**New rules governing ANVISA’s interaction on pharmaceutical patent applications in Brazil**

Today, April 12, 2017, during an official ceremony attended by Mr. Michel Temer (President of Brazil), Mr. Luiz Pimentel (President of the Brazilian Patent and Trademark Office - “INPI”) and Mr. Jarbas Barbosa (President of the National Agency for Sanitary Surveillance - “ANVISA”), and other governmental authorities, an agreement was formally signed between INPI and ANVISA on examination of pharmaceutical patent applications, whereby, in brief, the following measures have been determined:

- as far as prior consent for granting pharmaceutical patents is concerned, as currently required by Article 229-C of Brazilian Industrial Property Law no. 9,279/1996, ANVISA will limit itself to analyze public health matters only, *i.e.* to check whether the application covers a substance the use of which is prohibited in Brazil. Considering that the majority of patent applications do not cover prohibited drugs, they will in principle receive prior consent from ANVISA and will be sent to INPI;

- at ANVISA’s discretion, *i.e.* when such Agency understands that the drug in question is strategic to the Brazilian Health System, ANVISA will also perform an examination on the merits and will check novelty, inventive activity, enablement, etc. However, the corresponding patentability opinion will not interfere in said prior consent and it will be considered by INPI as a contribution for aiding its analysis during examination phase. According to current patent practice and provisions of Article 31 of the IP Law, utilization of said contribution during examination of a patent application depends on the Brazilian examiner’s discretion;

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1 “Article 229-C - The grant of patents for pharmaceutical products and processes will depend on prior consent from the National Agency for Sanitary Surveillance [ANVISA].”

2 “Article 31 - Documents and information for aiding examination may be filed by interested parties between publication of the application and termination of examination. Sole Paragraph - Examination will not be initiated prior to 60 (sixty) days counted from publication of the application.”
- this new rule will be applied to pending patent applications that have already been subjected to ANVISA’s examination on the merits and were approved or denied. It will be necessary to wait in order to see how INPI and ANVISA will execute this rule in practice;

- patent applications considered by ANVISA to be against public health will not receive Agency’s prior consent, and subsequently INPI will publish their definitive shelving/withdrawal.

ANVISA is the equivalent authority in Brazil of the US Food and Drug Administration – FDA and European Medicines Agency – EMA. ANVISA’s prior consent for granting pharmaceutical patents is a legal requirement that was introduced in the Brazilian legal system as of December 14, 1999 (Provisional Measure MP no. 2,006), which was converted into Brazilian Law no. 10,196 of February 14, 2001.

Article 229-C of the IP Law mentioned above states that any pharmaceutical patent application must be submitted to prior consent of ANVISA, instead of being exclusively prosecuted at INPI. The Agency used to understand that it would have the right at least sometimes to review patentability criteria in patent applications as a condition for giving or denying prior consent. This created an impasse between ANVISA and INPI, since it resulted in the prosecution of patent applications not accepted by the Agency due to patentability objections simply being frozen.

The measures agreed by INPI and ANVISA today aim at finally solving the above conflict and polemic.

The present agreement will be in force 60 (sixty) days after its publication.

The original version of the agreement can be downloaded at INPI’s website: http://www.inpi.gov.br/noticias/cerimonia-com-presidente-temer-marca-assinatura-de-acordo-com-anvisa-e-anuncio-da-nova-in-de-contratos/PortariaConjuntan1.pdf. If you need an English version thereof, please contact us.