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Brazil – Pharma PDPs and challenges for IP owners

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On Friday June 21, 2024, the government formally introduced regulations addressing the new framework for Partnerships for Productive Development (PDP). The Ministry of Health published new guidelines (Ordinance #4,472/20241) as part of the government policy to foster the "National Strategy for the Development of the Economic-Industrial Health Complex" (Decree No. 11,715/2023).

The policy aims to increase access to health in the Public Health care System (SUS). The government is fostering the development of transfer of technology agreements to strengthen local production of medicines and medical devices. PDP agreements were introduced in the past as a governmental program consisting of deals between private companies (local or foreign), government-owned industry (such as publicly funded manufacturing plants) and the Ministry of Health, that would include the transfer of technology to produce drugs.?

The original PDP program had a major setback after an audit by the Government's Accountability Office (GAO) which found a series of weaknesses, leading to the suspension and termination of several partnerships. The GAO concluded that existing partnerships lacked?**(i)**?objective criteria for defining the list of products of strategic relevance to SUS, and parameters for evaluating compliance with such criteria;?**(ii)**?objective parameters for carrying out analysis of PDP proposals and pre-defined criteria for grading proposals (in order to observe the principles of transparency, legality, and ethical conduct);?**(iii)**?a clear definition of deadlines for analyzing monitoring reports and carrying out technical visits;?**(iv)?**transparency regarding the allocation of the unit price paid, as it is unclear whether the price reflects the cost of the product itself or the transfer of technology; and?**(v)**?objective criteria regarding the definition of the percentages of the demand for each PDP, as in some cases there is more than one PDP for the same product.

On April 15, 2024, the government presented clarifications on the measures taken to comply with the GAO's determinations. These included **(i)** stating the draft ordinance (now, Ordinance 4,472/2024) addressed the identified weaknesses; **(ii)** informing that the internal regulations of the Technical Evaluation Commission (CTA) and the Deliberative Committee (CD) will be updated after the publication of the new ordinance (this is important, as the new ordinance requires the internal regulations to define, on a complementary basis, among other things, the methodology for carrying out analysis of PDP proposals); **(iii)** stating that the government-owned industries were informed about the need to carry out a selection process for the private partner, or adequate justification in the event of unfeasibility; and **(iv)** requesting that the 180-day deadline set by the

GAO to verify compliance with the principles of transparency, legality, and ethical conduct among the criteria for approving PDPs should start to run from the publication of the new regulations.

A big issue considered by the community was the potential non-compliance with IP rights. The agreements included provisions that allowed parties to up to 10 years of exclusivity in the supply to the government, regardless of the existence of granted patents, which ended up with lawsuits challenging PDPs contract due to patent infringement.

The summary below provides information on the relevant references to Intellectual Property Rights in the new PDP guidelines.

I – The approval process and eligible products

Article 2, II, which sets the definition of the agreement between the Ministry of Health, government-owned industry and private companies, states that the proposal must mention existing IP rights.

Furthermore, the PDP Project proposal must now include information on?"*intellectual property, exclusivity contracts or commercial agreements, including details of any agreements or restrictions on licensing or 3rd-party access to the technology"*?(Annex CX, article 8, V).

In order for a product to be eligible for PDP, it must not only be listed in the Matrix of Productive and Technological Challenges in Health as a technological solution for SUS (Ordinance 2,261/2023), as well as it must fulfill the requirements set in article 4, which includes the lack of?**patent protection or its expiration within 3 years of the proposal's submission**.?

Not only are the parties obliged to provide information on the existence of patent protection, but also the existence of a patent that is still in force for more than three years after the submission of the proposal is now an obstacle.?

II – PDP development timeline and IP monitoring

The PDP is divided into 4 stages/phases. Each one has milestones from start to finish (Annex CX, article 6). Phase II encompasses the preparations for the transfer of technology and begins with the approval of the PDP project submitted in phase I, following the publication of the agreement between the Ministry of Health, government-owned industry and private companies. This phase has a maximum duration of 3 years (Annex CX, article 6, II, and article 8, paragraph 1).

?Phase III is the most important as it sets the first acquisition of the product. Phase III will only begin after, among other requirements, the submission by the applicant?**of an update on intellectual property rights that would demonstrate the lack of constraints**?on the acquisition of the product by the government (Annex CX, article 34, VI).

It is also in Phase III that the Secretariat of Science, Technology and Innovations and of the Health Economic-Industrial Complex (SECTICS/MS) must send a technical note that includes the status of the product's IP rights to the Ministry of Health (Annex CX, article 43, VI, g).?

If a company intends to proceed with the PDP but doesn't have the IP rights for the product (for instance, the company might try to complete Phase II before the patent expires), it will have to get the patent invalidated before Phase III. Otherwise, as a rule, the PDP will be automatic suspended

for evaluation after the end of the approved term for Phase II (Annex CX, article 32).? If, on the other hand, the company engaged in the PDP is the owner/controller of the relevant IP rights, this limitation does not apply, and phase III may begin as soon as the government-owned industry is ready to receive the transfer of technology.

Although the scenario for IP owners is a bit clearer compared to the previous system, one issue that has not yet been resolved is the lack of objective criteria for defining "guaranteeing the transfer of technology". It is still a requirement that has been maintained in the new guidelines as one of the responsibilities of the private company (Annex CX, article 58, VI). This should be monitored with caution by the IP community.

III – Introduction of a new contract: Local Development and Innovation Program (PDIL)?

In parallel with the PDP Program, the Ministry of Health is also creating the Local Development and Innovation Program (PDIL, Ordinance 4,473/20242). As part of the "National Strategy for the Development of the Economic-Industrial Health Complex" the PDIL is similar to the PDP program as it aims to reduce SUS' vulnerability (Anexo CIX, article 1).?

PDIL is focused on the joint development of innovative solutions or products, without the need for the transfer of technology (although it is a possibility).

?PDIL establishes strategic cooperations between government-owned institutions or nonprofit organizations and other government-owned institutions or private companies/startups. The PDIL can be implemented through a variety of contractual instruments, some of which are already established under Statute #14,878/2004 (Innovation Law) and it also allows the MoH to sign agreements for the supply of the technology or product resulting from the PDIL, for up to 10 years, counting from the technological solution/product's execution (CIX, art. 5, § 3th).

?Additionally, PDIL requires that there should be counterparts for SUS. These may take the form as (i) co-ownership of intellectual property for the Ministry of Health or a public institution;(ii) economic rights; (iii) transfer of technology and know-how; or (iv) free services or products (Anexo CIX, article 8, VIII). In any case, the decree states that only projects containing one of these counterparts, with the guarantee of the availability of the technology for the SUS in the event of its successful development, will be accepted (CIX, article 8, sole paragraph).

According to the government, interested entities have until the end of September 2024 to submit PDIL and PDP project proposals.

The current priority areas include preparations for health emergencies, products at risk of shortages, digital health, and contributions to More Access to Specialists Program and the National Queue Reduction Program (e.g., oncology, cardiology, orthopedics, and ophthalmology).

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