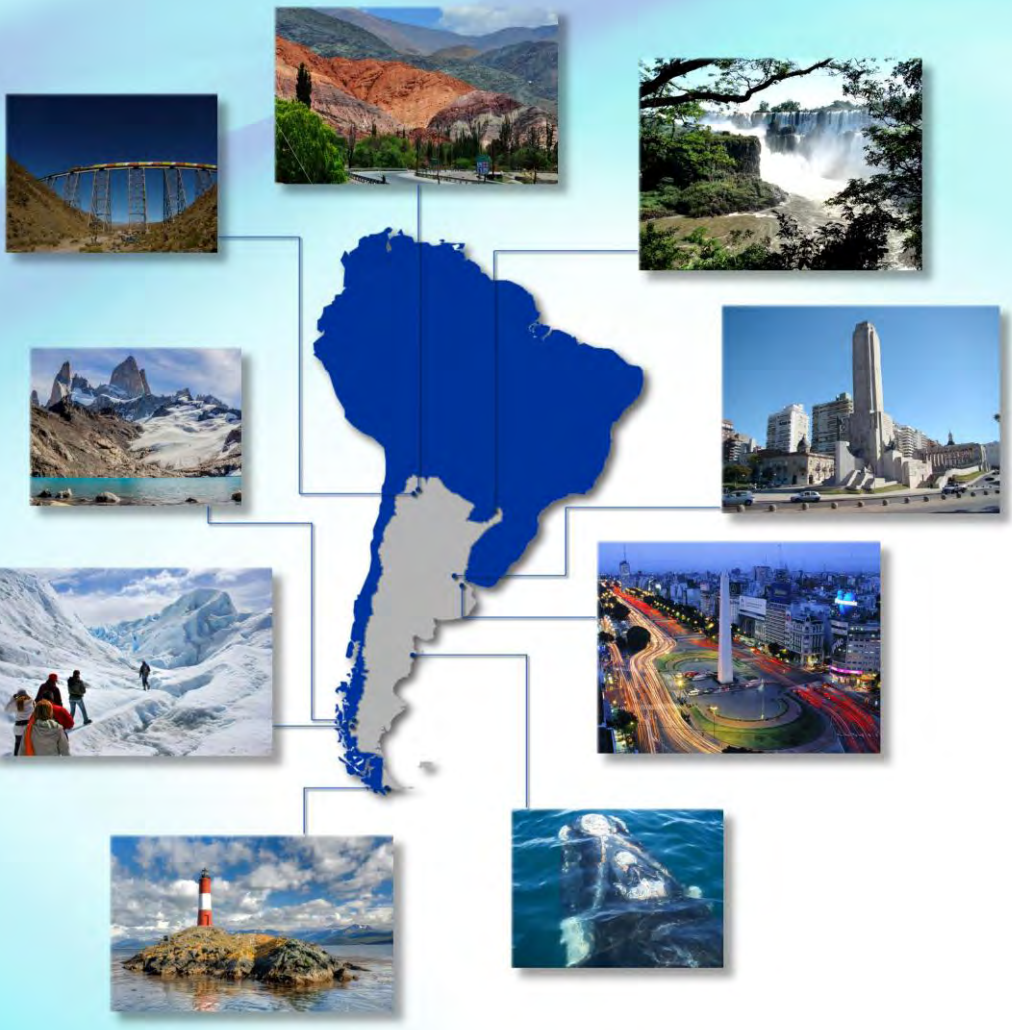

8vo Congreso Latinoamericano de Órganos Artificiales, Biomateriales e Ingeniería de Tejidos

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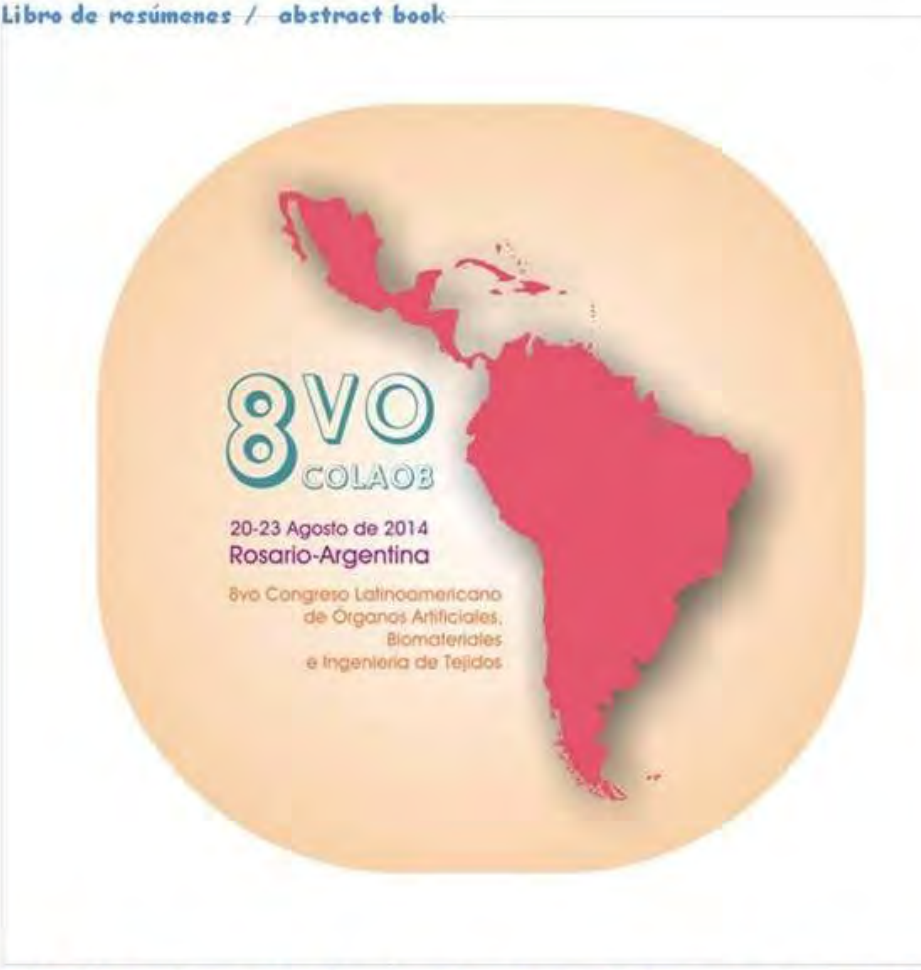

8th Meeting of the Latin American Society of Biomaterials and Artificial Organs *(SLABO)*

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2E-02

PATENTING OF POLYMORPHIC BIOMATERIALS AND SECOND MEDICAL USE: CONCEPTUAL ISSUES AND CRITICISM STEMMING

LIMA, J.A.A.[1,2], FIDÉLES, T.B.[1], SILVA, D.B.[2], LIMA, J.C.S.[2], RODRIGUES, C.A.O.[2]
[1] Laboratório de Avaliação e Desenvolvimento de Biomateriais – CERTBIO, Universidade Federal de Campina Grande, Unidade Acadêmica de Engenharia de Materiais, Campina Grande, BRASIL
[2] Faculdade de Ciências Sociais Aplicadas, Centro de Ensino Superior e Desenvolvimento, Campina Grande, BRASIL

D. Giron, Ch Goldbronn, M. Mutz, S. Pfeffer, Ph. Piechon, Ph. Schwab (2002:453-465) define "polymorphism" as the existence of changes in the crystalline arrangement of a substance without observing in it a modification in its molecular structure (both molecular conformation and spatial one). The chemical properties of different crystalline forms of a substance are identical, which did not happen with their physical and physicochemical properties, such as melting point, conductivity, volume, density, viscosity, color, index refraction, solubility, hygroscopicity, stability and dissolution profile.

Polymorphic obey, therefore, the intrinsic properties of the molecules and cannot – In many ways – be considered as an invention, not derived by human ingenuity, but only be as a discovery that, as such, should not be subject to patent, under penalty of non-compliances with the fundamental criteria of novelty (N), inventive step (IS), and industrial applicability (IA).

In the other hand, about the "second medical use" patents, those are nothing more than a new way of expanding intellectual property rights, which seeks to protect the applicability of a new medicinal substance, like a new patent privilege. So, the "first medical use" is defined as a new use as a medicine, a known product, but not used in the medical field; beside, the second use, in turn, constitutes a new application of a known compound, and a known therapeutic purpose.

Second medical use patents, as well, seek the protection of a new medicinal or therapeutic use of a known compound with applications in the medical field. According Newton Lima (2013:128-129), about the studies for the reform of the Brazilian Patent Law, the second use framed into three categories: new application for a product already registered; application of a new therapeutic compound formulation and presentation of different dosages of those registered product; or new therapeutic application of compounds with known biological activity, but did not reach the market or were not considered promising for the first indication.

In this present article, so, the authors address the issue both from the conceptual perspective, in the light of the science of biomaterials – primor focus – such as regarding the legal position on the subject, including the arguments associated with the "evergreening" – a kind of a legal and a business strategies by which the technology producers with patents over products that are about to expire retain the intellectual property rights, by either taking out new privileges, as a new pharmaceutical mixtures, for example, or by buying out or frustrating competitors, for longer periods of time than would normally be permissible under the law.

2E-03

PRIOR CONSENT OF THE HEALTH SURVEILLANCE SYSTEM TO GRANT PATENTS OF PHARMACEUTICAL PRODUCT/PROCESSES: STRENGTHS AND CRITICISMS OF THE BRAZILIAN MODEL

LIMA, J.A.A.[1,2], FIDÉLES, T.B.[1], SILVA, D.B.[2], LIMA, J.C.S.[2], RODRIGUES, C.A.O.[2]

[1] Laboratório de Avaliação e Desenvolvimento de Biomateriais – CERTBIO, Universidade Federal de Campina Grande, Unidade Acadêmica de Engenharia de Materiais, Campina Grande, BRASIL

[2] Faculdade de Ciências Sociais Aplicadas, Centro de Ensino Superior e Desenvolvimento, Campina Grande, BRASIL

The Brazilian National Health Surveillance Agency – Anvisa, linked to the Ministry of Health of Brazil, is a regulatory agency in charge of the sanitary control of health products, such as drugs, medical devices and food, and has the mission to protect and promote health, ensuring the hygiene and safety of products and service and taking part in developing access to it, by exercising sanitary control of all goods and services (national or imported one) subject to sanitary surveillance. Besides those majors functions, the Agency participate, as an administrative consultant, with a value judgment procedure for the grant of a patent of pharmaceutical products and processes, in accordance with local standards is guaranteed. For this event is given the name “prior consent”.

Although occurs rejections regarding the legitimacy of the existence of such an attribute, that, according to some authors, would be an affront to Intellectual Property Laws, and the autonomy of the patent examiner, the prior consent can be considered a demonstration that Brazilian rules are on the right way to the fair process of pharmaceutical patent applications and, plus, that the its acquiescence before the formal exam of the Brazilian National Institute of Industrial Property (INPI) is correct.

About this system, the applicant must request examination of patentability of its pharmaceutical products or processes within the period prescribed by law and according the rules of INPI, that, just after the formal examination of the documentation, sends them to appreciation of Anvisa. Then, only after receipt of the relevant request files sent, the Anvisa examine whether applications are capable to well attend the public health, whose decision shall be embodied in technical opinion issued by the competent organizational unit within the Agency.

This process might seem, at first sight, as well said, a decrease of INPI’s authority or even – for the most critical – a weakening of national patent structure itself, but is actually a measure of protection to public health and is fully in line with international rules on Industrial Property. Notwithstanding be bureaucratic, experts say that it is a guarantee that the public interest will always be defended in the evaluation of these rights sought and helps avoid distortions, including undue patents.

Therefore, this article seeks to demonstrate, through favorable circumstances and also a resulting criticism, as the system of prior consent is applied in the Brazilian patent law. Moreover, it’s a paper with more suggestions which may be proposed about that.