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# The debate over ANVISA's role in the examination of pharmaceutical patent applications continues

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 also required prior to granting the desired patent. This provision, however, has been the source of never-ending controversy and subject to growing attacks since it entered into effect in 2001.

The lack of statutory power of ANVISA to analyse patentability requirements of pharma applications was supported by the Attorney-General's Office in legal opinions published in 2009 and 2011. Indeed, in their opinion, ANVISA should only make health-based assessments of applications sent for prior consent; prior consent should only be denied to applications in instances that granting the patents would pose health risks. How ANVISA would assess "health risks" on the basis of the information included in patent applications was left unanswered though.

Following said reports published in 2009 and 2011, Ordinance No. 1,956/11 created an Interministerial Working Group to address ANVISA's role in the examination of pharma applications and its cooperation with the Brazilian PTO in light of the article 229-C of the Brazilian IP Law. However, the recommendations given by this group, published through Ordinance No. 1,065/12, appear to be highly contentious.

Briefly, the major change suggested is that, after the Brazilian PTO's formal examination, all applications in the pharmaceutical area will be forwarded to ANVISA for prior consent proceeding. If consented to, these cases will then be sent back to the Brazilian PTO for substantive examination. On the other hand, if ANVISA does not grant prior consent to these cases, they will be sent to the Brazilian PTO in order to be shelved. In addition, general principles of public health have been suggested as basis for the health-based assessment to be made by ANVISA.

Ordinance No. 1,065/12 sets out that both ANVISA and the Brazilian PTO should publish administrative acts in order to put the recommendations given by the group into practice. Considering that the acts to come, if and when published, may still give a different course to the ideas suggested, the exact role to be assigned to ANVISA in the examination of pharmaceutical patent applications is yet uncertain.

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.

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