New rules for eligibility of pharmaceutical products and processes to interest of the Brazilian Unified Healthcare System and its effects on the examination flow of pharmaceutical patent applications

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Through Ordinance No. 2,466/2020 of October 2020, the Ministry of Health (MS) created two new organizations to act on Intellectual Property matters, namely the Commission on Intellectual Property in Health (COMPIS) and the Articulation Group of Intellectual Property and Health (GAPIS). Further, the ordinance introduced an important change, with the update of eligibility criteria for patent applications in the pharmaceutical field to be considered of interest to the Unified Healthcare System (SUS), which may have repercussions on the technical examination of these applications by the Brazilian PTO (INPI).

COMPIS will be entitled to prepare and monitor the implementation of policies in the field of intellectual property and health, indicating technical priorities and offering support for decision making involving matters of intellectual property in health, including those related to expedite examination at INPI. In addition, the Commission will work with the Interministerial Group on Intellectual Property (GIPI)[1] to reconcile internal and external policies for IP-related goods and services. GAPIS will prospect and identify patent applications for pharmaceutical products and processes, especially those considered strategic for public health policies, in order to provide support for decision making by MS and also for the activities of COMPIS.

In this sense, it is important to mention that, in addition to the newly created COMPIS and GAPIS, and GIPI, the Interinstitutional Articulation Group (GAI) also intervenes on the subject of intellectual property and health, particularly

by analyzing and suggesting mechanisms, procedures and formal instruments for articulation between the National Health Surveillance Agency (ANVISA) and INPI.

The ordinance also defines new criteria for medications and related processes to be considered of interest to SUS assistance policies, allowing the presentation of third party observations by ANVISA to assist technical examination of the related applications at INPI, in addition to the provision of prior consent notice by the Agency[2]. These requirements change the scope of a 2017 consolidation on the subject[3], in particular considering the eligibility of pharmaceutical applications for submission of technical examination observations by ANVISA.

As of the publication of the ordinance, the following criteria, applied independently, become valid to determine whether a patent application for a pharmaceutical product or process should be considered of interest to SUS policies and, thus, subject to filing of third party observations by ANVISA:

I - patent application with request by MS for expedite examination to INPI;

II - technology of the patent application as object of a lawsuit to obtain access to the medicine, upon request from the MS to ANVISA.

III - patent application related to a topic of relevance to the actions of MS, through technological prospecting; and

IV - selection of the patent application, by ANVISA, according to the therapeutic purposes, among the following groups, a) infectious and parasitic diseases; b) diseases of the Respiratory System; c) diseases of the Nervous System; d) diseases characterized as rare; e) diseases of the Digestive System; f) diseases of the blood or blood-forming organs; g) diseases of the Immune System; h) diseases of the Circulatory System; i) neoplasms; and j) vaccines and serums.

Potentially as a consequence of the COVID-19 pandemics, the ordinance specifically defines the category of diseases of the Respiratory System as relevant to SUS, enabling ANVISA to file third party observations for related patent applications

pending examination at INPI, for example, directed to new drugs or uses to minimize the disease's symptoms or its cure. Also relevant is the removal of the neglected diseases category, with the proviso that these could be considered within the new generalist category of infectious and parasitic diseases, besides the fact that the therapeutic indication groups listed on item IV above can be revised according to SUS's interests.

Following the publication of Ordinance 2,466/2020 by MS, ANVISA published on November 19, 2020 four manuals on examination of pharmaceutical patent applications subject to prior consent[4], to elucidate the operationalization of the activities related to patents assessed by the health agency.

Hence, the implementation of the ordinance provisions will depend on the articulation capacity of the various groups involved in management of intellectual property in the field of pharmaceuticals, including those created thereby, with the remark that the beginning of activities of COMPIS and GAPIS has yet to be defined by MS. Thereafter, the effective outcomes in the administrative prosecution of pharmaceutical applications at INPI will require further evaluation.

NOTES:

[1]Created with Presidential Decree of August 21, 2001 within the Foreign Trade Chamber (CAMEX), it was recreated under the Ministry of Economy through Decree No. 9,931/2019. GIPI is composed of representatives from various ministries, wherein INPI is invited to participate in discussions within its competence.

[2]Law No. 9,279/1996, Industrial Property Law (LPI), as modified by Law No. 10,196/2001. "Art. 229-C The granting of patents for pharmaceutical products and processes will depend on the prior consent of the National Health Surveillance Agency - ANVISA".

[3]Joint Ordinance No. 01/2017 of ANVISA/INPI. "Art. 5. In patent applications that contain a pharmaceutical product or process considered to be of interest for the policies of pharmaceuticals or pharmaceutical assistance within the scope of SUS, ANVISA may issue an opinion, based on patentability requirements, which will correspond to third party observations, during the examination by INPI, pursuant to article 31 of Law No. 9,279, of 1996".

[4]https://www.gov.br/anvisa/pt-br/assuntos/noticias-anvisa/2020/anvisa-publica-manuais-com-orientacoes-sobre-pedidos-de-patentes

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