

# Newsletter

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## BRAZILIAN PATENT OFFICE DEBATES NEW GUIDELINES FOR EXAMINATION OF LIFE SCIENCES-RELATED PATENT APPLICATIONS

The Brazilian Patent Office (BPO) currently faces a huge backlog of patent applications awaiting examination (the figure of 120,000 was unofficially quoted by the BPO's Commissioner of Patents, Mr. Carlos Pazos), a considerable slice of which being applications within the pharmaceutical art.

This backlog is ever increasing since only about 14,000 examination reports are issued annually whilst more than 20,000 new patent applications are filed yearly.

To worsen the scenario regarding patent applications within the pharmaceutical art, re-examination of such applications is being routinely made by the Brazilian FDA (ANVISA), in consequence of an amendment to the Patent Statute implemented in 2001.

Differences in examination standards observed between the BPO and ANVISA have led to many controversial decisions or indeed, in some cases, have resulted in the halting of final decisions owed in several patent applications.

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The BPO has initiated a cycle of debates with the objective of drafting new guidelines for the examination of life sciences-related patent applications. The BPO has invited different members of the IP world, including representatives of the national pharmaceutical associations, representatives of the multinational pharmaceutical groups, ANVISA, IP Law Offices and representatives of the Government.

Although a Public Consultation as such has not been provided, an email address has been offered ([cintiat@inpi.gov.br](mailto:cintiat@inpi.gov.br)) at the BPO official site (<http://www.inpi.gov.br/>) which can be used for providing comments, suggestions by those with an interest on the matters discussed. Papers can also be sent to such email, all of which with an objective of aiding the BPO in drafting the new guidelines.

The themes that have been listed by the BPO as being the objective of such new guidelines are:

- Polymorphs;
- Second Medical Uses;
- Selection patents;
- Combinations
- Dosage forms;
- Salts, esters, etc;
- Pro drugs;
- Isomers, enantiomers and others;
- Interpretation and interface between synthetically obtained product and its similar found in nature;
- Interpretation of the Biosafety Law vis-à-vis Industrial Property Law in what concerns processes for obtaining transgenics.

Up to now, two topics have been object of debates, polymorphic forms and second medical uses.

The BPO has the intention of further discussing until the end of this year a third topic, namely, selection patents.

It should be stressed that discussions on each topic are not concluded with an immediate issuance of the BPO's guidelines but rather aim at providing them with arguments and materials to issue such guidelines in a still undetermined future.

Moreover, and importantly, whichever guidelines are finally issued by the BPO do not bind at all ANVISA's re-examination procedures, this meaning that ANVISA will retain the liberty of applying whichever standards they believe adequate, never mind the fact that they may differ from those that will be applied by the BPO's still-to-be issued guidelines.

Comments, suggestions, papers in support thereof, can be forwarded either directly (including English Language material) to the email address provided by the BPO (see above) or to our firm, to the attention of our partner João Luis D.F. Vianna ([jldfvianna@leonardos.com.br](mailto:jldfvianna@leonardos.com.br)).