

## Legal Opinion About the Attributions of The Brazilian PTO and ANVISA.

Luiz Leonardos  
Maurício Leonardos  
Flávio Leonardos  
Filipe da Cunha Leonardos  
Gustavo Leonardos  
Gabriel Francisco Leonardos  
Denise Leite de Oliveira Dale  
Elisabeth Kasznar Fekete\*  
Gustavo José Ferreira Barbosa  
Eduardo Colonna Rosman  
João Luís d'Orey Facco Vianna  
☆

Tomaz Francisco Leonardos\*\*  
☆

Ana Lucia Mamede Carneiro  
Antonio Carlos Ramos  
Cláudio Roberto Barbosa\*  
Fernanda Burin Leonardos  
Gabriela Muniz Pinto  
Liz Starling  
Louise Prutchi  
Marcelo Canellas Leite  
Marcelo de Oliveira Muller  
Otto Banho Licks  
Ricardo Cardoso Costa Boclin  
Ronaldo M. Varella Gomes  
Rosane Rego Tavares da Silva  
Sonis de Moraes Souza  
Tatiana Almeida Silveira

\* São Paulo  
\*\* of Counsel

**RIO DE JANEIRO OFFICE**  
RUA TEÓFILO OTONI 63 / 10th FLOOR  
CENTRO  
20090-080 - RIO DE JANEIRO - RJ BRASIL

TEL.: 55 (21) 2136-4100  
FAX : 55 (21) 2136-4200

E-MAIL: momsens@leonardos.com.br  
WEBSITE: www.leonardos.com.br

**SÃO PAULO OFFICE**  
AV. NOVE DE JULHO, 3147 / 11th FLOOR  
JARDIM PAULISTA  
01407-000 - SÃO PAULO - SP  
BRASIL

TEL.: 55 (11) 2122-6600  
FAX : 55 (11) 2122-6633

E-MAIL: momsensp@leonardos.com.br

**POSTAL ADDRESS**  
P.O. Box 21214  
AGÊNCIA PRAÇA MAUÁ  
20110-970 - RIO DE JANEIRO - RJ  
BRASIL

**The Attorney General Office issues opinion about the attributions of the Brazilian Patent and Trademark Office and ANVISA (Brazilian FDA) as far as the examination of patent applications is concerned**

The Federal Attorney General issued a legal opinion (Opinion No. 210/PGF/AE/2009) on October 16, 2009, concluding that the National Sanitary Surveillance Agency (Brazilian FDA) cannot analyze the patentability requirements of patent applications related to pharmaceutical products and processes during the prior consent proceeding set out in article 229-C of the Brazilian Industrial Property Law. The assessment of novelty, inventive activity and industrial applicability requirements can only be made by the Brazilian Patent and Trademark Office.

The Federal Attorney General took the view that the attributions of each Agency are private, specific and cannot overlap. The attributions of the Brazilian PTO are

set forth in Law 5,648/70, whereas those of ANVISA are established in Law 9,782/99. Hence, in deciding whether or not consent should be given to a pharma patent application, ANVISA must only bear in mind its legal mission, that is, to prevent the production and marketing of products and services potentially detrimental to human health.

Although this legal opinion shed some light on the construction of article 229-C of the Brazilian Industrial Property Law, it is not binding, since it was requested to instruct a specific court action. Hence, even if the Court follows this understanding, the effects of the decision will remain inter partes only.

In an attempt to put an end to the controversy arising from article 229-C, the Federal Attorney General suggested that the Executive should then enact a Decree ruling on this matter or that these Agencies should go into administrative partnership.

JLDFVianna 30102009