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INTELLECTUAL PROPERTY BRAZIL

08/12

#6

ANVISA's role

limited by Courts again

In our newsletters #3 and #4 we reported about the role of the Brazilian Health Surveillance Agency – known by its acronym in Portuguese, ANVISA – in the examination of patent applications. As Brazilian law requires that ANVISA must grant its prior consent, before the Brazilian Patent & Trademark Office – BPTO may grant a patent application in the pharmaceutical field, there are several doubts as to which criteria should govern the examination made by ANVISA.

We are now pleased to inform that in a recent case we obtained an important preliminary injunction, issued by the judge of the 14th Federal Court of Brasília, determining the annulment, within 48 hours, of an ANVISA decision denying the prior consent and the issuance of a new decision in 30 days, this time, with ANVISA's scrutiny limited solely to public health considerations. Meanwhile, ANVISA has indeed already published in the Official Gazette a Resolution complying with such decision, in this case.

Such injunction was rendered in connection with the writ of mandamus #38253-57.2012.4.01.3400 filed by our firm with aim to annul the denial of the prior consent of a client's pharmaceutical patent application, supposedly (as per ANVISA's allegations) due to the lack of inventive step and sufficient disclosure requirements.

In his decision, the judge of the 14th Federal Court reiterated the understanding of the Federal General Attorney's according to which during the prior consent procedure ANVISA must limit its analysis to its statutory attributions, that is, to verify whether the invention at stake poses any risk to the public health, and, according to the Brazilian legal framework, the BPTO is the sole agency with authority to analyze the traditional patentability requirements. A different understanding could give rise to insuperable conflicts between these agencies, if they had different opinions concerning the patentability of an invention. Such opinion from the Federal General Attorney clearly undermines the role of ANVISA, and for such reason ANVISA has been trying to reverse it, but, so far, without success.

It is important to note that while several decisions have been rendered by the Brazilian Courts in the last few years, limiting ANVISA's analysis to public health factors, this usually happens only after a long prosecution of each case, while in the present case the judge determined it as a preliminary injunction, within few days after filing of the law-suit. In fact, the Judge ordered the immediate annulment of ANVISA's rejection of the prior consent decision, and the issuance of a new decision. This happened because the Judge understood that it was clear that ANVISA does not have any authority to assess patentability requirements, and that there is an actual risk of damages by the delay in granting the corresponding patent, since the applicant has not been able yet to exploit its invention with exclusivity.

In case you are interested in receiving additional information concerning possible judicial measures to overrule ANVISA's denial of its prior approval, please do not hesitate to contact our Litigation Department and we will be pleased to provide you with all the assistance deemed necessary.

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