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New Developments in The Examination of Pharmaceutical Patent Applications

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Further to the ongoing discussion regarding ANVISA (Brazilian FDA)'s role in the examination of pharmaceutical patent applications, this is to briefly inform you that the Attorney General's Office just recently issued the legal opinion number 0006-2015-AGU/PGF/PFE/INPI/COOPI-LBC-1.0 affecting Brazilian PTO's (BPTO) procedure on applications forward to ANVISA for purposes of prior consent approval.

As you may be aware, due to article 229-C of the Brazilian IP Law, as amended by Law No. 10,196/01, whenever a patent application claims a pharmaceutical product or process, consent from the National Sanitary Surveillance Agency (ANVISA) is required prior to granting the desired patent.

The lack of statutory power of ANVISA to analyze patentability requirements of pharma applications was supported by the Attorney-General's Office in legal opinions published in 2009 and 2011. Following said reports, in view of Ordinance No. 1,065, of 24 May 2012, the Brazilian PTO has started forwarding cases to ANVISA's consent before substantive examination has begun ("new flux" of applications going and coming from ANVISA, as opposed to the "old flux", in which applications were firstly examined by the BPTO and after by ANVISA).

If consented to, these cases would then be sent back to the Brazilian PTO for substantive examination. On the other hand, whenever ANVISA denies the prior consent to these cases, they would be sent to the BPTO in order
to be shelved.

This provision, however, has been the source of additional controversy, subject to judicial questionings, as ANVISA's prior consent should only be denied to applications which corresponding patents would relate to products that clearly would pose health risks.

In this connection, this new legal opinion establishes the following main points related to the prior consent approval mechanism:

I. Whenever ANVISA analyzes the patentability of a patent application in light of section 229C of the Brazilian Industrial Property Law (Law 9279/1996), the BPTO should consider ANVISA's opinion as subsidies for aiding examination, pursuant to Section 31* of Law 9279/1996.

II. Whenever ANVISA denies prior consent to a patent application based on public health issues, the BPTO should definitely shelve the application.

In view of the conclusion of the report cited above, the BPTO has published a memorandum (MEMO/INPI/DIRPA/Nº 055/2016) accepting the terms established in this legal opinion, whenever:

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(I) Patent applications are being examined according to the "old flux" (prior to Interministerial Ordinance nº 1.065/MS/MDIC/AGU, of May 25, 2012); and

(ii) The Brazilian PTO's technical reports have decided in favor of the granting of the patent; and

(iii) ANVISA's written opinions have decided for the granting of prior consent, having analyzed and commented on patentability requirements.

Please note, however, that this MEMO does not concern patent applications following the "new flux" of examination. In these cases, the Brazilian PTO has not yet indicated the position to be adopted. The practical consequences of such legal opinion for cases following the "new flux" cannot be predicted yet.

Please be sure that we shall 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.

In case you need further information on these new regulations, our legal and technical teams are at your disposal in our offices of Rio de Janeiro, São Paulo and Porto Alegre, as well as through the email **mail@kasznarleonardos.com**.

**Section 31 - Documents and information for aiding examination may be filed by interested parties between the publication of the application and the termination of examination. Sole Paragraph - Examination will not be initiated prior to 60 (sixty) days from publication of the application.*