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Brazilian government resurrects its Partnership for Productive Development (PDP) program. A new threat to pharma IP rights?

Roberto Rodrigues Pinho, Brenno Telles (RNA Law) · Tuesday, October 3rd, 2023

Brazil's president published, on September 27, Decree No. 11,715/2023 which institutes the "National Strategy for the Development of the Economic-Industrial Health Complex". This decree aims at directing public and private investments towards the health and innovation sectors to reduce the Public Health System's (SUS) vulnerability and increase access to medicines. It aims to do this by means of development and also absorption of technology to strengthen local production.

One of its main goals is to contribute to the implementation of a national industrial policy to be proposed by the National Council of Industrial Development, for example, by using the Government's substantial budget and large volume of yearly acquisitions as incentives. During the announcement of the Decree, the government released a presentation in which it pledged to invest 8.9 billion reais to finance the building and completion of Government-owned facilities and 10 billion in production and innovation by the end of 2026, as well as estimating that the private sector would invest another 23.2 billion reais in that same period.

Although the Decree does not implement concrete measures (which will be proposed by the Executive Group of the Economic-Industrial Health Complex in the coming months), one of the main pillars highlighted is the Partnership for Productive Development (PDP) program.

PDPs, which were mostly left untouched during the previous administration (2019-2022), consist of agreements between private companies (local or foreign), government-owned industry (such as publicly funded manufacturing plants) and the Ministry of Health, for the transfer of technology for the production of medicaments relevant to the SUS as well as their supply to the Brazilian market (as provided for in the Ministry of Health's Consolidation Ordinance No. 5/2017).

The program has previously caused consternation amongst IP owners, as the agreements contained provisions that entitled parties to the agreements to up to 10 years of exclusivity in the supply to the government, regardless of the existence of granted patents. From 2014 to 2017, several agreements were signed by third parties, without the involvement or consent of the patentees and even though relevant patents were still expected to be in force for almost another 10 years. Lawsuits were filed at the time and a trial judgment acknowledged that the PDP proposal presented by a private party violated patent rights, as it constituted an illegal offer for sale of the claimed product.

On the same day that Decree No. 11,715/2023 was published, however, the Full Panel of the Government's Accountability Office (GAO) held a session in which it noted that the Ministry of Health had failed to comply with determinations and recommendations regarding PDPs issued after a 2017 audit to the then existing partnerships (Ruling No. 1730/2017, TC 011,547/2014-6) and issued a new decision (Ruling No. 2015/2023, TC 034.653/2018-0). In it, the GAO recommends that the signing of new PDPs ceases until the several previously identified weaknesses of the program are addressed by the Ministry of Health, which must (i) establish objective criteria for defining the list of products of strategic relevance to SUS, and parameters for evaluating compliance with such criteria; (ii) establish 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); and (iii) adopts a definition of deadlines for analyzing monitoring reports and carrying out technical visits.

We can expect more developments relating to PDPs in the next couple of months while the Ministry of Health navigates the TCU's recommendations and determinations.

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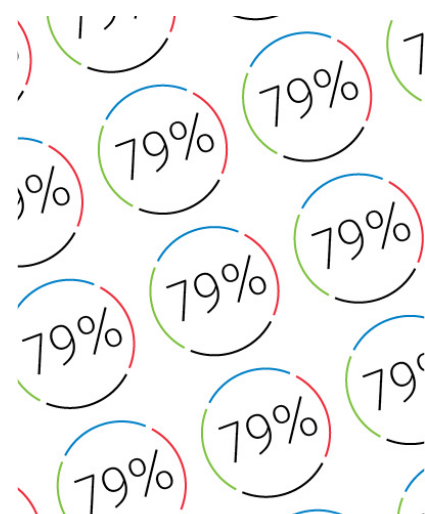
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