



## Vaccine R&D in Brazil: The effectiveness of push and pull regulations



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### ABSTRACT

Government regulations can guide the technological progress, investment in research and development (R&D), and institutional organization of a specific sector. In this context, using patent data, this study aimed to analyze the effectiveness of three laws that pertain to R&D in Brazilian pharmaceutical market for vaccines. The results reveal an increasing international interest in the Brazilian market since the promulgation of the Industrial Property Law. Despite its limitations, this study reveals significant efforts and promising results in Brazil with respect to ensuring that technological and industrial policies and strategies incorporate innovation in vaccine R&D and change the economy's competitive circumstances.

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### 1. Introduction

Government regulations can guide the technological progress, investment in research and development (R&D), and institutional organization of a specific sector [1]. In Brazil and worldwide, there is strong government intervention in the pharmaceutical sector that aims at balancing public-health spending and the sector's technological and industrial goals [2,3]. To analyze R&D in the Brazilian pharmaceutical market for vaccines, this study sought to evaluate by patent data the impact of three specific laws: the Industrial Property Law ('Lei de Propriedade Industrial' - LPI) No. 9279/1996 [4], the Technological Innovation Law ('Lei da Inovação

Tecnológica' - LIT) No. 10,973/2004 [5], and the Good Law ('Lei do Bem' - LDB) No. 11,196/2005 [6], which operate at different stages of the innovation chain. The LPI can be considered to be a pull mechanism that operates downstream and that aims to increase the attractiveness of the market for new companies through the management of intellectual property (IP) rights [7–9]. In contrast, the LIT and LDB are push mechanisms that operate upstream and attempt to decrease the cost of R&D through direct public funding, tax credits for R&D, and investment in research infrastructure [7–9].

Innovations in vaccines have not always been the target of the IP rights [10,11]. The negative outcomes caused by the inadequate control of production and processes have made these laws more stringent and significantly increased R&D costs. Therefore, to guarantee a return on the large investments, the granting of IP rights has been required [10]. Previously, in Brazil, many private laboratories ceased the production of serums and vaccines [12]. To solve the shortage crisis [11], the government encouraged domestic production by public institutions [12]. However, these institutions lacked sufficient technological expertise to produce complex immunobiologicals.

In addition, the 1990s were marked by increased efforts in the R&D sector to produce novel vaccines through the application of novel technologies so that foreign pharmaceutical companies could

*Abbreviations:* R&D, Research and Development; LPI, Industrial Property Law ('Lei de Propriedade Industrial'); LIT, Technological Innovation Law ('Lei da Inovação Tecnológica'); LDB, Good Law ('Lei do Bem'); IP, Intellectual Property; WIPO, World Intellectual Property Organization; WTO, World Trade Organization; TRIPS, Trade-Related Aspects of Intellectual Property Rights; IPC, International Patent Classification; PNI, National Immunization Program ('Programa Nacional de Imunizações'); INPI, Brazilian National Institute of Industrial Property ('Instituto Nacional de Propriedade Industrial').

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identify an entry point for promising new markets in this sector. Consequently, an activity that for many years relied on public, academic, and private institutions, which perform activities of a social nature, became the subject of large private investments [13]. During the same period, important regulatory changes in IP rights in the pharmaceutical area occurred in Brazil.

The transfer of the debates from the World Intellectual Property Organization (WIPO) to the World Trade Organization (WTO) stimulated the standardization and strengthening of IP rights [14]. The regulatory framework that was responsible for this change was the promulgation of Trade-related Aspects of Intellectual Property Rights (TRIPS) in 1995 [11], which a short time later culminated in the approval of the LPI in Brazil. This new legal framework in the pharmaceutical area aimed to promote technological development and capacity in Brazil to stimulate economic and social development. However, approximately 20 years after the LPI's promulgation, it is unclear whether this pull mechanism promotes national innovation and is indirectly responsible for Brazil's economic and technological growth [14–18] or whether IP policies are simply an attraction for the increase in the consumer market of foreign companies [19–22].

More recently, again with the aim of encouraging investment in R&D, the Brazilian government has provided legal instruments that encourage innovation activities that can generate solutions for the country's public health system [23,24]. The LIT was launched in 2004, followed by LDB in 2005. The LIT is a push mechanism organized around three axes [5]: (i) the creation of an environment that is conducive to the formation of strategic partnerships between universities, technological institutes, and private companies with the potential to share infrastructure, equipment, and human resources, (ii) the stimulation of the participation of science and technology institutes in the innovation process, and (iii) the encouragement of innovation in the private sector. The LDB grants tax incentives to companies that conduct R&D on technological innovation and uses this push mechanism to encourage private investment in innovation and to connect private companies with universities and research institutes [6]. There have been no studies on the impact of the LIT and LDB in promoting vaccine R&D.

In the global context of economic crisis, there is an increasing awareness among policy makers of the crucial role that vaccines can play in preventive medicine and their potential to obtain economic and public health benefits [25,26], particularly in developing countries in which many vaccine-preventable diseases are endemic [27,28]. In addition, the worldwide demand for vaccines has emphasized the need to increase the local capacity for vaccine R&D in emerging economies, such as Brazil [24], which is considered to be an innovative developing country [29].

Thus, using patent data, this study aimed to evaluate the impact of three Brazilian laws on vaccines innovation chain, i.e. the innovative strength of Brazil and the degree of autonomy in innovation production as well as the attractiveness of the Brazilian market for foreign companies active in the pharmaceutical market for vaccines. To the best of our knowledge, few empirical studies have recently evaluated the Brazilian pharmaceutical market from the IP perspective. Such studies primarily investigate Brazilian biodiversity [1,30,31] or focus on biotechnology patents [32,33] but do not specifically analyze vaccines. In addition, industrial incentive policies in Brazil achieve different results for similar industrial segments [1], which indicate the need for studies that consider the development of a specific industrial sector through changes in the process of renewal of national innovation policies [23,24] and in the process of adaptation to international harmonization agreements [11].

This paper is structured as follows. After this introduction, in Section 2, we examine the literature on three Brazilian innovation

policies. Section 3 describes our research method. In Section 4, we examine the results and discuss the relevant insights. Finally, in Section 5, our concluding remarks are put forward.

## 2. Literature review

This section presents a literature review on three Brazilian innovation policies and their objectives and limitations. This is accomplished in order to better interpret patent data.

### 2.1. Industrial property law (LPI)

None industrial sector excite stronger feelings than the pharmaceutical industry in regard to balance in the protection of intellectual property between the short-term interests in maximizing access and the long-term interests in promoting creativity and innovation [34]. Pharmaceutical patents have always been objects of divergence, but the discussions have significantly increased in last two decades. The displacement of the discussions in the field of IP of the World Intellectual Property Organization (WIPO) to the World Trade Organization (WTO) has pressed countries to standardize and strengthen IP rights [35] in order to remove obstacles to international trade. The TRIPS agreement established the minimum parameters for intellectual property protection of pharmaceutical products and processes to member states of the WTO [36].

According to the TRIPS agreement, the purpose of a patent system is to promote appropriate balance contributing to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of users and producers of technological knowledge and in a manner conducive to social and economic welfare and to a balance of rights and obligations [34]. Studies evaluating the effectiveness of the patent system in meeting these goals show contradictory results [37], especially when it refers to developing countries. Some studies suggest that the patent system feeds innovation and, indirectly, it is responsible for the economic growth of developing countries [18,35,38,39]. Others studies argue that IP policies only increase the attractiveness of specific market in developing countries and the income transfer for multinational companies [40–42] installed in these countries.

It was only in 1996 that Brazilian Congress approved the patent law, assuring patent protection of pharmaceutical products and processes (LPI, Law 9279/1996) [4]. Patent law reform fundamentally changed the knowledge appropriability regime since local pharmaceutical firms could replicate medicines until 1996 through reverse engineering process. Contested is whether patent laws have promoted indigenous technology innovation in developing countries as the Brazil. On the other hand, new regulatory arrangements can increase the attractiveness of the Brazilian market for foreign companies and thus LPI can be considered to be a pull mechanism to encourage innovation [7–9].

### 2.2. Technological innovation law (LTI)

In order to achieve technological autonomy and industrial development, the Brazilian congress has enacted an intellectual property-oriented technology law, Law 10,973, in 2004 [5]. This new policy framework named technology innovation law introduced provisions on incentives for innovation and scientific and technological research in the production environment. Among other things, this piece of legislation attempts to facilitate the public-private R&D cooperation, with engagement of Brazilian public research institutes and private-sector enterprises.

Aside from tax incentives to provide public-private cooperation, important aspects of this law are the creation of science and

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