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# Proposal of changes on Brazilian FDA's Resolution RDC #45 dated 2008, which regulates the administrative proceedings for prior consent analysis

The Brazilian FDA (ANVISA) has offered, for public consultation, a proposal of a new resolution relative to the prior consent proceedings applied to applications encompassing pharmaceutical products and processes, as set forth in Section 229-C of the Brazilian IP Law.

This Public Consultation #66 was published in the Official Federal Gazette on October 16, 2012, opening a 60-day term for submission of any comments/suggestions on the changes in the examination procedures that will proposedly be applied by ANVISA in the future. Such term of 60 days started on October 24, 2012, when the proposal actually became available to the public, so that anyone is able to make comments and criticize the proposal up to December 22, 2012.

This comes in consequence to previous opinions raised by the Brazilian Federal Attorneyship (AGU) which stated that, upon complying with the dispositions of Section 229-C, ANVISA should limit their analysis to public health factors and should not examine the applications regarding patentability issues.

ANVISA refused to follow the determinations of AGU and went on issuing technical reports questioning patentability, then taking the matter for discussion within a Working Group composed of members of Ministry of Health, Ministry of Development, Industry and Foreign Trade, ANVISA itself, AGU and the Brazilian Patent Office (BPO).

As you may be aware, and as noticed in our Newsletters #3 and #4/2012, this Working Group issued a final report in which it was defined that there would be an inversion in the patent applications' examination procedures pathway: once a pharma application is filed, the BPO will firstly make a formal examination and will forward the application to ANVISA. ANVISA will then issue their decision, consenting, or not, on the granting of the patent, sending the case back to the Patent Office. If the consent is granted, the BPO will proceed with examination on the merits. In the negative, according to ANVISA, the application is to be shelved.

Although the report issued by the Working Group is not very clear as to whether or not ANVISA would go on examining patentability criteria, ANVISA decided to open this Public Consultation, asking the different branches of our Society to manifest themselves.

The main change to Resolution RDC #45 that is being proposed by ANVISA is in the interpretation of what would consist in “prior consent”, which is now defined as the analysis carried out by the Agency in order to verify whether the subject matter of a pharma patent application is contrary to public health.

In accordance with ANVISA's proposal, the application is said to be contrary to human health when (i) the product/process encompassed thereby poses health risks or (ii) it is of interest to the policies on population's access to medicines and pharmaceutical assistance within the National Public Health System (SUS) and lacks patentability requirements and other criteria set forth in Brazilian IP Law. Hence, it can be immediately verified that ANVISA will continue examining patentability issues in this specific scenario, which is against the determination of AGU, as pointed out above.

In the text of the proposal, there is also a reference to the publication of a future Normative Act, detailing the criteria for the prior consent analysis.

The English version of Public Consultation #66 is attached hereto, as well as a marked-up version of Resolution RDC #45, including the proposed changes.

We shall keep you updated on the next developments on this matter as they arise. Should you have any queries or concerns in this connection, please do not hesitate to contact us.

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