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## Three is The Charm: 3 Good News from the Brazilian Patent Office

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April 12, 2017 was an unusual day for the Brazilian Intellectual Property System. The Brazilian Patent Office (BPO) announced 3 good news for IP owners.

### PHARMACEUTICAL PATENTS

In the most important event of the day, Brazil's President Michel Temer, in a ceremony at the Presidential Palace in Brasília attended by our firm's Senior Partner Gabriel Leonardos, presided over the signature of a Memorandum of Understanding between the BPO and the Brazilian Health Regulatory Agency (known by its acronym in Portuguese, ANVISA).

The feud between the BPO and ANVISA dates back to 1999 when a statutory change gave ANVISA the power to reject (the law set forth that ANVISA must give its "prior approval") pharmaceutical patent applications.

However, the scope of the examination to be conducted by ANVISA was never clear and while ANVISA held that it could examine all patentability requirements, specially if the drugs are to be purchased by the Brazilian public health system, the BPO held that ANVISA's examination of patent applications should be limited to health and safety aspects. In several lawsuits, some of which won by our firm, the Courts have consistently rejected ANVISA's superlative interpretation of its own authority and decided that patentability criteria (namely novelty, non-obviousness, industrial use and sufficiency of disclosure) can only be examined by the BPO.

Now, it seems that there shall be no more a double and separate examination of patentability requirements by both the BPO and ANVISA.

While this is not a complete solution for a complicate problem (because ANVISA is still empowered to examine patent applications in relation to health and safety concerns),

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today's understanding has the potential of reducing litigation and the time of prosecution of pharmaceutical patent applications (which is currently around 12 years!)

The symbolism of today's act being presided by Brazil's President should also not be understated. For the first time in several decades IP and the BPO became a priority of the Federal Government, which gives us hopes that a political environment more friendly towards innovation is finally arriving in Brazil.

Please email us in case you wish to receive a full English translation of this new resolution.

#### TECHNOLOGY TRANSFER AND IP LICENSE AGREEMENTS

The BPO also published today Normative Instruction 70, of 2017, in which it reduced and simplified the scope of its own examination of technology transfer and IP license agreements. We are preparing an English translation of the new act, and please email us in case you wish to receive such translation in the following days.

Basically, the BPO decided that it will no longer examine the merits of an agreement but only limit itself to an analysis of the applicable formalities. (In a recent newsletter of our firm we explained the details of the Brazilian mandatory registration procedure of technology transfer & IP licenses: please email us in case you wish to receive such newsletter.)

Specially, it is worth noting that henceforth the BPO will no longer examine the payment clause of the agreements and will approve the registration thereof, simply noting in the certificate of recordal of the agreement the following waiver: "The BPO has not examined the agreement under the statutory rules pertaining to tax and foreign exchange control law.»

This means that while the Brazilian party of the agreement may remit the payments, any lack of compliance of the Brazilian tax and foreign exchange control regulations may entail the penalties set forth therein, and the fact that the agreement has been "approved" by the BPO will not serve as a defense. Needless to say, this new system is less patronizing to the parties and give them an increased responsibility in assuring that all Brazilian laws (specially the cumbersome tax and foreign exchange control laws) are being respected by the parties of the agreement.

#### BPO HIRES NEW EXAMINERS

Finally, on the same day 70 new patent & trademark examiners started to work at the BPO. They were approved in exams made in 2014 and only now the Federal Government authorized that they be actually admitted. They join 140 new examiners admitted in 2016, and all those new personnel (comprising approximately 20% of the total number of civil servants at the BPTO) are expected to contribute to the reduction of the backlog in the examination of patent & trademark applications.

We have confidence that these three long-awaited measures are the beginning of a new trend in our IP system, with the reduction of the applications' prosecution delay, and policies that are more predictable and business-friendly.

We remain at your disposal for any further assistance herein.