BRPTO will provide to the ANVISA the final claim chart of the patents granted by the Institute, subject to this Ordinance, through its database or equivalent.

Article 8. For the patent applications in progress and those with the administrative instance before the ANVISA over, it is applied the provisions of this Ordinance.

Article 9. An Interagency Policy Group will be instituted, with the participation of representatives of the BRPTO and the ANVISA, with the purpose of providing a wide exchange of technical information and the harmonization of understandings between the Agencies.

Sole ¶. The BRPTO and the ANVISA, in order to guarantee transparent procedures on the examination of patent applications of pharmaceutical products and processes to the patent applicants, will discuss, within the Interagency Policy Group, common understandings on the interpretation of patentability conditions for the categories of claims listed on the appendix of this Ordinance.

Article 10. The petitions sent to ANVISA shall be received by the Agency's docketing division, according to ANVISA's Rule #25 from June 20th, 2011, or its updates.
Article 11. This Ordinance acquires full force and effect 60 days after its publication.

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Brazilian Patent and Trademark Office

APPENDIX

Claim categories that will be discussed by the Interagency Policy Group

1. Compounds – Markush formula
2. Selections of compounds and/or composition
3. Usual salts of the compound
4. Chemical and pharmaceutical processes
5. Polymorphs/Co-crystals
6. Enantiomers
7. Prodrugs
8. Pharmaceutical compositions, carriers and combinations
9. Pharmaceutical forms and of modified release
10. New uses
11. Nucleotide or peptide sequences
12. Antibodies
13 Hybridomas
14. cDNA
15. (Biological) purifying, extraction and isolation processes
16. Microorganisms.