The Evolution of Mexico's Pharmaceutical Sector: Legal Reforms, Trade Liberalization and Global Integration (1876-2020)

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Abstract: This article explores the legal and institutional transformation of the Mexican pharmaceutical sector, focusing on the period following Mexico's entrance into the General Agreement on Tariffs and Trade (GATT) in 1986. The shift from protectionist policies to economic liberalization reshaped the regulatory and competitive landscape of the industry. Key legislative reforms, including the 1991 Industrial Property Law, the 1984 General Health Law, and the 1993 Foreign Investment Law, aligned the sector with global trade standards, thus affecting intellectual property, foreign investment, and pharmaceutical production. This article also examines the impact of international agreements like TRIPS, NAFTA, and USMCA. These legal and trade reforms fostered opportunities for multinational corporations, but also created challenges for domestic firms, particularly regarding intellectual property and growing reliance on generic drugs. This research article evaluates how these changes have affected competitiveness in the sector, innovation, and access to medicine, shedding light on the evolving dynamics of Mexico's pharmaceutical industry in a globalized context.
Keywords: Mexican pharmaceutical industry; legal and regulatory frameworks; late 20th century and early 21st Century.

Resumen: Este artículo explora la transformación legal e institucional del sector farmacéutico mexicano, enfocándose en el periodo posterior a la integración de México al Acuerdo General sobre Aranceles Aduaneros y Comercio (GATT) en 1986.

El cambio de políticas proteccionistas a la liberalización económica reconfiguró el panorama regulatorio y competitivo de la industria. Reformas legislativas clave, como la Ley de Propiedad Industrial de 1991, la Ley General de Salud de 1984 y la Ley de Inversión Extranjera de 1993, alinearon al sector con los estándares comerciales globales, afectando la propiedad intelectual, la inversión extranjera y la producción farmacéutica. El estudio también analiza el impacto de acuerdos internacionales como el TRIPS, el TLCAN y el T-MEC. Estas reformas legales y comerciales favorecieron a las corporaciones multinacionales, pero generaron desafíos para las empresas nacionales, especialmente en lo relacionado con la propiedad intelectual y la creciente dependencia de medicamentos genéricos. La investigación evalúa cómo estos cambios afectaron la competitividad, la innovación y el acceso a medicamentos en el contexto globalizado de México.
Palabras clave: industria farmacéutica mexicana; marcos legales y regulatorios; finales del siglo XX y principios del siglo XXI.

I. Introduction

The Mexican pharmaceutical sector has undergone a significant institutional and legal evolution, revealing the complex interplay between national development objectives and pressures of global economic integration. From its early foundations in the 19th century to the structural reforms of the late 20th century, the Mexican pharmaceutical industry has undergone profound transformations driven by changes in political priorities, regulatory frameworks, and international economic trends. Mexico's entry into the General Agreement on Tariffs and Trade (GATT) in 1986 marked a decisive turning point, reshaping the regulatory landscape and the commercial dynamics of the sector, which had previously been characterized by a protectionist approach toward domestic companies aimed at reducing reliance on foreign entities. However, the economic liberalization imposed by this agreement and subsequent trade opening led the country to substantially modify its legislation on intellectual property protection, foreign investment, and pharmaceutical production.

Throughout this process, key reforms were implemented, such as the 1991 Industrial Property Law, the 1984 General Health Law, and the 1993 Foreign Investment Law, which redefined trade relationships and sector competitiveness. These laws, along with international treaties like TRIPS, NAFTA, and USMCA, created a regulatory environment aligned with global standards, but also posed challenges for national actors, who were displaced by large multinational corporations. In a globalized context, foreign companies increased their participation in the Mexican market while national companies faced barriers

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such as intellectual property in the hands of a few and a growing reliance on generic medicines.

This article aims to analyze the legal and trade restructuring processes of the Mexican pharmaceutical sector, focusing on the implications of legislative reforms and international agreements on the growth of this industry. Through a detailed examination of the effects on industrial property, foreign investment, and health regulation, the goal of this article is to understand how these changes have reshaped competitiveness, innovation, and access to medicine in the globalized context. Additionally, this analysis explores how legal reforms, driven by international pressures, have transformed the sector's landscape, presenting new challenges and opportunities for both national companies and multinational corporations operating in Mexico.

II. Institutional and Legal Evolution of the Pharmaceutical Sector in Mexico

1. Evolution and Regulatory Foundations of the Mexican Pharmaceutical Industry

The emergence of the Mexican pharmaceutical industry dates back to the late 19th and early 20th centuries, with notable scientific and research activities taking place during the Porfiriato period (1876-1911).[1] Despite this initial development, a fully-fledged national industry did not come into being until after the Mexican Revolution, when European and US pharmaceutical companies identified opportunities in Mexico and invested in the production and sale of medications.[2]

Significant imports and sales of medications from abroad prompted the Mexican government to regulate the industry. In 1926, the Sanitary Code was issued, followed by the implementation of the Medication Registry in 1927. This regulatory framework categorized medicine dispensaries into pharmacies, drugstores, and similar establishments, regulating the production and sale of pharmaceutical products in the country.[3] However, between 1917 and 1940, the government did not implement short-term or long-term policies to encourage the development of the pharmaceutical industry.[4]

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[1] This term refers to the period of government of President Porfirio Díaz.

[2] Rogelio Godínez Reséndiz & Patricia Aceves Pastrana, *El Surgimiento de la Industria farmacéutica en México*, 45 Rev Mex. Cienc. Farm. 55, 55-68 (2014)

[3] Rogelio Godínez Reséndiz & Patricia Aceves Pastrana, *La Regulación del Medicamento Industrial en México*, 43 Rev. Mex. Cienc. Farm. 49, 49-57 (2012). (In response to rising drug imports, Mexico established pharmaceutical regulations in the 1920s, including the 1926 Sanitary Code and 1927 Medication Registry.)

[4] Godínez Reséndiz & Aceves Pastrana, *El Surgimiento de la Industria Farmacéutica en México*, *supra* note 2, at 55–68.

Before World War II, only finished medication was imported.[5] Between 1945 and 1960, 35 foreign-dependent laboratories and 130 small domestic laboratories were established, manufacturing medications internally with raw materials from abroad. The production of domestic raw materials also started at this time. From 1960 to 1978, the number of laboratories increased to 860, with 70 belonging to international corporations, 10 of national origin, and 780 small laboratories.[6]

In 1977, Soria[7] highlighted Mexico's heavy reliance on foreign capital, with 208 subsidiaries and affiliates in the pharmaceutical industry, which represented 87.1 percent of foreign investment. However, between 1978 and 1987, the number of establishments dropped to 380 laboratories, with 320 manufacturing finished pharmaceutical products and 60 producing chemical-pharmaceutical products. During this period, 76 drew on foreign capital and 304, on national capital.[8]

By 1987, the production of new chemical compounds to be used as raw materials increased, replacing several of the imported ones. This shift contributed to stabilizing the trade balance, considering that in 1982 approximately 80 percent of inputs were imported. By 1985, national production reached 45 percent, reducing imports by 25 percent.[9]

The domestic pharmaceutical industry's dependence on international providers was unmistakable in 1983 when there was a shortage of medications caused by global economic events, which included external imbalances in influential countries, issues related to the Uruguay Round of the GATT, the acceleration of European integration, and the rise of the market economy in Central and Eastern European countries.[10]

In response to the economic crises of the early 1980s, triggered by Mexico's declaration of its inability to repay its debt in 1982, the government sought to strengthen the domestic pharmaceutical sector through various public poli-

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[5] Mario Lieberman Litmanowitz, *Estado Actual de La Industria Farmacéutica En México: Avances y Problemas*, v.29, n.3 Salud Pública de México 249 (1987), http://saludpublica.mx/index.php/spm/article/view/285

[6] Lieberman Litmanowitz, *Estado Actual de la Industria Farmacéutica en México*, *supra* note 5. (Lieberman mentions the growth of the pharmaceutical industry in Mexico between 1945 and 1978, highlighting the increased number of laboratories and the beginning of domestic raw material production.)

[7] Víctor M. Soria, *Estructura y comportamiento de la industria farmacéutica en México. El papel de las empresas transnacionales*, 02 Revista de Ciencias Sociales y Humanidades 111, 111-141 (1980), https://revistaiztapalapa.izt.uam.mx/index.php/izt/article/view/650/799

[8] Lieberman Litmanowitz, *Estado Actual de la Industria Farmacéutica en México*, *supra* note 5 at 250.

[9] Lieberman Litmanowitz, *Estado Actual de la Industria Farmacéutica en México*, *supra* note 5 at 250. (Mexico's shift toward self-sufficiency in pharmaceutical raw materials in the 1980s.)

[10] José M. Pérez de Villarreal, *La Economía Mundial en los Años Ochenta y la Política Económica de los Noventa*, No. 20 ekonomiaz 215, 215 (1991).

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cies aimed at addressing the limited national supply of medications.[11] However, government support for the industry underwent a radical change halfway through the 1982-1988 presidential period, as it grappled with international austerity measures proposed to reverse the effects of the economic crisis.

According to Dussel,[12] the pharmaceutical industry in Mexico exhibited the following characteristics in the last quarter of the 20th century:

- The country produced most medications, with annual domestic and international sales ranging between 700 million and 1.5 billion US dollars.
- There were approximately 300 pharmaceutical laboratories, 75 of which were foreign, dedicated principally to making products primarily for the private market (individual purchases).
- Research and development (R&D) to identify new molecules or create new technology was limited. The national industry and public research centers focused on improving processes or studying the industry, respectively.
- The State largely controlled drug prices, and its policies influenced the sector. Noteworthy measures included granting patents for processes rather than chemical substances, restricting imports of pharma chemicals produced or created domestically, limiting foreign direct investment participation to 49 percent, and requiring participation in public tenders to win bids to supply the public sector. Additionally, the State played a crucial role in creating, fostering, and strengthening the national pharmaceutical industry.

2. Legal and Programmatic Foundations Shaping the Mexican Pharmaceutical Industry: An In-Depth Overview

In order to better understand the state of the Mexican pharmaceutical sector, we need to conduct a critical examination of the laws and programs that define the contextual landscape. Building on Brodovsky's proposals,[13] this analysis encompasses watershed legislation and initiatives, such as the Law of the Transfer of Technology and the Use and Exploitation of Patents and Trademarks (1972), the Foreign Investment Law (1973), the General Health Law (1984), and the Comprehensive Pharmaceutical Industry Development Program (1984). And we will add additional elements below in order to provide a nuanced perspective.

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[11] Lieberman Litmanowitz, *Estado Actual de la Industria Farmacéutica en México*, *supra* note 5 at 250. (In the 1980s, Mexico used public policies to boost its pharmaceutical sector in response to an economic crisis.)

[12] Enrique Dussel Peters, Las industrias farmacéuticas y farmoquímica en México y el Distrito Federal 3-31 (Economic Commission for Latin America and the Caribbean, 1999).

[13] Joan Brodovsky, *La Industria Farmacéutica y Farmacoquímica Mexicana en el Marco Regulatorio de los Años 90*, cepal/ciid 3 (1995), https://repositorio.cepal.org/server/api/core/bitstreams/28e3c8c2-1053-4494-b9cd-4bb31c17b2ce/content

The Law of the Transfer of Technology and the Use and Exploitation of Patents and Trademarks[14] gave the State the ability to scrutinize contracts and licenses, as well as the authority to refuse them if the conditions were unfavorable for the country. This law fueled the development of the national industry, fostering the inclusion of endogenous knowledge and blocking the entry of certain technologies by establishing higher costs or convoluted bureaucratic registration procedures. However, in the 1970s, patent protection in sectors like the pharmaceutical one was eliminated, leaving only process-related patents.

The Law to Promote Mexican Investment and to Regulate Foreign Investment governed foreign capital participation in domestic enterprises. Noteworthy points of this law include the explicit statement that foreigners acquiring any type of property in Mexico are considered nationals in view of those assets.[15] It also stipulated that foreign investment may not exceed forty-nine percent, as a way to prevent the company from being dominated by foreign control[16]Nevertheless, with this law the National Foreign Investment Commission could adjust the investment percentage based on benefits and in the best interests of the national economy, under the stipulated conditions and reservations.

The General Health Law[17] helped boost the production of medications needed to meet the 1984 public health demand. It established a Basic Inventory of Health Sector Inputs to ensure a stable supply of medicine and essential health supplies for the general population. Additionally, it set the foundations for selling quality medication at fair prices.

Miguel de la Madrid's government policy to encourage growth in the pharmaceutical industry was laid out in the National Development Plan (NDP)[18] through programs like the National Program for Industrial Development and Foreign Trade [PRONAFICE] (1982-1988), the National Program for Technological and Scientific Development [PNDTC] (1982-1988), and the Comprehensive Program for the Development of the Pharmaceutical Industry [PIDIF] (1984-1988).

Important events took place between 1982 and 1988, including the 1982 economic crisis that led to the international debt moratorium and paved the way for the liberalization of the national economy. Consequently, there was a

[14] H. Congreso de la Unión de los Estados Unidos Mexicanos, *Ley sobre el Registro de Transferencia de Tecnología y el Uso y Explotación de Patentes y Marcas* [Law of Transfer of Technology and the Use ad Exploitation of Patents and Trademarks], Diario Oficial de la Federación, Dec. 30, 1972 (Mex.).

[15] H. Congreso de la Unión de los Estados Unidos Mexicanos, *Ley para Promover la Inversión Mexicana y Regular la Inversión Extranjera* [Law to Promote Mexican Investment and to Regulate Foreign Investment], art. 3, Diario Oficial de la Federación, Mar. 9, 1973 (Mex.).

[16] *Ley para Promover la Inversión Mexicana*, *supra* note 15, art. 5.

[17] *Ley para Promover la Inversión Mexicana*, *supra* note 15, art. 5.

[18] Miguel de la Madrid Hurtado, *Plan Nacional de Desarrollo 1983-1988*, Poder Ejecutivo, 8–92 (1983).

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shortage of medicine and intermediate products, prompting emergency plans to address these issues.[19]

The NDP was concerned about a technological dependency in the production, distribution, and quality control of pharmaceutical products required and consumed in the country. It aimed to strengthen national industry through various programs that promoted development, fortified strategic industries, and met the national demand, with an eye on potential exports after joining the GATT.[20] [21]

PRONAFICE created a technological base and a social, efficient, and competitive State-owned industry. The program strategy gave priority to areas with high final demand, abundant national resources, and the potential to create a demand for capital goods produced domestically and efficiently.[22] According to the presidential report at the time,[23] the program supported measures for tax and financial incentives, increased investment and employment, promoted exports, encouraged small and medium-sized industries, and stimulated industrial decentralization. Companies received technical assistance, tax incentives, and financial resources.

The PNDTC[24] steered the national production apparatus towards prioritized technological areas, including the pharmaceutical sector. It aimed to regulate the flow of imported technology, enhance negotiation capabilities, assimilate and adapt technology-importing companies, increase postgraduate human resource formation, and boost investment in science and technology.

Stemming from the National Development Plan 1983-1988, the Decree for the Promotion and Regulation of the Pharmaceutical Industry was established to meet the needs of the country's industry. Some strategies included a revolving fund managed by Nacional Financiera and other government institutions, as well as purchasing medicine from national pharmaceutical industries, contingent on timely delivery at pre-agreed prices and quality.[25]

At the time, Mexico underwent a critical economic-structural adjustment due to the country's debt from the 1970s and its inability to pay it back in the

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[19] Lieberman Litmanowitz, *Estado Actual de la Industria Farmacéutica en México*, *supra* note 5 at 250. (Between 1982 and 1988, an economic crisis led to a debt moratorium and economic liberalization, causing shortages that required emergency measures.)

[20] *Plan Nacional de Desarrollo 1983-1988*, *supra* note 18, at 88.

[21] Lieberman Litmanowitz, *Estado Actual de la Industria Farmacéutica en México*, *supra* note 5 at 250-251.

[22] *Plan Nacional de Desarrollo 1983-1988*, *supra* note 18, at 90.

[23] Miguel de la Madrid Hurtado, *Informe de Gobierno del Presidente Constitucional de los Estados Unidos Mexicanos*, Diario Oficial de la Federación, 198 (1985).

[24] Miguel de la Madrid Hurtado, *Programa Nacional de Desarrollo Tecnológico y Científico 1984–1988*, Diario Oficial de la Federación, 338–47 (1984).

[25] H. Congreso de la Unión de los Estados Unidos Mexicanos, *Decreto para el Fomento y la Regulación de la Industria Farmacéutica*, Tomo CCCLXXII, No. 39, Diario Oficial de la Federación, Feb. 23, 1984, at 8–14 (Mex.).

1980s because of trade imbalances between industrialized countries.[26] This made it difficult to import the necessary inputs for pharmaceutical manufacturing. Therefore, measures to promote the pharmaceutical industry focused on manufacturing strategic pharmaceutical raw materials (such as beta-lactam antibiotics, fermentation derivatives, and synthetic products) essential for producing the medicines in short supply in the country. The State instituted programs that prioritized companies founded with national capital. However, if these companies lacked the necessary conditions for production, foreign-capital companies would benefit at a secondary level.

As part of the same Decree for the Promotion and Regulation of the Pharmaceutical Industry, the Agreement establishing the Comprehensive Program for the Development of the Pharmaceutical Industry (PIDIF) was published with the following objectives:[27]

- Contribute to national health protection by producing affordable and quality medicines essential for the country's population.
- Plan and propose strategies in the pharmaceutical market to manufacture what society demands.
- Assist the national industry in achieving economic and technological independence from abroad (import substitution).
- Strengthen local pharmaceutical production for national consumption and export.

It should be noted that on May 9, 1990, the presidential decree signed by Carlos Salinas de Gortari abrogating the Decree for the Promotion and Regulation of the Pharmaceutical Industry was published in the Official Gazette.[28] As observed, this institutional framework, originally geared towards promoting domestic production chains in the country, then shifted towards adopting a free market approach with the country's entry into the GATT and later with the North American Free Trade Agreement (NAFTA).

III. Legal and Trade Restructuring of the Mexican Pharmaceutical Sector in the Context of Globalization

In 1986, Mexico entered the fold of the General Agreement on Tariffs and Trade (GATT), a pivotal move that significantly altered the regulatory land-

[26] Pérez de Villarreal, *supra* note 10, at 203-204.

[27] H. Congreso de la Unión de los Estados Unidos Mexicanos, *Decreto para el Fomento y la Regulación de la Industria Farmacéutica*, Tomo CCCLXXII, No. 39, Diario Oficial de la Federación, Feb. 23, 1984, at 13 (Mex.).

[28] H. Congreso de la Unión de los Estados Unidos Mexicanos, *Decreto por el que se extingue la Comisión Intersecretarial de la Industria Farmacéutica*, Diario Oficial de la Federación, Transitorios, art. segundo, May 9, 1990, http://dof.gob.mx/nota_detalle.php?codigo=4654748&fecha=09/05/1990&print=true

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scape governing the pharmaceutical industry. Prior to this, regulations were characterized by the logic of State protectionism for domestic companies, with President Miguel de la Madrid actively seeking to reduce reliance on foreign entities in the pharmaceutical sector, as seen in both the National Development Plan (1983-1988) and the Comprehensive Program for the Development of the Pharmaceutical Industry (1984).

National objectives included not only strengthening the domestic pharmaceutical industry, but also made a concerted effort to foster research and development in the country. However, these goals faced considerable challenges in the wake of Mexico's GATT-acquired trade commitments. As Brodovsky pointed out, "Mexico was forced to reduce its tariffs and eliminate the requirement of prior import permits for virtually all imported products."[29] This shift had a dual impact – while the pharmaceutical chemical industry struggled to compete with external prices due to market opening, it also benefitted from importing raw materials at lower costs, thereby reducing production expenses.[30] The negotiations and commitments Mexico undertook as a GATT member played a pivotal role in shaping a new economic, political, and legal structure within the country while laying the foundations for future trade agreements.

As the narrative unfolds, focusing on the restructuring period of the 1980s and 1990s, key laws proposed by Brodovsky come into sharp focus. In her view, these laws had a profound impact on the pharmaceutical industry during this transformative period, including the 1991 Industrial Property Law [LPI], the 1984 General Health Law, and the 1993 Foreign Investment Law [LIE]. These domestic regulations, alongside significant international agreements such as TRIPS and NAFTA, played a crucial role. The USMCA, signed in 2018, further reshaped the legal and trade landscape, making these legal frameworks central to the ongoing development and analysis presented in this study.

1. The Impact of Legal Frameworks on the Pharmaceutical Landscape

The 1991 Industrial Property Law [LPI] played a decisive role in shaping the dynamics of industrial property rights and trade-related matters in Mexico. This legislation marked a significant turning point by establishing the Mexican Institute of Industrial Property (IMPI) and introducing crucial amendments to the application process, particularly in the realms of trademarks and patents. Noteworthy changes included the extension of the validity period from five to

[29] To provide clarity and maintain linguistic integrity, certain quotations originally in Spanish have been translated into English in the main text. The original Spanish versions are provided in the footnotes for reference purposes

Original Spanish version: "México se vio obligado a reducir sus aranceles y eliminar el requisito de permisos previos de importación para prácticamente todos los productos importados". Brodovsky, *supra note 13, at 5*.

[30] Brodovsky, *supra* note 13, at 5-6.

ten years for trademarks, with an option for renewal, and from ten to twenty years for patents. These modifications, as well as those to licenses, rights transmission, and sanctions, were influenced by international pressures from economically influential nations seeking to fortify commercial expansion, safeguard investments, and maintain control over innovations in the context of heightened trade openness.

The Industrial Property Law grants patent owners the exclusive right to exploit their inventions, creating a temporary monopoly that empowers patent holders to take actions like setting prices. In the pharmaceutical sector, the implications of the 1994 amendments have led to notable disparities between entities that benefited from these changes[31] and those actively engaged in extensive research in the pharmaceutical field. Foreign companies holding or having held pharmaceutical patents possess the means to license or litigate against both national and foreign entities, leveraging their advantageous position in terms of technological, research, and development capabilities. This, in turn, allows them to swiftly increase the number of patent registrations.

The creation of new pharmaceutical patents inherently requires substantial investments in R&D. It should be highlighted that Mexico allocates a mere 0.27 % of its Gross Domestic Product (GDP) to R&D, a significantly lower percentage than countries like the United States, Germany, and Denmark, where it exceeds 2 % across all fields of knowledge, including the pharmaceutical sector.[32] External organizations, such as the Mexican Association of Pharmaceutical Research Industries (AMIIF), play a crucial role in conducting research in the sector.

Finally, there was an important legislative development in 2003, when Article 47b of the Industrial Property Law Regulation was modified in order to require the publication of pharmaceutical patents in a public gazette. This measure aimed to "control the entry of medicines that did not comply with intellectual property requirements."[33] Simultaneously, a reform to Article 167B of the Health Inputs Regulation was enacted on the same date, which further contributed to a comprehensive regulatory framework for pharmaceutical-related issues.

In 1991, a major shift in health legislation took place with the amendment of the 1984 General Health Law, which expanded the role of the health sector in science and technology to protect citizen health. This amendment, specifically to Article 2, introduced scientific and technological research as integral components of the right to health protection. Mexico's inclusion of detailed defini-

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[31] H. Congreso de la Unión de los Estados Unidos Mexicanos, *Ley de Propiedad Industrial* [Industrial Property Law], *Diario Oficial de la Federación* Jun. 3, 1991 (Mex.).

[32] Banco Mundial, *Gasto en investigación y desarrollo (% del PIB)* (2025), https://datos.bancomundial.org/indicador/GB.XPD.RSDV.GD.ZS

[33] Original Spanish version: "Controlar la entrada de medicamentos que no cumplieran con los requisitos de propiedad intelectual." In Jacqueline Arzoz Padrés, *Situación del sector farmacéutico en México*, CENTRO DE ESTUDIOS SOCIALES Y DE OPINIÓN PÚBLICA, 69 (2010).

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tions for medication, drugs, raw materials, additives, and materials, along with the classification of medication based on their preparation and nature, gave legal certainty to the production, distribution, and marketing of pharmaceuticals and bio-pharmaceuticals both nationally and internationally.

Another noteworthy amendment to the General Health Law took place on February 24, 2004. Addressing the issue of a five-year validity of sanitary registration,[34] this reform aimed at ensuring the safety and efficacy of medication. Concurrently, the 2008 elimination of the "plant requirement" for the commercialization and importing of foreign medicines in Mexico stoked policy debates. This significant change, formalized through a Decree amending Articles 168 and 170 of the Health Inputs Regulation, removed the need for a license, certificate, or document granting permission to manufacture medications in the home country. Additionally, the requirement for a legal representative residing in the country,[35] product storage facilities, and the need for quality control and bioequivalence tests were eliminated.[36]

Arguments both for and against surfaced in response to this legislative change. Proponents, primarily institutional, argued that removing the plant requirement would broaden access to generic and patented medicines, fostering competition in the domestic market.[37] This, they contended, would benefit consumers in terms of both price and quality. Notable suppliers from countries like the United States, Germany, France, and Switzerland were expected to benefit from fewer marketing limitations.[38]

On the other side, concerns were raised about less control and surveillance over the quality of external medications. One 2007 proposal to eliminate the plant requirement was countered with arguments intimating that this move might negatively impact investment and jobs in the country.[39] Despite these op-

[34] Jacqueline Arzoz Padrés, *Situación del sector farmacéutico en México*, CENTRO DE ESTUDIOS SOCIALES Y DE OPINIÓN PÚBLICA, 69 (2010).

[35] Misión de México ante la UE, *Lazos Comerciales*, Año 6, No. 8 OFICINA DE REPRESENTACIÓN DE LA SECRETARIA DE ECONOMÍA CENTRO DE ESTUDIOS SOCIALES Y DE OPINIÓN PUBLICA 1–2, (2008).

[36] Antonio Javier Severino, *Lineamientos para una unidad tercero-autorizada de registros sanitarios*, FACULTAD DE ESTUDIOS SUPERIORES ZARAGOZA, 8 (2013).

[37] María de la Luz Lara Méndez et al., *Historia de la regulación farmacéutica*, Año 3, No. 11, REV. COFEPRIS PROTECCIÓN Y SALUD (2018).

[38] Misión de México ante la UE, *Lazos Comerciales*, *supra* note 35, at 2.

[39] One of the opposing views was presented during a plenary session of the Permanent Commission on May 30, 2007, when Senator Gabino Cué Monteagudo submitted a proposed Point of Agreement on the procedure for reforms to the Health Inputs Regulation. With the intention of eliminating the plant requirement, the Senator argued that allowing entry and removing restrictions would reduce control and surveillance over the quality of imported medications. Furthermore, he stated that the plant requirement had increased investment and employment in the country. This matter was duly addressed, and the Presiding Officer instructed the removal of the issue from the records, considering it concluded and informing the proponent of this decision accordingly.

posing viewpoints, the removal of the plant requirement led to the closure of some pharmaceutical plants in Mexico.[40] [41]

The consequences were multifaceted. Some pharmaceutical corporations, like Merck and Roche, initiated plant closures and restructuring plans, which led to substantial job losses.[42] [43] Simultaneously, national consumers faced challenges as medication prices increased, leaving Mexico with the highest average medication prices among OECD member countries in 2009.[44] Notably, the public sector's limited participation in medication-related spending –accounting for only 15%– raised concerns, especially when compared to the OECD average public sector spending of 60%.[45]

The elimination of the plant requirement favored foreign corporations as it allowed them to become distributors, reduce operational costs, and source inputs globally, leaving smaller local suppliers at a disadvantage. Gradually, these health law reforms significantly transformed the pharmaceutical industry in Mexico, resulting in the dominance of transnational pharmaceutical corporations in the national market[46] with key players like Pfizer, Bayer, Merck, and GlaxoSmithKline.

In the late 1990s, Mexico's pharmaceutical industry was a substantial market, boasting an annual revenue of approximately 3.5 billion dollars and 1.8 billion units, as well as a diverse sector distribution. The private sector dominated 80% of the market with brand-name medications, followed by the secondary sector (5% with generic brand medications), and the government sector (15% with essential or generic medications).[47] Foreign Direct Investment (FDI) from 1994 to 1998 averaged 1.75% of total FDI, with notable investments from Bayer, Schering Plough, and Promeco-Boerhinger Ingelheim.[48]

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[40] Senado de la República, *Gaceta: LX/1SPR-23/12990*, Gaceta del Senado (June 27, 2007), https://www.senado.gob.mx/64/gaceta_del_senado/documento/12990.

[41] Arturo Fuentes Ramírez, *Situación del sector farmacéutico en México*, Centro De Estudios Sociales Y De Opinion Publica, 100 (2010).

[42] *Farmacéutica Merck cierra dos plantas en México*, El Economista (July 8, 2010), https://www.eleconomista.com.mx/empresas/Farmaceutica-Merck-cierra-dos-plantas-en-Mexico--20100708-0034.html.

[43] Eulalio Victoria, *Roche cierra planta en Estado de México*, El Financiero (Nov. 11, 2016). https://www.elfinanciero.com.mx/empresas/roche-cierra-planta-en-estado-de-mexico

[44] Victoria, *supra* note 42.

[45] Organisation for Economic Co-operation and Development (OECD), Manual de estadísticas de patentes de la OCDE, (Oficina Española de Patentes y Marcas, 2009).

[46] Rafael Pérez Miranda, Tratado de derecho de la propiedad industrial: patentes, marcas, denominación de origen, obtentores de vegetales, informática: un enfoque de derecho económico, 429 (Editorial Porrúa, Quinta edición) (2011)

[47] Pérez Miranda, *supra* note 46, at 54-55. (The author discusses the structure and economic weight of Mexico's pharmaceutical industry in the late 1990s.)

[48] Pérez Miranda, *supra* note 46, at 54-55.

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By 2004, the pharmaceutical industry had expanded significantly, with 480 raw material production companies employing 62,000 people.[49] Representing 0.2% of the total manufacturing companies and 1.5% of the employed workforce, the industry contributed 1.2% to the annual GDP. Some of the most notable market leaders were Pfizer, Sanofi-Aventis, and Schering Plough, with Pfizer claiming an 8% market share.[50]

The period from 2007 to 2013 witnessed a steady growth in sales value for companies producing medicines for human use, as seen in a 25.6% increase.[51] The industry also generated additional employment, creating 10,757 jobs to total 86,783 jobs in 2013. Despite this growth, the import-export gap widened, reaching 5.59 billion dollars in imports against 1.14 billion dollars in exports by 2014.[52]

In that same year, Mexico had 718 economic units engaged in pharmaceutical production, ranking third nationally in gross value added.[53] National production in 2014 reached 11.43 billion dollars, marking an Average Annual Growth Rate (AAGR) of 5.2% from 2015 to 2020.[54] Mexico became the second-largest market in Latin America in 2015, standing at 0.5% of the national GDP.[55]

Production concentrated mainly in Mexico City, the State of Mexico, and Jalisco, with 75.2% allocated to meet family and export demands.[56] Antibiotics constituted a significant share of national products, accounting for 14.8% of the value and 22.3% in volume.[57] Mexico stands out for its low production costs, which rank among the lowest in the world, after China and India.[58] Despite this, the pharmaceutical sector faced challenges such as a growing trade deficit and companies built on national capital focusing on generic drug manufacturing. Regulated since 1998, generic production plays a crucial role in addressing the high costs of treating chronic-degenerative diseases.[59]

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[49] Sandra Torres Guerra & Juan Pablo Gutiérrez, *Mercado farmacéutico en México: tamaño, valor y concentración*, 26(1) Rev. Panam. Salud Pública, 47–48 (2009).

[50] Torres Guerra & Gutiérrez, *supra* note 49.

[51] Cámara Nacional de la Industria Farmacéutica (CANIFARMA), *Datos económicos, (2025).*

[52] Cámara Nacional de la Industria Farmacéutica (CANIFARMA), *supra* note 51.

[53] Instituto Nacional de Estadística y Geografía, Estadísticas a propósito de la Industria farmacéutica (2016).

[54] Instituto Nacional de Estadística y Geografía, *supra* note 53; Unidad de Inteligencia PROMÉXICO, *Diagnóstico sectorial farmacéutico*, Secretaría de Economía, 4 (2015).

[55] Ingrid Chávez et al., *El Mercado de medicamentos en México: retos y oportunidades*, Instituto Mexicano para la Competitividad A.C., 9, 1-37 (2021).

[56] Instituto Nacional de Estadística y Geografía (INEGI), *supra* note 53, at 11–15.

[57] Instituto Nacional de Estadística y Geografía (INEGI), *supra* note 53, at 11–15.

[58] KPMG, La industria farmacéutica mexicana: industria farmacéutica y de dispositivos médicos, 11 (2018).

[59] René Leyva et al., *Hacia una política farmacéutica integral para México*, 48 Salud Pública De México 104 (2006); Instituto Nacional de Estadística y Geografía (INEGI), *Banco de Información*

By 2017, the industry experienced a reduction in the number of establishments, with 103,013 engaged in producing raw materials and 90 in preparations.[60] The industry's contribution to the GDP increased modestly from 32.36 billion pesos in 2003 to 47.99 billion in 2018, indicating a growth of only 2.3%.[61] This nuanced evolution underscores the complex dynamics and challenges faced by Mexico's pharmaceutical industry at the time.

With regard to the broader context in 1993, this was a decisive year for the transformation of the Mexican pharmaceutical sector in terms of foreign investment. In that year, the Mexican Congress approved a key reform to the Foreign Investment Law [Ley de Inversión Extranjera] (LIE),[62] replacing the 1973 version. This reform included significant changes, such as the modification of Article III of Chapter I, which granted "immigrant" status to foreign investments and favored the resolution of disputes through international agreements, rather than relying solely on national laws. Additionally, Article VII imposed a 49% capital participation limit, with exceptions for certain sectors. It is important to note that the pharmaceutical industry was not included among the exempted sectors, opening the possibility of exceeding this limit.

This alteration in the Foreign Investment Law hinted at a potential increase in foreign capital participation in the pharmaceutical sector, given its non-strategic classification and absence from the list of activities exclusively reserved for the State. This, coupled with the lack of specific regulations and restrictions on the amount of foreign participation, created a favorable environment for international involvement in the pharmaceutical industry.

An assessment of the FDI in Mexico's pharmaceutical scene revealed a diverse range of activities, including raw material production, pharmaceutical preparations, and various ancillary services. Notably, companies engaged in wholesale trade, pharmaceutical product manufacturing, and the wholesale trade of chemicals for the pharmaceutical industry played prominent roles in these categories. The PROMEXICO Business Intelligence Unit[63] pointed out the dominant investors in Mexico's pharmaceutical sector between 2005 and 2015, with the United States leading at 40%, followed by Luxembourg (11%), and Ireland (10%). Major transnational corporations, including Merck, Boehringer Ingelheim, Schering Plough, Bayer, AstraZeneca, Pfizer, and GlaxoSmithKline, employed a substantial workforce of approximately 58,749 people.

Económica (BIE) (2019), available at https://www.inegi.org.mx/app/indicadores/?tm=0&t=1040#tabMCcollapse-Indicadores.

60 Subsecretaría de Competitividad de la Dirección General de Inversión Extranjera, *Inversión Extranjera de Sociedades Mexicanas*, Secretaría de Economía (2019), available at http://www.datos.economia.gob.mx/InversionExtranjeraSociedadesmexicanas.xls.

61 Subsecretaría de Competitividad de la Dirección General de Inversión Extranjera, *supra* note 60.

62 Ley de Inversión Extranjera, 1993, https://www.diputados.gob.mx/LeyesBiblio/ref/lie/LIE_orig_27dic93_ima.pdf

63 Unidad de Inteligencia PROMÉXICO, *supra* note 54, at 5.

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2017 reports projected substantial investments of around forty billion pesos by Merck, Bayer, Pfizer, Roche, Novartis, and Takeda, among others, earmarked for plant expansions, equipment acquisition, and personnel training.[64] The evolving dynamics of foreign investment in Mexico's pharmaceutical industry underscore its adaptability to changing regulations and international economic trends. This, in turn, shapes the sector's growth, technological advancements, and its position in the global pharmaceutical scene.

2. Legal Frameworks and Implications: Navigating International Agreements Applicable to the Pharmaceutical Industry in Mexico

The abovementioned legislative measures and their subsequent reforms have played a pivotal role in establishing the essential requirements for the negotiation and implementation of agreements like TRIPS, NAFTA, and USMCA in Mexico. Although these agreements are grounded in the principle of equal treatment, which implies parity among signatory nations, in practice, their application results in substantial inequality. This is because, in many cases, international treaties grant foreign corporations certain privileges that are not equally applied to national entities, potentially affecting the competitiveness and conditions of local businesses.

In the event of a legal dispute between a foreign corporation and a national entity, or between a company and the State, it will be necessary to resort to a separate tribunal, as stipulated in international agreements and treaties. This dispute resolution process is generally carried out through international tribunals, such as the International Centre for Settlement of Investment Disputes (ICSID), or via arbitration clauses included in treaties like NAFTA and USMCA. In this context, international tribunals have the authority to annul or invalidate provisions of national legislation that are incompatible with the signed agreements, which may place national laws in a secondary position.

The Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement [65] and the North American Free Trade Agreement (NAFTA)[66] established key provisions that significantly impacted the pharmaceutical industry. Among these was the extension of the patent protection term to twenty years from the date of filing, with no possibility of renewal, as stipulated by international standards.

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[64] Miguel Ángel Pallares Gómez, *Invertirán farmacéuticas 40 mil mdp en México*, El Universal (Feb. 27, 2017), available at https://www.eluniversal.com.mx/articulo/cartera/negocios/2017/02/27/invertiran-farmaceuticas-40-mil-mdp-en-mexico.

[65] World Trade Organization (WTO), *Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), Annex 1C*, in The Legal Texts: The Results of the Uruguay Round of Multilateral Trade Negotiations 341–73 (1994).

[66] North American Free Trade Agreement (NAFTA), Dec. 17, 1992, Can.-Mex.-U.S., entered into force on Jan. 1, 1994.

The TRIPS Agreement also incorporated the figure of compulsory licensing, which is permitted under specific conditions such as national emergencies or anticompetitive practices. However, its implementation has encountered stricter limitations under the NAFTA framework and remains subject to ambiguities under the USMCA. The Bolar exemption, which was added into the Mexican Federal Law for the Protection of Industrial Property in 2020, allows the use of patented inventions for strictly experimental and regulatory purposes before patent expiration, thus facilitating the timely market entry of generic medicines.

While the scope of patentability was not expressly expanded under Mexican law, the pharmaceutical, chemical, and metallurgy sectors, among others, are fully protected. Moreover, under the framework of international trade and investment treaties, patents may be classified as investments, thereby allowing foreign patent holders to access investor-State dispute settlement mechanisms. These mechanisms have raised concerns over potential bias in favor of large multinational corporations. This dual legal framework, where international commercial disputes are resolved through international treaties while administrative or civil disputes are subject to domestic law, creates tensions in the protection of local interests.

Furthermore, the lack of legal clarity as to what constitutes a "national emergency" –a prerequisite for granting compulsory licenses– increases the risk of misuse or legal loopholes that may hinder its effective application. Compounding this issue is the data exclusivity requirement enforced by trade agreements, which restricts early access to critical clinical data needed to register generic medicines.

Guerrero[67] contends that NAFTA primarily benefited the United States and Canada, failing to succeed in attaining the envisioned equal trade footing. Despite the outcomes of previous commitments, the USMCA, ratified in early 2019, brought about changes in intellectual property that favor large pharmaceutical corporations. In 2019, the legislative branches of Mexico ratified the United States-Mexico-Canada Agreement (USMCA),[68] which underwent key amendments through a Protocol of Amendment. In its original form, the agreement included provisions that favored large corporations, especially those in the pharmaceutical industry. Notable among these were the protection of test data and the possibility of granting multiple patents for a single drug, whether based on its active ingredient, formulation, composition, or even new therapeutic uses. Such clauses posed a significant barrier to the entry of generic medicines and thus market competition.

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[67] Rodrigo A. Guerrero Castro & Roberto Gutiérrez R., *Los ADPIC y el TLCAN en la industria farmacéutica mexicana: Un análisis TradeCAN*, n. 35 Economía: teoría y práctica 93–129 (2011).

[68] Agreement Between the United States of America, the United Mexican States, and Canada (USMCA), signed July 1, 2020, entered into force July 1, 2020.

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The Protocol of Amendment removed some of these provisions, including the mandatory ten-year data exclusivity for new biological drugs and the patentability of new uses for known substances. Nevertheless, the Federal Law for the Protection of Industrial Property (LFPPI) [69] [70], enacted in July 2020 as part of Mexico's legal harmonization process with the USMCA and other international treaties, incorporated mechanisms that continue to benefit patent holders. Among these are the expansion of powers granted to the Mexican Institute of Industrial Property (IMPI) to enforce measures in favor of companies, many of which are foreign, and the possibility of extending patent terms by means of administrative delays, which may further postpone the market entry of generics.

One clear example of the critical importance of these legal provisions emerged during the COVID-19 pandemic. The global urgency for access to medicines, vaccines, and treatments requires States to enable local production or to import generic versions. However, in Mexico, the rigidity of the patent protection regime, coupled with the legal requirement for coordination between IMPI and the Federal Commission for the Protection Against Sanitary Risks (COFEPRIS) to safeguard test data, may have limited the State's response to the health emergency.

Furthermore, the implementation of compulsory licenses—a vital mechanism during public health crises—was hindered by the lack of legal clarity regarding what constitutes a "national emergency," a prerequisite for activation under international treaties. This legal ambiguity obstructed timely access to affordable treatments and disproportionately favored the interests of large transnational pharmaceutical companies.

These developments have reignited the debate over the delicate balance between protecting innovation and ensuring equitable access to public health. In countries like Mexico, where the development of a robust generic pharmaceutical industry is essential to safeguard the right to health, it is imperative to review and adjust the legal framework to prevent it from becoming a barrier in future public health emergencies.

IV. Conclusions

The history of the pharmaceutical industry in Mexico from the 1970s to the present is a narrative rich in transformations and adaptations. The emergence of this industry in the late 19th and early 20th centuries laid the foundation for

[69] H. Congreso de la Unión de los Estados Unidos Mexicanos, Ley Federal de Protección a la Propiedad Industrial [Federal Law on the Protection of Industrial Property], July 1, 2020 (Mex.).

[70] H. Congreso de la Unión de los Estados Unidos Mexicanos, *Dictamen de las Comisiones Unidas de Economía, de Salud y de Estudios Legislativos, Segunda con Proyecto de Decreto por el que se expide la Ley Federal de Protección a la Propiedad Industrial y se abroga la Ley de la Propiedad Industrial*, Cámara de Diputados del H. Congreso de la Unión, June 29, 2020.

its growth during the Mexican Revolution. At this time, foreign investment and government regulations were key factors in shaping the industry.

The 1940s marked the beginning of domestic drug production, even if it remained dependent on imported raw materials. From 1960 to 1978, the industry experienced a surge in the number of laboratories, but foreign capital dependence was still high. The early 1980s economic crisis led the government to strengthen the pharmaceutical sector through public policies, although these strategies were significantly altered in response to international measures.

In the late 1980s, Mexico achieved greater autonomy in the production of raw materials, which helped stabilize the trade balance. However, the Mexican pharmaceutical industry was strongly affected by a shortage of medicines in 1983 due to global economic events and trade imbalances. At this point, State regulation played a crucial role in price control, patent granting, import restrictions, and the advancement of the national pharmaceutical industry. However, challenges persisted, such as limited investment in R&D and a lack of focus on creating new molecules.

Mexico's entry into the GATT in 1986 marked a significant shift towards market opening. This process intensified with the signing of the North American Free Trade Agreement (NAFTA) in 1994 and the subsequent US-Mexico-Canada Agreement (USMCA) in 2019. These agreements led to legal and regulatory adjustments that transformed the industry's dynamics.

The 1991 Industrial Property Law and the 1984 General Health Law were fundamental to this process as they extended patent protection and established the Mexican Institute of Industrial Property (IMPI), thus creating a legal framework that favored foreign participation and protected intellectual property rights.

The 1993 Foreign Investment Law opened new possibilities by allowing higher percentages of foreign investment in the pharmaceutical industry, which led to a growing presence of transnational companies in the Mexican market. Despite these changes, the industry faced significant challenges. A lack of investment in R&D persisted while patent regulation became a point of conflict, especially with the ushering in of generic drugs. Ambiguities around compulsory licenses and international trade disputes also negatively impacted the industry.

The implementation of the USMCA in 2020 presented a new framework for data and intellectual property protection, with significant implications for access to generic drugs and the balance between national and international interests. In conclusion, the evolution of the pharmaceutical industry in Mexico has been a complex story of legislative changes, market opening, and persistent challenges. Although greater autonomy in production has been achieved, dependence on foreign investment and strains between intellectual property protection and access to affordable drugs remain critical issues. The industry's future will depend on Mexico's ability to find a sustainable balance between innovation, competition, and equity in access to healthcare.

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V. References

Agreement Between the United States of America, the United Mexican States, and Canada (USMCA), signed July 1, 2020, entered into force July 1, 2020.

Jacqueline Arzoz Padrés, *Situación del sector farmacéutico en México*, CENTRO DE ESTUDIOS SOCIALES Y DE OPINIÓN PÚBLICA, (2010).

Banco Mundial, *Gasto en investigación y desarrollo (% del PIB)* (2025), https://datos.bancomundial.org/indicador/GB.XPD.RSDV.GD.ZS.

Joan Brodovsky, *La Industria Farmacéutica y Fármacoquímicos Mexicana en el Marco Regulatorio de los Años 90*, CEPAL/CIID 3 (1995), https://repositorio.cepal.org/server/api/core/bitstreams/28e3c8c2-1053-4494-b9cd-4bb31c17b2ce/content.

Cámara Nacional de la Industria Farmaceutica (CANIFARMA), *Datos económicos, (2025)*.

Ingrid Chávez et al., *El Mercado de medicamentos en México: retos y oportunidades*, INSTITUTO MEXICANO PARA LA COMPETITIVIDAD A.C., 9, 1-37 (2021).

ENRIQUE DUSSEL PETERS, LAS INDUSTRIAS FARMACÉUTICAS Y FARMOQUÍMICA EN MÉXICO Y EL DISTRITO FEDERAL 3-31 (Economic Commission for Latin America and the Caribbean 1999).

Farmacéutica Merck cierra dos plantas en México, EL ECONOMISTA (July 8, 2010), https://www.eleconomista.com.mx/empresas/Farmaceutica-Merck-cierra-dos-plantas-en-Mexico--20100708-0034.html.

Arturo Fuentes Ramírez, *Situación del sector farmacéutico en México*, *Centro de Estudios Sociales y de Opinión Publica*, 100 (2010).

Rogelio Godínez Reséndiz & Patricia Aceves Pastrana, *El Surgimiento de la Industria farmacéutica en México*, 45 *Rev Mex Cienc Farm* 55, 55-68 (2014).

Rogelio Godínez Reséndiz & Patricia Aceves Pastrana, *La Regulación del Medicamento Industrial en México*, 43 *Rev Mex Cienc Farm* 49, 49-57 (2012).

Rodrigo A. Guerrero Castro & Roberto Gutiérrez R., *Los ADPIC y el TLCAN en la industria farmacéutica mexicana: Un análisis TradeCAN*, n. 35 *Economía: teoría y práctica* 93–129 (2011).

H. Congreso de la Unión de los Estados Unidos Mexicanos, *Decreto para el Fomento y la Regulación de la Industria Farmacéutica*, Tomo CCCLXXII, No. 39, DIARIO OFICIAL DE LA FEDERACIÓN, Feb. 23, 1984, at 13 (Mex.).

H. Congreso de la Unión de los Estados Unidos Mexicanos, *Decreto por el que se extingue la Comisión Intersecretarial de la Industria Farmacéutica*, DIARIO OFICIAL DE LA FEDERACIÓN, Transitorios, art. segundo, May 9, 1990, http://dof.gob.mx/nota_detalle.php?codigo=4654748&fecha=09/05/1990&print=true.

H. Congreso de la Unión de los Estados Unidos Mexicanos, *Dictamen de las Comisiones Unidas de Economía, de Salud y de Estudios Legislativos, Segunda con Proyecto de Decreto por el que se expide la Ley Federal de Protección a la Propiedad Industrial y se abroga la Ley de la Propiedad Industrial*, CÁMARA DE DIPUTADOS DEL H. CONGRESO DE LA UNIÓN, June 29, 2020.

H. Congreso de la Unión de los Estados Unidos Mexicanos, *Ley para Promover la Inversión Mexicana y Regular la Inversión Extranjera* [Law to Promote Mexican Investment and to Regulate Foreign Investment], Diario Oficial de la Federación, Mar. 9, 1973 (Mex.).

H. Congreso de la Unión de los Estados Unidos Mexicanos, *Ley de Propiedad Industrial* [Industrial Property Law], Diario Oficial de la Federación, Jun. 3, 1991 (Mex.).

H. Congreso de la Unión de los Estados Unidos Mexicanos, *Ley Federal de Protección a la Propiedad Industrial* [Federal Law on the Protection of Industrial Property], Diario Oficial de la Federación, July 1, 2020 (Mex.).

H. Congreso de la Unión de los Estados Unidos Mexicanos, *Ley sobre el Registro de Transferencia de Tecnología y el Uso y Explotación de Patentes y Marcas* [Law on the Registration of Technology Transfer and the Use and Exploitation of Patents and Trademarks], Diario Oficial de la Federación, Dec. 30, 1972 (Mex.).

Instituto Nacional de Estadística y Geografía, Estadísticas a Propósito de la Industria Farmacéutica (2016).

Instituto Nacional de Estadística y Geografía (INEGI), *Banco de Información Económica (BIE)* (2019), available at https://www.inegi.org.mx/app/indicadores/?tm=0&t=1040#tabMCcollapse-Indicadores.

KPMG, *La Industria Farmacéutica Mexicana: Industria Farmacéutica y de Dispositivos Médicos*, 11 (2018).

René Leyva et al., *Hacia una política farmacéutica integral para México*, 48 *Salud Pública de México* 104 (2006).

Mario Lieberman Litmanowitz, *Estado actual de la industria farmacéutica en México: avances y problemas*, 29 *Salud Pública de México* 3, 249 (1987), http://saludpublica.mx/index.php/spm/article/view/285.

María de la Luz Lara Méndez et al., *Historia de la regulación farmacéutica*, 3 *Rev. Cofepris Protección y Salud* 11, (2018).

Miguel de la Madrid Hurtado, *Informe de Gobierno del Presidente Constitucional de los Estados Unidos Mexicanos*, Diario Oficial de la Federación, 198 (1985).

Miguel de la Madrid Hurtado, *Plan Nacional de Desarrollo 1983-1988*, Diario Oficial de la Federación, 8–92 (1983).

Miguel de la Madrid Hurtado, *Programa Nacional de Desarrollo Tecnológico y Científico 1984–1988*, 338–47 (1984).

Misión de México ante la UE, *Lazos Comerciales*, Año 6, No. 8 Oficina de representación de la secretaria de economía entro de estudios sociales y de opinión pública, (2008).

North American Free Trade Agreement (NAFTA), Dec. 17, 1992, Can.-Mex.-U.S., entered into force Jan. 1, 1994.

Organisation for Economic Co-operation and Development *(*OECD*), Manual de estadísticas de patentes de la OCDE,* Oficina Española de Patentes y Marcas (2009).

Miguel Ángel Pallares Gómez, *Invertirán farmacéuticas 40 mil mdp en México*, El Universal (Feb. 27, 2017), available at https://www.eluniversal.com.mx/articulo/cartera/negocios/2017/02/27/invertiran-farmaceuticas-40-mil-mdp-en-mexico.

José M. Pérez de Villarreal, *La Economía Mundial en los Años Ochenta y la Política Económica de los Noventa*, No. 20 ekonomiaz 215, 215 (1991).

Rafael Pérez Miranda, Tratado de derecho de la propiedad industrial: patentes, marcas, denominación de origen, obtentores de vegetales, informática: un enfoque de derecho económico, 429 (Porrúa Quinta edición) (2011)

Senado de la República, *Gaceta: LX/1SPR-23/12990, Gaceta del Senado* (June 27, 2007), https://www.senado.gob.mx/64/gaceta_del_senado/documento/12990.

Antonio Javier Severino, *Lineamientos para una unidad tercero-autorizada de registros sanitarios*, facultad de estudios superiores zaragoza, (2013).

Víctor M. Soria, *Estructura y comportamiento de la industria farmacéutica en México. El papel de las empresas transnacionales*, 02 *Revista de Ciencias Sociales y Humanidades* 111, 111-141 (1980), https://revistaiztapalapa.izt.uam.mx/index.php/izt/article/view/650/799.

Subsecretaría de Competitividad de la Dirección General de Inversión Extranjera, *Inversión Extranjera de Sociedades Mexicanas*, Secretaría de Economía (2019), available at http://www.datos.economia.gob.mx/InversionExtranjeraSociedadesmexicanas.xls.

Sandra Torres Guerra & Juan Pablo Gutiérrez, *Mercado farmacéutico en México: tamaño, valor y concentración*, 26 *Rev. Panam. Salud Pública* 1, 47–48 (2009).

Unidad de Inteligencia PROMÉXICO, *Diagnóstico sectorial farmacéutico*, Secretaría de Economía, 4 (2015).

Eulalio Victoria, *Roche cierra planta en Estado de México*, El Financiero (Nov. 11, 2016), https://www.elfinanciero.com.mx/empresas/roche-cierra-planta-en-estado-de-mexico.

World Trade Organization (WTO), *Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), Annex 1C*, in The Legal Texts: The Results of the Uruguay Round of Multilateral Trade Negotiations 341–73 (1994).