Intellectual Property Rights, Trade and Access to Medicines: From the Uruguay Round to the USMCA

Derechos de propiedad intelectual, comercio y acceso a medicamentos: de la Ronda de Uruguay al T-MEC

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Abstract:
Production and distribution of therapeutics, such as medicines, vaccines and diagnostics are governed by intellectual property rights (IPRs). Prior to the Marrakech Agreement, each country established its own rules for the duration, scope and enforcement of patents. The TRIPS Agreement standardized these three elements, leaving limited room for maneuver in the implementation of public-health-related policies. Implementation of the IPR system in the developing world has, however, varied, depending on the structure of the pharmaceutical industry of the country in question, shaped over the decades by foreign direct investment and State investment in science and technology. This article discusses the implementation of the IPR system in Mexico, from the reforms required for the approval of NAFTA up to the signing of the USMCA by the Mexican Senate.

Resumen:
La producción y la distribución de objetos terapéuticos, como medicamentos, vacunas o diagnósticos, están delineadas por los derechos de propiedad intelectual (DPI). Antes del Acuerdo de Marrakech, cada país establecía normas en términos de rango, duración y alcance de la patente. El Acuerdo sobre los DPI relacionados con el comercio homogeneizó estos tres ejes. Un espacio limitado ha permanecido para la instrumentación de políticas sensibles al interés público y la salud pública. Su instrumentación en los países en desarrollo ha variado, de acuerdo con la estructura industrial farmacéutica de cada país, modificada a través de las décadas por la IED y la inversión del Estado en ciencia y tecnología. El artículo habla sobre la instrumentación del régimen de DPI en México desde las reformas necesarias en DPI para la firma del TLCAN hasta el T-MEC por el Senado mexicano.

Key Words:
Intellectual property rights, TRIPS, free trade agreements, access to medicines, business associations.

Palabras clave:
Derechos de propiedad intelectual, ADPIC, tratados de libre comercio, acceso a medicamentos, asociaciones empresariales.

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Introduction

Throughout the COVID-19 syndemic,[1] coordinating biomedical strategies for the production and distribution of therapeutics like medicines, vaccines and diagnostics has been essential to checking the spread of the virus. Within the ranks of the World Trade Organization (WTO), this concern has translated into the election of a director-general with a background in global health—Ngozi Okonjo-Iweala of Nigeria, former board chair of Gavi, the Vaccine Alliance—[2] and the proposals put forward by India and South Africa to exempt medicines, vaccines and diagnostics from intellectual property rights (IPR) until global herd immunity

[1] According to Richard Horton, editor of *The Lancet*, the COVID-19 pandemic would be better classified as a syndemic in that it affects populations suffering from chronic-degenerative diseases like diabetes. Public health measures alone are therefore not sufficient to combat the virus; action also needs to be taken to address these prevalent non-communicable diseases, such as higher taxes on certain products like soda. Richard Horton, "Offline: COVID-19 Is Not a Pandemic", in *The Lancet,* vol. 396, no. 10255, 874, September 26, 2020, at *https://doi.org/10.1016/S0140-6736(20)32000-6* (date of reference: January 28, 2021). The term syndemic was coined by the anthropologist Merrill Singer.

[2] Elaine Ruth Fletcher and James Hacker, "Gavi Board Chair Okonjo-Iweala Recommended As World Trade Organization Director-General–U.S. Opposition Stalls Final Decision", in Health Policy Watch, October 28, 2020, at *https://healthpolicy-watch.news/okonjo-iweala-wto-us-stalls/* (date of reference: January 28, 2021).

has been achieved.[3] This is not the first time public health has attracted the attention of the WTO. In the late 1990s, during the AIDS epidemic, the WTO became engaged in a heated debate on whether or not to allow for greater flexibility in the enforcement of the IPR system regarding the scenarios (for example, national security threats and health emergencies) and mechanisms (*i.e.* compulsory licenses, parallel imports and Bolar exemptions)[4] in which the State can intervene in the interest of the public over that of the owners of knowledge, as provided for in the international legal framework described in Annex C of the Marrakech Agreement. It was a diplomatic battle between the United States and Global South countries like South Africa, backed by non-government organizations like Act-Up, Public Citizen and Doctors Without Borders. The main topic of debate was compulsory licensing and other flexibilities that would free medicines used to treat HIV of patents, thereby facilitating mass local production, with a view to reducing the cost of these treatments. However, the debate was not limited to waiving the enforcement of patents on HIV-related drugs for a specific period, which is what the United States advocated; other delegations were in favor of having patent protection lifted from pharmaceutical products used to treat all diseases indefinitely. The outcome of the discussion is reflected in the Doha Declaration of 2001, which provides flexibilities for the

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3 Brook Baker, "South Africa and India's Proposal to Waive Recognition and Enforcement of Intellectual Property Rights for COVID-19 Medical Technologies Deserves Universal Support, But Countries Also Have to Take Domestic Measures", in Health GAP Global Access Project, October 10, 2020, at *https://healthgap.org/south-africa-and-indias-proposal-to-waive-recognition-and-enforcement-of-intellectual-property-rights-for-covid-19-medical-technologies-deserves-universal-support-but-countries-also-have-to/* (date of reference: January 28, 2021).

4 These terms are defined as follows in the WTO glossary. *Compulsory* licensing is "when the authorities license companies or individuals other than the patent owner to use the rights of the patent—to make, use, sell or import a product under patent (*i.e.* a patented product or a product made by a patented process)—without the permission of the patent owner." *Parallel imports* are "when products made legally abroad are imported without the permission of the patent owner," based on the legal principle of exhaustion of rights. The *Bolar provision* is when "manufacturers of generic drugs are allowed to use the patented invention to obtain marketing approval without the patent owner's permission and before the patent protection expires", World Trade Organization, "Glosario de términos", at *https://www.wto.org/spanish/thewto_s/glossary_s/glossary_s.htm* (date of reference: February 15, 2021).

treatment of all diseases, and the decision of the WTO General Council on the "Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health" of 2003, which stipulates the option of using compulsory licenses to export to third counties that do not have the capacity to produce locally.[5] Over the course of almost two decades, these flexibilities have not only been applied to HIV treatments, but to drugs for non-communicable diseases (NCD) like diabetes and cancer, especially now that a reduction in their incidence is one of the Sustainable Development Goals (SDG).

The media, at least in Mexico, has tended to train its intellectual property radar on Global South countries like Brazil, India, South Africa and Thailand, which, with the backing of international organizations, have availed themselves of the flexibilities in the TRIPS Agreement motivated by public health concerns, highlighting a moral dilemma that pits commercial interests against the public good, expressed by slogans like "Corporate Greed Kills", "Medicines Should Not be a Luxury", "Patents Kill Patients" and "Unfair Patents on Medicines Cost Lives". But if we compare the legal concepts of intellectual property and property rights, compulsory licensing (one of the flexibilities provided for in the Doha Declaration) would be tantamount to expropriation, whereby the State is legally empowered to take such actions under certain circumstances, such as threats to national security or public health.

Each country establishes its own regulations for compulsory licensing as regards legal procedure, the scenarios in which these can be exercised and royalties. And it is not only Global South countries that have availed themselves of these flexibilities; northern ones have too. For example, after the terrorist attack of September 11, 2001, the United States introduced compulsory licensing for the manufacture of a drug to treat anthrax. More recently, during the COVID-19 pandemic, Germany, Canada and France

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5 Frederick M Abbott, "The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health", in *American Journal of International Law*, vol. 99, no. 2, April 2005, 317-358; Duncan Matthews, "The WTO Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: A Solution to the Access to Essential Medicines Problem?", October 20, 2003, at *https://core.ac.uk/download/pdf/30695054.pdf* (date of reference: January 28, 2021).

introduced reforms to facilitate compulsory licensing for the mass production of medical supplies to combat the disease, including vaccines and diagnostics.[6] But while international campaigns championing access to medicines have associated WTO flexibilities with a reduction in the price of medical supplies, in political science, this correlation is not so simple, since there is no evidence that their use by governments to purchase pharmaceuticals necessarily keeps prices in check, as illustrated by the case of Ecuador.[7] Other strategies, like the price controls implemented by Colombia,[8] have proven more effective at bringing prices down, but have come under immense strain during the negotiation of free trade agreements with, for example, the European Union.

International campaigns advocating access to medicines in the interests of public health have turned the public eye to the intellectual property rights system, yet all countries have been reforming their regimes since the 1990s, Mexico included, resulting in the virtual standardization of the system via its inclusion on the trade agenda in the form of Annex 1C of the Marrakech Agreement (TRIPS Agreement). Nevertheless, the implementation of this system on a local level during health emergencies called into question the balance with the public interest, giving rise to new international reforms. In the last three decades, there has been constant interaction between international intellectual property law and its implementation on the local level, mediated by State entities like the Legislature (which represents local industrial sectors and transnationals), the Executive, patent offices, regulatory

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6 Andrew Greene, "COVID-19: Countries Race to Strengthen Compulsory Licensing Legislation", in Devex, June 30, 2020, in *https://www.devex.com/news/sponsored/covid-19-countries-race-to-strengthen-compulsory-licensing-legislation-97595* (date of reference: January 28, 2021); Susan K. Sell, *Private Power, Public Law: The Globalization of Intellectual Property Rights,* Cambridge, Cambridge University Press, 2003.

7 Tatiana Andia, "The Inverse Boomerang Pattern: The Global Kaletra Campaign and Access to Antiretroviral Drugs in Colombia and Ecuador", in *Studies in Comparative International Development,* vol. 50, no. 2, June 2015, 203-227; T. Andia, "Pharmaceutical Intellectual Property Rights Protection and Access to Medicines in Ecuador. State Sovereignty and Transnational Advocacy Networks", in Rochelle Dreyfuss and César Rodríguez-Garavito (eds.), *Balancing Wealth and Health: The Battle over Intellectual Property and Access to Medicines in Latin America*, Oxford, Oxford University Press, 2014, 195-221.

8 T. Andia, "The Inverse Boomerang Pattern...".

and antitrust authorities. Outcomes have depended not only on the ideology of the agency in question, but the structure of local industry. These interactions between international reforms and their implementation on a local level have been called *waves*.

The first wave of global reforms was spurred by the WTO trade agenda. Disparities between developing countries were minimal and attributable to their implementation, whether a strong local pharmaceutical industry caused internal forces to adhere to the provisions of the TRIPS Agreement as the result of a dispute between the Executive and the Legislature, as was the case in Argentina, or whether a weak local industry resulted in standards that exceeded TRIPS provisions, as the result of an agreement between the Executive and the Legislature, as occurred in Mexico.[9] Differences in the implementation of IPR reforms have been identified in three areas: duration (*i.e.* the 20-year patent term or its extension to offset delays by the patent office), tensions between the public interest and the owners of the knowledge (*i.e.* the ease with which flexibilities like compulsory licensing or the Bolar provision can be used), and the scope of protection (*i.e.* whether it applies only to the process and the pharmaceutical product, as provided for in the TRIPS Agreement, or whether it also applies to secondary processes related to the protection of a new use of a product already on the market).[10] In Mexico, the first wave of reforms did not come about with membership of the WTO, but during the negotiation of the North American Free Trade Agreement (NAFTA): one of the petitions of the Office of the U.S. Trade Representative was that Mexico first make sweeping reforms to its IPR system, namely the Inventions and Brands Law and the Law on the Control

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9 Kenneth C. Shadlen, *Coalitions and Compliance: The Political Economy of Pharmaceutical Patents in Latin America*, Oxford, Oxford University Press, 2017; Inside NAFTA, *Reporting on NAFTA implementation and trade policy in the Americas from the publishers of Inside U.S. Trade,* no. 26, Washington, Inside NAFTA, December 1996.

10 K. C. Shadlen, "The Politics of Patents and Drugs in Brazil and Mexico: The Industrial Bases of Health Policies", in *Comparative politics*, vol. 42, no. 1, October 2009, 41-58; Manuel Becerra Ramírez (coord.), *Propiedad intelectual y farmacéuticos: hacia una política de Estado*, México, Instituto de Investigaciones Jurídicas-UNAM,/Asociación Nacional de Fabricantes de Medicamentos, 2013); Inside NAFTA, *Reporting on NAFTA implementation and trade policy in the Americas from the publishers of Inside U.S. Trade,* no. 24, Washington, Inside NAFTA, November 1995. K. C. Shadlen, "The Politics of Patents and Drugs..."; M. Becerra Ramírez (coord.), *op. cit.*

and Registration of Technology Transfers and the Use and Exploitation of Patents and Trademarks and its Regulations, something the Executive had categorically refused to do in the 1980s.[11]

The second wave was driven by Global South countries and international public health movements in the public interest, which paved the way for the WTO Doha Declaration and the "Implementation of Paragraph 6 of the Doha Declaration".[12] This international environment, married with the expansion of universal health coverage in Mexico, set the stage for initiatives to transform the IPR system in local congresses, in the spirit of public health. In Mexico, the extension of health coverage manifested in the creation of the Seguro Popular, via the Fund for Protection against Catastrophic Expenses, which covered expensive patented medicines for different types of cancer, HIV and hepatitis C.[13] This, however, stretched the public expenditure budget thin and initiatives for greater IPR flexibility (for example, more flexible use of compulsory licensing and the introduction of patent opposition mechanisms) and government procurement were subsequently discussed. The goal was not to control prices, but to centralize government acquisition processes so as to negotiate lower prices based on higher volumes.[14] These attempts at reform depended on the industrial structures erected after the first wave. In Mexico, the first wave merely served to reinforce and expand

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11 U.S. Trade Representative, "Fact Sheet. Special 301 on Intellectual Property", May 25, 1989, at *https://ustr.gov/sites/default/files/1989%20Special%20301%20Report.pdf* (date of reference: February 13, 2021).

12 María Cristina Rosas, "La Ronda de Doha: alcances y límites", in M. C. Rosas (coord.), *Que las "Rondas" no son buenas... La OMC y la Ronda de Doha: ¿proteccionismo vs desarrollo?,* Mexico, UNAM/Sistema Económico Latinoamericano, 2003, 33-60; WTO, "Declaración relativa al Acuerdo sobre los ADPIC y la salud pública", WT/MIN(01)/DEC/2, November 20, 2001, at *https://www.wto.org/spanish/thewto_s/minist_s/min01_s/mindecl_trips_s.htm (date of reference: January 28, 2021);* Pascale Boulet and Rachel M. Cohen, "La crisis del acceso a los medicamentos en materia de propiedad intelectual de la Ronda de Uruguay: los pacientes frente a las ganancias", in *M. C. Rosas* (coord.), *op. cit.,* 423-441; D. Matthews, *op. cit.*

13 Julio Frenk, Eduardo González-Pier, Octavio Gómez-Dantés, Miguel A Lezana and Felicia Marie Knaul, "Comprehensive Reform to Improve Health System Performance in Mexico", in *The Lancet,* vol. 368, no. 9546, October 28, 2006, 1524-1534; De la Redacción, "Atenderá Seguro Popular a más pacientes con hepatitis C", *La Jornada*, July 31, 2018, 33, at *https://www.jornada.com.mx/2018/07/31/sociedad/033n2soc* (date of reference: January 28, 2021).

14 This initiative applies to the public sector only, which purchases just a fourth of all medicines in terms of value, while the private sector accounts for the remaining three quarters of the market.

the international industrial structure, thereby obstructing the public health reforms of the second wave.

The third wave of reforms has been defined by a series of regional free trade agreements endorsed by the United States, like the Trans-Pacific Partnership (TPP) and the renegotiation of NAFTA, which have incorporated new concepts in intellectual property law, such as protection for clinical trials for a specific length of time and patents for new uses, due to the expiration of the 20-year term of patents granted following the passing of the Federal Industrial Property Law (LFPI) in 1991. If the outcome of discussions has been determined by transnational industry, represented by the U.S. Trade Representative and conditioned by the negotiation of multiple agendas, like rules of origin, implementation in local congresses has depended on internal coalitions. And while transnational industry has shored up its structure over the decades, coming to account for 70% of the value of the local pharmaceutical market,[15] a fledgling local industry has emerged on the technological frontier thanks to State investment in science and technology. At the same time, the generic pharmaceutical industry has been consolidated by means of development strategies like government procurement. These phenomena are all reflected in the implementation of the USMCA.

Although numerous academics have said that access to medicines hinges on several factors,[16] such as proximity to clinics and health coverage, since the intellectual property law was reformed in 1991, price increases in the

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15 Juan de Villafranca, "Punto de quiebre para la industria farmacéutica mexicana", in *Comercio Exterior*, no. 22, April-June 2020, 32-35, at *http://www.revistacomercioexterior.com/revistas/22/1588640874278.pdf* (date of reference: February 12, 2021).

16 Janeth Tenorio-Mucha, María Lazo-Porras, Liliana Hidalgo-Padilla, David Beran and Margaret Ewen, "Precios, disponibilidad y asequibilidad de insulina en farmacias públicas y privadas en Perú", in *Revista Panamericana de Salud Pública*, no. 43, October 2019, at *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6822689/* (date of reference: February 12, 2021); Pierre Moïse and Elizabeth Docteur, *Pharmaceutical Pricing and Reimbursement Policies in Mexico,* Paris, OECD (OECD Health Working Papers, 25), 2007, at *https://doi.org/10.1787/302355455158* (date of reference: January 28, 2021); Veronika J Wirtz et al., "Essential Medicines for Universal Health Coverage", in The Lancet, vol. 389, no. 10067, January 28, 2017, 403-476, at *https://www.thelancet.com/action/showPdf?pii=S0140-6736%2816%2931599-9* (date of reference: March 5, 2021); Margaret Ewen, Huibert-Jan Joosse, David Beran and Richard Laing, "Insulin Prices, Availability and Affordability in 13 Low-income and Middle-income Countries", in *BMJ Global Health,* vol. 4, no. 3, June 2019, at *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6570978/* (date of reference: February 12, 2021).

pharmaceutical industry have outpaced general inflation in Mexico.[17] In the 2000-2008 period, the price of medicines increased 59.7%, compared to general inflation of 43.5%.[18] In the early 1990s (prior to the IPR reforms and the more flexible price controls introduced in 1997), medicines were five times cheaper in Mexico than in the United States and three times cheaper than in the European Union,[19] but five years later, adjusting for income in Mexico, medicines were five times more expensive than in the United States.[20] As of 2017, the gap between inflation in the pharmaceutical industry and general inflation began to close, due, it was argued, to the expiration of patents and the approval of generic products by the health authorities, which led to greater competition on the market.

In Mexico, intellectual property issues involving topics like the Internet and transgenic crops have received much more public attention than the pharmaceutical industry, where reforms to the system have been shrouded in silence. This is not to be made light of, since the IPR system establishes standards for the production and distribution of medicines, and the exceptions stipulated by the State for interrupting or expediting the extinguishing of these rights so as to encourage more manufacturers to enter the market. For these reasons, I have chosen to analyze the three waves of reforms to the IPR system in Mexico's pharmaceutical sector that have resulted in the extension of compliance with IPRs to the multilateral TRIPS sphere. My analysis will be based on documents from the Mexican Congress, the U.S. Trade Representative, the Inside NAFTA collection[21] and interviews with representatives of national and transnational associations.

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17 Banco de México, "Principales índices mensuales (CP154)", at *https://www.banxico.org.mx/SieInternet/consultarDirectorioInternetAction.do?accion=consultarCuadro&idCuadro=CP154&locale=es* (date of reference: January 28, 2021).

18 Comité de Competitividad and Centro de Estudios Sociales y de Opinión Pública, *Situación del sector farmacéutico en México*, Mexico, Chamber of Deputies LXI Legislature, 2010, 36.

19 Pierre Moïse and Elizabeth Docteur, *Pharmaceutical Pricing and Reimbursement Policies in Mexico*, Paris, OECD (OECD Health Working Papers, 25), 2007, 29, *https://doi.org/10.1787/302355455158* (date of reference: January 28, 2021).

20 *Ibid*., 30.

21 This collection was revised between 1995 and 1997.

The first wave: the linking of IPRs and trade (WTO proposals and NAFTA)

Issues involving intellectual property rights are discussed at WTO forums, not by the World Intellectual Property Organization (WIPO), created in 1967. This is because, in the 1970s, the Office of the U.S. Trade Representative attempted to tie the intellectual property agenda in with the multilateral trade agenda, first at the Tokyo Round and later at the Uruguay Round, as part of the now defunct General Agreement on Tariffs and Trade (GATT). The goal was not merely to extend IPR protection, but enforce trade sanctions on countries that infringed on these rights.[22] While these attempts proved unsuccessful during the Tokyo Round, they bore fruit at the Uruguay Round, resulting in the TRIPS Agreement, contained in Annex 1C of the Marrakech Agreement, which countries had to sign to join the WTO.

This agreement sparked a global wave of reforms to domestic intellectual property laws, reforms that had been rejected by developing countries in the 1980s,[23] namely non-aligned countries, a movement that emerged in the 1970s and for which the subject of pharmaceuticals became pivotal. In this international context, many developing countries transformed their IPR systems, including Mexico, which, in 1977, under a nationalist, populist Executive, reduced to ten years the term of patents exclusively for processes (not products, making reverse engineering possible) and simplified compulsory licensing procedures.[24] In the following decade, the Executive bowed to external pressure and made only moderate changes in 1987, granting patents to processes and promising protection for products until 1997,[25] without extending their term.

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22 S. K. Sell, *op. cit.*

23 Kenneth Shadlen, "Patents and Pills, Power and Procedure: The North-South Politics of Public Health in the WTO", in *Comparative Studies in International Development,* vol. 39, no. 3, September 2004, 76-108.

24 Jaime Álvarez Soberanis, "La Ley de Invenciones y Marcas y las facultades que otorga al Registro Nacional de Transferencia de Tecnología", in *Revista Mexicana de la Propiedad Industrial y Artística,* XIV, no. 27-28, January-December 1976, 67-95.

25 Manuel Becerra Ramírez, *La propiedad intelectual en transformación*, Mexico, Instituto de Investigaciones Jurídicas-UNAM, 2009.

To become a member of the WTO, countries had to sign Annex 1C (the TRIPS Agreement), which, for all intents and purposes, meant standardizing the term, scope and enforcement of IPRs. This was a radical change from preceding centuries. In the early nineteenth century, IPR systems were diverse and flexible, meaning industrial policies based on reverse engineering and knowledge borrowed from foreign technologies could be implemented.[26] In some countries, foreigners had no patenting rights at all. The first international agreement to regulate IPRs was the Paris Convention for the Protection of Industrial Property. Adopted in 1883, it established national treatment as its sole principle. Throughout the entire twentieth century, States retained sovereignty over the term and scope of patents, in a balancing act that squared tensions between the public interest and the owners of the knowledge. This assorted mix of systems existed until 1995, when 13 companies took their standardization agenda to the Office of the U.S. Trade Representative and requested that countries grant patents to both the process and the pharmaceutical product for a term of 20 years. According to interviews with industry representatives, the TRIPS Agreement incorporated 95% of their petitions, with the exception of retroactive patents and restrictions on compulsory licenses.[27]

IPRs were linked to the trade agenda, not just on the multilateral arena, but regionally and bilaterally via 14 free trade agreements entered into by the United States that extended the baseline intellectual property standards created by the TRIPS Agreement in favor of patent owners in various dominions, including the pharmaceutical industry, by means of pressure from the U.S. Trade Representative.[28] This post-TRIPS expansion was known as TRIPS-Plus[29] and for two decades now, international campaigns have been

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[26] Ha-Joon Chang, *Pateando la escalera. Estrategias de desarrollo económico desde una perspectiva histórica*, Mexico, Fundación México Social Siglo XXI, 2011.

[27] S. K. Sell, *op. cit*.

[28] U.S. Trade Representative, "1989 Special 301 Report", May 25, 1989, at *https://ustr.gov/sites/default/files/1989%20Special%20301%20Report.pdf* (date of reference: February 13, 2021).

[29] Samira Guennif and N. Lalitha, "TRIPS Plus Agreements and Issues in Access to Medicines in Developing Countries", in *Journal of Intellectual Property Rights*, vol. 12, no. 5, September 2007, 471-479; S. K. Sell, "TRIPS Plus Free Trade Agreements and Access to Medicines", in *Liverpool Law Review*, vol. 28, no. 1, April 2007, 41-75; David Vivas-Eugui, *Regional and Bilateral Agreements and a TRIPS Plus World: The Free Trade Area of the Americas (FTAA)*, Geneva, Quaker United Nations Office, 2003.

arguing that these higher standards of protection are to blame for an increase in prices and more limited access to patented products, reason why concerns have been raised regarding the expansion of the system through bilateral and regional free trade agreements with the United States or under pressure from the Special 301 Reports, which are essentially "black lists" of countries that have breached IPRs, published every year by the Office of the U.S. Trade Representative based on the suggestions of transnationals.[30]

Despite warnings of the threat they pose to public health, countries have continued to enter into free trade agreements with the United States because these are an opportunity to negotiate the substitution of removable preferential mechanisms with fixed quotas,[31] which effectively eliminates any discretionary aspects of access to the U.S. market. This has prompted numerous sectors not invested in this agenda to support changes to the IPR system that favor the petitions of the U.S.-based transnational pharmaceutical industry, turning it into an ally of such agreements.[32] The result has been trade dependence on the United States and the structure of the transnational and local pharmaceutical industries,[33] which determines internal coalitions.

An analysis of the structure of the transnational pharmaceutical industry in Mexico reveals that, in 1980, foreign companies accounted for 46 of the 50 main active industries, including the top ten, and three quarters of private sales.[34] However, in the 1985-2000 period, dependence on the U.S. market and levels of political trade dependence (*i.e.* trade conducted via the removable preferential mechanisms of the United States) was extremely high.[35] So when

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30 Special 301 reports for 1989 through 2020 can be consulted at the U.S. Trade Representative, "Special 301 Report", at *https://ustr.gov/issue-areas/intellectual-property/special-301* (date of reference: February 13, 2021).

31 The raising of import duties on steel and aluminum, and the determination of import quotas imposed on both Mexico and Canada during the Donald Trump presidency cast doubt on the purpose of the agreement to the extent that it made trade predictable.

32 K. C. Shadlen, *Coalitions and Compliance*...

33 For example, the number of domestic industries or their sales position compared to transnationals.

34 K. C. Shadlen, *Coalitions and Compliance*..., 97.

35 *Ibid*., 101.

the Office of the U.S. Trade Representative requested that Mexico reform its intellectual property laws as a prerequisite to the negotiation of NAFTA, exporters alien to this agenda—organized in associations like the Mexican Business Council for International Affairs (CEMAI)—, but interested in getting a foothold in the U.S. market, were willing to accept the reforms.[36]

Mexico reformed its intellectual property laws in 1991, but unlike in other countries such as Argentina, Brazil and Guatemala, it was a hushed affair. In April 1991, at a nighttime session, Congress passed the reform with no pressure whatsoever from local industry or transnational organizations. The package consisted of the provisions of the TRIPS Agreement plus retroactive patents and restrictions on compulsory licensing.[37] Granting retroactive patents meant increasing the number of patents issued by the State. The only concession to local industry was to maintain the protectionist strategy that applied to government procurement,[38] one of the few development tools States still have in their kit in the twenty-first century.[39]

The second wave: championing public health. The Doha Declaration

In 2000, due to the excessive price of antiretroviral drugs in South Africa imposed by transnationals, the WTO held a debate on the flexibilities of the TRIPS Agreement. Although these were stipulated in the Agree-

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36 *Ibid.*, 102.

37 While several countries asked to be allowed to produce patented products locally to avoid compulsory licensing, Mexico offered to comply with this requirement by importing these products instead of manufacturing them itself.

38 Local pharmaceutical industries supplied 70% of the purchases made by the Mexican Social Security Institute (IMSS) and the State Workers Social Security and Services Institute (ISSSTE). Mauricio de María y Campos, former undersecretary of Industrial Promotion in interview with Talia Rebeca Haro Barón, February 28, 2020.

39 Cristina Puga, *Los empresarios organizados y el Tratado de Libre Comercio de América del Norte,* Mexico, Faculty of Political and Social Sciences-UNAM/Miguel Ángel Porrúa, 2004; H.J. Chang and Antonio Andreoni, "Industrial Policy in the 21st Century", in *Development and Change*, vol. 51, no. 2, March 2020, 324-351, at *https://doi.org/10.1111/dech.12570* (date of reference: January 28, 2021).

ment, doubts persisted as to their use *vis-à-vis* local production and the importation of patented products to guarantee access to medicines. While the United States was in favor of restricting the use of flexibilities to HIV treatments for a specific period of time, other delegations, like the South African one, supported their indefinite use for all types of diseases, including AIDS, tuberculosis and hepatitis C. This was the version that made it into the Doha Declaration of 2001. Flexibilities included compulsory licensing, parallel imports (the option of importing a medicine from abroad without the consent of the patent owner) and the Bolar provision (which provides for the conducting of generic drug trials using a patented invention before the patent of the reference product has expired).[40] One question remained unanswered however: what about countries that had no local manufacturing capacity? This was resolved with the WTO decision on the "Implementation of Paragraph 6 of the Doha Declaration", which stipulated that countries with manufacturing capacity could use compulsory licenses to export to countries that had no such capacity. For example, Canada used a compulsory license to export its production of the antiretroviral TriAvir to Rwanda in 2007. The purpose of this set of instruments was to enable States to make use of TRIPS flexibilities to encourage more producers to enter the market, in compliance with international law. But although transnational campaigns touted it as a public health victory over IPRs, the Doha Declaration did not revert the original terms of the TRIPS Agreement (for example, it did not reduce the term of patents to ten years, nor did it eliminate patents on the product or the pharmaceutical process); rather, it reaffirmed areas where there was still room for maneuver.[41]

The international system incorporated flexibilities, but an essential step was implementing them on a country level, because this hung on internal coalitions. In Mexico, every attempt to make use of them was thwarted by transnational industry, represented by the Mexican Association of Pharmaceutical Research Industries (AMIIF), making it more difficult to take

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[40] OMC, *op. cit.*

[41] Nitsan Chorev, "Narrowing the Gaps in Global Disputes: The Case of Counterfeits in Kenya", in *Comparative Studies in International Development*, vol. 50, no. 2, May 2015, 157-186.

advantage of them. Even when no FTA was being renegotiated, Mexico ceded to threats that the negotiation of other agendas, like migration, would be jeopardized. During this second wave of reforms, three are particularly noteworthy: compulsory licensing, patent linkage and the introduction of the patent opposition mechanism. In 2002, in support of Farmacias Similares, a generic drug company owned by Víctor González Torres, the Green Party submitted a draft bill to the Chamber of Deputies for the reform of compulsory licensing in the event of a "serious disease".[42] The bill focused on reducing the duration of pharmaceutical patents to ten years, which contravened the 20-year term stipulated in Mexico's international obligations, set forth in both the TRIPS Agreement and NAFTA. The proposal was rejected, but it was not put to bed; instead, it was modified by the Science and Technology Commission.[43] The second version, inspired by the Doha Declaration, stated that if a disease was declared "serious" by the health authorities, a compulsory license could be granted via a simplified process that provided for the payment of royalties.[44] The proposal was not accepted by transnational industry, represented by the AMIIF, or the Office of the U.S. Trade Representative, or the patent offices of the United States and Europe.[45] The AMIIF warned local industries of the potential threat the proposal posed to investment in the country and received the backing of the Business Coordination Council (CCE). And even though it was not related to the negotiation of any trade agreement, Foreign Minister Jorge Castañeda Gutman—who was more interested in negotiating the migratory agenda—quickly caved in to pressure from the transnational industry. Nor was there any opposition from local industry, represented by the National Pharmaceutical Association of Mexico (ANAFAM), in this matter so crucial to the copying of innovative drugs.[46] And so a counterproposal was submitted, whose final version, approved

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42 Cori Hayden, "A Generic Solution? Pharmaceuticals and the Politics of the Similar in Mexico", in *Current Anthropology,* vol. 48, no. 4, August 2007, 475-495.

43 K. C. Shadlen, *Coalitions and Compliance*..., 76.

44 *Ibid.*, 177.

45 *Idem*.

46 The reasoning was that it would be easier to import antiretroviral drugs from India than manufacture them locally.

by then president Vicente Fox, made it harder to use compulsory licenses than it had been under the Intellectual Property Law of 1991.[47]

With regard to the linkage mechanism, the Special 301 Report of 2003 listed Mexico as a country in breach of IPRs on the grounds that it did not have such an instrument in place.[48] In the United States, where this mechanism is in operation, before approving a product, the health authorities are required to confirm with the patent office whether or not the product is patented and if so, grant market exclusivity so as to protect the patent owner. Mexico was not in breach of any international agreement, given that this mechanism was not required by NAFTA or the TRIPS Agreement; the Special 301 Report was simply a means of coercing it into adopting this legal concept, thereby extending its IPR system to the benefit of patent holders.

In September 2003, the Executive issued a decree incorporating the linkage mechanism into national law.[49] The original mechanism, devised in the United States, strikes a balance between protecting owners of knowledge and the public interest, *i.e.* it protects patent owners by linking the patent office and the health authorities, but it also includes a mechanism whereby other companies can litigate patents and, in the event they are invalidated (which generally happens in the case of secondary patents), all parties share the market. However, its implementation in Mexico, aside from being confusing, completely disregarded the public interest aspect: the patent office and the health authority were linked, but no patent litigation mechanisms were provided. The decree stated that the Mexican Industrial Property Institute (IMPI) was required to publish the patents it granted every six months in the *Gaceta de Medicamentos*, but these were not cross-referenced with the medicines they protected, meaning manufacturers of generics had no way of knowing when a drug entered the public domain.

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47 K. C. Shadlen, *Coalitions and Compliance*...

48 U.S. Trade Representative, "2003 Special 301 Report", May 1, 2003, at *https://ustr.gov/sites/default/files/2003%20Special%20301%20Report.pdf* (date of reference: February 12, 2021)

49 "Decreto por el que se reforma el Reglamento de Insumos para la Salud y el Reglamento de la Ley de la Propiedad Industrial", *Diario Oficial de la Federación*, September 19, 2003, at *http://www.ordenjuridico.gob.mx/administracion_1/DECRETO%20por%20el%20que%20se%20reforma%20el%20Reglamento%20de%20Insumos%20para%20la%20Salud.pdf* (date of reference: January 28, 2021).

Furthermore, since 2005, the IMPI had refused to include a growing number of patents, generally secondary ones (*i.e.* not patents on the active ingredient, but for secondary uses) in the *Gaceta*. The transnational industry took these decisions to the Federal Administrative Court, which ruled that secondary patents must be included in the *Gaceta*, thereby forcing the health authority to grant market exclusivity.[50] Local industry and health authorities like the Federal Commission for Protection Against Health Risks (Cofepris) subsequently filed multiple complaints, but the final decision fell to the Supreme Court, which, in 2012, ratified that secondary patents must be published in the *Gaceta*. The ruling was deemed a victory for transnational industry. It is estimated that, at the end of 2010, 20% of patented drugs on the Mexican market had their terms extended via this system.[51]

Finally, in light of the large number of patent applications granted due to permissiveness in the examination process, in 2009, a coalition in the Chamber of Deputies, spearheaded by the Institutional Revolutionary Party (PRI) and the Party of the Democratic Revolution (PRD), proposed incorporating an opposition mechanism, like the ones in place in India and Brazil, whereby third parties, such as members of civil society or universities could challenge a patent application filed with the IMPI before it is granted.[52] Under the proposal, the information provided by third parties would form part of the review process and become binding on the patent office. The AMIIF came out against the proposal, arguing that it would slow down the examination process, reduce the innovation rate and lead to new drugs

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[50] María Guadalupe Ríos Sánchez, *Análisis del sistema de vinculación entre las patentes farmacéuticas y los registros sanitarios en México,* Mexico, Master's thesis, UNAM, 2018, at *http://132.248.9.195/ptd2018/julio/0776084/Index.html* (date of reference: January 29, 2021); Hedwig Lindner, "Medicamentos genéricos y medicamentos patentados: una disputa no resuelta", in Arturo Oropeza García and Víctor Manuel Guízar López (cords.), *Los retos de la industria farmacéutica en el siglo XXI. Una visión comparada sobre su régimen de propiedad intelectual*, Mexico, Instituto de Investigaciones Jurídicas-UNAM, 2012, 327-350.

[51] K. C. Shadlen, *Coalitions and Compliance*..., 184.

[52] Senate, "Iniciativa con proyecto de decreto por el que se reforman y adicionan diversos artículos de la Ley de Propiedad Industrial que presentan los Senadores María de los Ángeles Moreno Uriegas, Carlos Lozano de la Torre y Ramiro Hernández García del Grupo Parlamentario del Partido Revolucionario Institucional", March 26, 2008, at *https://www.senado.gob.mx/64/gaceta_del_senado/documento/15655* (date of reference: January 29, 2021).

being withdrawn from the Mexican market.[53] These were the arguments the AMIIF used to garner the support of the industrial sector and the IMPI. The reform was passed, but because the evidence submitted by third parties was included as merely observational, it was not binding. These different examples show how public health reforms have been blocked by transnational industry, represented the AMIIF, allegedly to protect investment and innovation. Their cause has also found allies in embassies, the Office of the U.S. Trade Representative and even local businesses.

This tightening of the IPR system took place parallel to the extension of health coverage via the Seguro Popular (part of the IMSS-Oportunidades program).[54] Created in 2004, the Seguro Popular extended health coverage to expensive drugs protected by IPRs, starting with those used to treat diseases like HIV and later incorporating ones for hepatitis C and different types of cancer.[55] All the while, medicine prices continued to rise, to the point where Mexico became the OECD country with the second-highest spending on drugs as a percentage of total spending on health, and also as a percentage of GDP.[56] At the turn of the millennium, not much attention was paid to the relationship between IPRs and the price of medicines, but this changed in 2008 with the creation of the Commission for the Negotiation of Patented Medicines, the purpose of which was to negotiate lower prices by centralizing the purchases of all government health bodies. This policy was not intended to control prices or make use of any flexibility; its only goal was to use volume-based procurement to negotiate lower drug prices, although

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53 As regards the innovation rate, it should be added that 95% of all patent applications filed with the IMPI were submitted by foreigners and the remainder by Mexicans. These figures have not changed in the last three decades. Mexican Industrial Property Institute, *IMPI en cifras 2018,* Mexico, IMPI, 2019, at *https://www.gob.mx/cms/uploads/attachment/file/441198/IMPI_en_CIFRAS_enero-diciembre_2018_FINAL.pdf* (date of reference: January 29, 2021).

54 Marcos Cueto and Steven Palmer, *Medicine and Public Health in Latin America: A History,* New York, Cambridge University Press, 2014.

55 J. Frenk, E. González-Pier, O. Gómez-Dantés, M. A. Lezana and F. M. Knaul, *op. cit*.

56 Health Ministry, "Versión estenográfica de la Presentación de la Estrategia de Liberación del Segundo Paquete de Medicamentos Genéricos para el Ahorro de las Familias Mexicanas, llevada a cabo en el Auditorio 'Dr. Miguel E. Bustamante', de la Secretaría de Salud", November 16, 2011, at *http://www.salud.gob.mx/ssa_app/noticias/datos/2011-11-16_5474.html* (date of reference: January 29, 2021).

it should be noted the public sector only represents a fourth of the market, with the private sector accounting for the other three quarters.[57]

The third wave: implementation of the USMCA in Mexico

While the second wave was characterized by attempts to make public health-oriented reforms by the Legislature (whether in support of certain local industries or due to increasing pressure on the public expenditure budget), the following decade brought with it the expiration of the first patents after 20 years of protection. Both the TPP and the renegotiation of NAFTA were used as Trojan horses to incorporate new legal concepts for the protection of ground-breaking therapeutics like biopharmaceuticals[58] and to artificially prolong the term of that protection. For example, because preceding international legal instruments did not allow for the patenting of living cells (essential to the manufacture of biologics), both agreements managed to negotiate market exclusivity for biologics for a ten-year period (*i.e.* the protection of clinical trials for a specific period) or patents for new uses.[59] The final texts of these agreements illustrate just how influential the transnational industry is when it comes to positioning its interests, with countries like Mexico finding themselves cornered by their aspirations of negotiating other agendas, such as rules of origin.[60]

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57 P. Moïse and E. Docteur, *op. cit.*

58 The manufacture of biopharmaceuticals marks the third pharmaceutical revolution, initiated in the 1970s in the United States thanks to hefty investment in basic science by National Health Institutes (NIH), accompanied by a State-supported institutional and legal framework for the manufacture and marketing of drugs. Major biomed manufacturers include Genentech and Amgen. Manufactured using living organisms, these are high-tech drugs used to treat diseases that range from cancer and diabetes to multiple sclerosis. They include insulin, vaccines and some of the more innovative cancer treatments.

59 The clinical trial phase is one of the longest phases in the drug manufacturing process.

60 U.S. Trade Representative, "[Trans-Pacific Partnership] Chapter 18: Intellectual Property", at *https://ustr.gov/sites/default/files/TPP-Final-Text-Intellectual-Property.pdf* (date of reference: February 13, 2021); U.S. Trade Representative, "United States-Mexico-Canada Agreement", in *https://ustr.gov/tra-*

Notwithstanding, even more so than its negotiation or ratification, implementation of the USMCA was crucial for all actors, the AMIIF included.[61] To this end, clauses with international implications were discussed, but it was also an opportunity to address local conflicts that had been simmering for years. The outcome reflected a stronger industry whose structure had been a decade in the making. On the one hand, the first patents had expired in 2008, but the health authority (Cofepris) had refused to allow clinical trials using these products prior to this (*i.e.* the application of the Bolar provision), even though this exception was provided for in the Doha Declaration. This decision by Cofepris met with the support of the transnational industry,[62] but had become a subject of debate in the Senate and the Federal Commission for Economic Competition (Cofece), which had asked the health authority to allow trials so that generic drugs could enter the market as soon as the patents expired and avoid artificially prolonging the period of protection.[63] And on the other hand, even though international public health guidelines, including those published by the WTO, do not recommend secondary patents, the IMPI has adopted these as part of its internal guidelines.[64] It has been argued that these do not comply with the innovation standards

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de-agreements/free-trade-agreements/united-states-mexico-canada-agreement (date of reference: January 28, 2021).

61 Fernando Portugal Pescador, director of Intellectual Property at the Mexican Association of Pharmaceutical Research Industries, in interview with Talia Rebeca Haro Barón, July 2019.

62 Alejandro Luna Fandiño and Erwin Carlos Cruz Saldívar, "Legal Overview", in *México Health Review 2015*, Mexico, Mexico Business Publishing, 2015, 370-377.

63 Ministry of the Interior, Oficio a los integrantes de la Mesa Directiva de la Comisión Permanente del H. Congreso de la Unión sobre la aplicación de Cláusula Bolar, SELAP/300/1808/18, May 28, 2018, at *https://www.senado.gob.mx/sgsp/respuestas/63/2/2017-08-23-1/CP2R2A-6026_SEGOB_SALUD.pdf* (date of reference: January 28, 2021); Federal Economic Competition Commission, "Estudio sobre el comportamiento de precios y ventas de medicamentos que perdieron patente. Versión pública", January 13, 2017, at *https://www.researchgate.net/profile/Mariana_Barraza-Llorens/publication/322342159_Estudio_sobre_el_comportamiento_de_precios_y_ventas_de_medicamentos_que_perdieron_patente_Estudio_preparado_para_COFECE/links/5a66141aa6fdccb61c5a67c0/Estudio-sobre-el-comportamiento-de-precios-y-ventas-de-medicamentos-que-perdieron-patente-Estudio-preparado-para-COFECE.pdf* (date of reference: January 28, 2021).

64 Emelia Hernández Priego, director of Pharmaceutical Patents at the Mexican Institute of Industrial Property, in interview with Talia Rebeca Haro Barón, December 9, 2018.

of developing countries like Mexico, but with those of the United States and Europe, whose patent offices train the personal of developing countries in their standards. The implementation of the USMCA was an opportunity to put these conflicts to rest.

Over the course of a decade, State investment in science and technology has been channeled into local industries that push the technological envelope, giving rise to manufacturers of antiretroviral and oncological drugs.[65] In this regard, the State, through universities,[66] has guided locales industries like the Probiomed and Pisa laboratories toward compliance with standards for the manufacturing of biotech products.[67] Like government procurement, investment in science and technology is one of the strategies the State still has at its disposal to create local industries with added value.[68] So even though the negotiated text of the USMCA provided protection for clinical trials for a specific period, local industry rallied around and found allies in congress to block this clause, which would have hampered the entry of locally manufactured biopharmaceuticals on the market. The results were mixed: while the Federal Law for the Protection of Industrial Property of 2020[69] does not protect clinical trials for a given period, it does extend patentability to living organisms, which was prohibited under the Federal

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65 Mauricio de Maria y Campos, former undersecretary of Industrial Promotion, in interview with Talia Rebeca Haro Barón, February 28, 2020; Juan de Villafranca, director of the Mexican Association of Pharmaceutical Laboratories (AMELAF), in interview with Talia Rebeca Haro Barón, July 2019.

66 These include the Biotechnology Institute at the National Autonomous University of Mexico (UNAM), the Preclinical Research Unit at the UNAM's Faculty of Chemistry, and the Bioprocesses Research and Development Unit at the National Polytechnic Institute's (IPN) School of Biological Sciences.

67 Néstor Pérez, Operations Director, Laboratorios Probiomed, in interview with Talia Rebeca Haro Barón, May 10, 2020.

68 H.-J. Chang and Antonio Andreoni, "Industrial Policy in the 21st Century", in *Development and Change*, vol. 51, no. 2, March 2020, 324-351, at *https://doi.org/10.1111/dech.12570* (date of reference: January 28, 2021).

69 This is the law for the enforcement of the IPR chapter of the USMCA.

Industrial Property Law (LFPI) of 1991 and by TRIPS.[70] This was a win for transnational industry.

The outcome of these conflicts is laid down in the USMCA signed by the Mexican Senate and implemented via the Federal Law for the Protection of Industrial Property of July 2020. Opposition to the IPR chapter of the USMCA initially came from the Senate's Health Commission, headed by the National Regeneration Movement (Morena). Some Democrats in the United States even alerted their Mexican counterparts to the threat a tighter IPR system would pose to public health. The fact that it was a closed-door debate only fueled speculation. In the final version, patentability was extended (to new uses and living organisms used in the manufacture of biologics); the term of patents was artificially prolonged to compensate for delays by the patent office;[71] local laws like linkage were elevated to international status; the proposal to provide protection for clinical trials for a specific period was rejected; and results for the use of the flexibilities provided for in the Doha Declaration were ambivalent (for example, the use of the Bolar provision was explicitly reaffirmed, but parallel imports were rejected).

Conclusions

Public and private entities are racing to manufacture vaccines, medicines and other technologies to combat the COVID-19 syndemic, but while these have benefits for society at large, it is private parties that benefit exclusively from the production of certain drugs in the United States, like those used to treat rare diseases and vaccines.[72] One of the questions left up in the air is whether these anti-COVID-19 technologies will be a global public good

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70 Federal Law for the Protection of Industrial Property (new law, July 1, 2020), in *DOF,* July 1, 2020.

71 Maribel Ramírez Coronel, "¿Qué negociaron por atrás los senadores?", *El Economista*, June 29, 2020, in *https://www.eleconomista.com.mx/opinion/Que-negociaron-por-atras-los-senadores-20200629-0010.html* (date of reference: January 28, 2021); Federal Law for the Protection of Industrial Property (new law, July 1, 2020), in *DOF*, July 1, 2020.

72 Mariana Mazzucato, *The Entrepreneurial State. Debunking Public vs Private Sector Myths,* New York, Public Affairs, 2015; Fred Block and Matthew R Keller, *Where Do Innovations Come From? Transformations in the U.S. Economy, 1970-2006*", Tallinn, Other Canon Foundation/Technology

or if they will come under the protection of intellectual property rights. This depends on who answers the question—the country financing the technology or the company. Regardless, certain countries, anticipating mass local production of these technologies, have streamlined procedures for the use of the compulsory licensing flexibility of the Doha Declaration. With a view to providing universal access to vaccines, Mexico has adhered to the multilateral COVAX mechanism, entered into purchase agreements with various foreign companies and received several Phase III clinical trials. In the short term at least, vaccines will be imported, not produced locally.[73] No debate has arisen regarding the use of flexibilities to encourage their manufacture locally or import them from a third country (without the consent of the patent owner). Silence reigns on this issue, even though the USMCA came into force in the full throes of the COVID-19 syndemic. In the long term, however, the issue of access to these technologies must surely prompt us to reflect on the broader questions of how the IPR system has been implemented in Mexico's pharmaceutical sector over the last three decades, how this has impacted public health and the county's industrial policy in this strategic sector.

Governance Program at Tallinn University of Technology (Working Papers in Technology Governance and Economic Dynamics, 35).

[73] Initiatives by the UNAM Biotechnology Institute and other higher education institutions for the production of the vaccine are barely at the first phases of development.