Roundtable Report

Promoting Objective Academic Research on IP and the Life Sciences in Mexico

August 2023

About this report

Fundación IDEA and *Tecnológico de Monterrey Campus Ciudad de México*, collaborated with Geneva Network and the University of Akron´s Center for IP & Technology Law (UAIP) in the development of the Roundtable "Promoting Objective Academic Research on IP and the Life Sciences in Mexico".

The Roundtable is part of a joint project to improve and re-balance the scholarly and policy debate regarding intellectual property in the life sciences worldwide and build a global network of scholars and policy experts focused on IP and the life sciences to encourage better, more rigorous, fact-based research, to socialize new ideas, and to develop new policy proposals about IP and life sciences issues.

In that regard, **this Report assembles the main points of discussion and findings** from the Roundtable held in Mexico City on August 8th, 2023, in Mexico City.

Fundación IDEA

It is a Mexican non-profit, independent and non-partisan organization, whose mission is to generate knowledge and provide technical assistance to public and private to public and private organizations in the implementation, design, evaluation, and analysis of public policy. It operates under a think-and-do a think-and-do-tank model.

Tecnológico de Monterrey

It is a non-profit institution, for society and by society, an unprecedented effort of private initiative in Mexico. *Tecnológico de Monterrey* has transformed the lives of thousands of people who have been and continue to be agents of change in their organizations, communities, and the environment where they live."

Geneva Network

It is a research and advocacy organization focusing on international innovation, trade, and development policy. Our main objectives are, conducting original research, explaining complex policy issues in the media and providing a platform for discussion between experts, opinion leaders and policymakers. We work with think tanks, scholars, and opinion leaders from all over the world.

University of Akron

Our mission is to promote justice, the protection of individual liberty, and the rule of law through our commitment to excellence in teaching, scholarship, and service, and through our continuing commitment to expanding opportunities for legal education. Akron Law's commitment to this mission and our students' success is furthered by an outstanding faculty of leading scholars, teachers, and practitioners, who are

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First Section: Roundtable Overview

The Roundtable gathered 22 national and international researchers, policy experts, and industry representatives to discuss key life sciences innovation challenges in Mexico. The main objectives of the Roundtable were:

- Develop a stronger fact-based understanding and share approach among participants for expressing in their work the importance of intellectual property rights to life sciences innovation and access to medicine, and;
- Address the need to convert scholarship into relevant, compelling policy work that directly improves the Industrial Property (IP) policy debate.

The Roundtable comprised three sessions:

- Session one: The importance of effective IP institutions to innovation in Mexico
- Session two: The role of the IP system and institutions to develop Mexico's innovative industries, and
- Session three: Importance of the effectiveness and efficiency of the pharma and regulatory sector to the development and access to medicines.

Each session was led by a moderator who guided the discussion based on questions taken out of several readings provided to the participants with anticipation. To encourage inclusive and an open dialogue, the Roundtable was held under the Chatham House Rule.

Second Section: Roundtable Takeaways

Session 1: The importance of effective IP institutions to innovation in Mexico.

The first session addressed institutional barriers to innovation in the field of intellectual property. The main lines of discussion focused on the asymmetries between small and medium-sized companies, entrepreneurs, researchers, and the government; the challenges involved in the social perception of IP; and some good practices that can be implemented to circumvent these problems.

Challenges

Firstly, participants identified the disengagement between small and medium-sized companies, entrepreneurs, researchers, and the government, participants identified two central problems: **lack of trust** and **institutional design**. Concerning the first point, participants pointed out that researchers and authorities are reluctant to collaborate to translate research into innovation because researchers do not have certainty about the protection of their research when cooperating with the government. In this regard, they mentioned that the new Science and Technology Law establishes that the government will control all research projects funded with public resources, which takes away the agency capacity of researchers to identify innovation opportunities. In addition, the substantial reduction in public funding for research has incentivized a decline in the number of projects developed among researchers.

Concerning the second point, participants agreed that the current institutional arrangement leaves innovation aside, as it encourages researchers to publish articles or participate in conferences presentations, but not to transform research into patents. Participants mentioned that only one National Health Institute in Mexico has a project incubator to enhance innovation, and although the mechanism works, it cannot effectively gather researchers and funds to foster research into patented medical technology.

A final point regarding institutional design is that the high turnover of officials in the government offices in charge of IP makes it impossible for researchers or innovators to follow up on their projects in the long and medium term, especially in the Technology Transfer Offices in public universities or research centers.

Second, cultural perception of IP acts as a barrier to its extensive usage by entrepreneurs, researchers, and society because it's conceived as a legal requirement and not as a tool that can generate value to their business. Participants also agreed that a problem in this sector is that small and medium-sized companies and entrepreneurs are more concerned with strengthening “key areas” of their businesses or developing strong business models that can assure them income then protecting their innovations because IP is perceive as a cost. In this regard, participants suggested that there should be more incentives to reduce the

costs of generating patents and programs that foster education people in the field to increase the value of IP for innovation.

Finally, participants acknowledge the importance of addressing these challenges in IP because they hinder innovation at a crucial moment for Mexico and Latin America. It was mentioned that the region raised about fourteen billion dollars in the last fifteen years to finance startups, suggesting that in the next 30 years there will be the need to collect between 20 and 30 trillion dollars to finance innovative startups. In this matter, participants highlighted that Mexico is a privileged country because it has the largest domestic market in Latin America. Therefore, Latin American innovators and research centers seek collaboration with Mexico to generate business strategies. In that sense, they agreed that it is important that Mexico´s intellectual property protection ecosystem is prepared to take advantage of the commercial opportunities that the coming years present.

Best practices

Participants identified three solutions to increase trust between researchers and the government to promote collaboration among stakeholders by correcting institutional design.

- Concerning best practices, participants identified two models to follow. The first is the **collaborative model**, which seeks to remedy the lack of cooperation between the academia and the government to translate research into innovation. Specifically, this model implies that institutions play a proactive role in seeking innovation opportunities and go out to find researchers to accompany them in the process of patenting, branding, and commercialization of the product. A clear example is *Science Connexion* of the Tecnológico de Monterrey, which functions as an innovation platform that identifies potential opportunities and assists researchers during the innovation process. The collaboration of Latin American and Mexican universities with Tecnológico de Monterrey also stands out in this point, as it uses its innovation platform to support the technology transfer process to other institutions and commercialize its products in the Mexican market.
- The second is **product-oriented innovation**, which overcomes the problem of lack of institutional support. In this model, innovators focus on creating products to commercialize and not in the development of technologies. This is important for the Mexican context because the lack of governmental support makes it difficult for start-ups to spend a long time in the development phase. Thus, with product-oriented innovation, innovators subsist on their own because they manage to commercialize their products in less time.
- In addition, participants were in favor of creating a network that allows researchers, entrepreneurs, industry, and legal representatives to come together and work on possible solutions to IP issues. Participants agreed that such a network would allow all interested parties to create an ecosystem of collaboration that vanishes the current lack of trust.

Picture 1: Participants during Roundtable's sessions

Session 2: The role of the IP system and institutions to develop Mexico's innovative industries.

The second session dealt with the challenges of the IP system and regulatory institutions in Mexico for innovation in the health sciences sector. The main idea of this session was to identify and propose solutions to the current challenges to allow Mexico to become a stronghold for innovation in the health sciences sector.

Challenges

The main problem identified is the obstacle posed by the regulatory sector to innovation in the Health Sciences sector in Mexico. Participants agreed that there are two major problems, the first issue is the **limited technical capacity** of government officials, and the second is the **regulatory process for new drugs.**

Participants acknowledge that the innovation process in health sciences is affected by the flaws of technical capacity among government officials who work for intellectual property institutions, who lack capacity building schemes and face a continuous turnover. This is a problem because it makes it difficult to implement innovative pharmaceutical regulatory schemes that promote health sciences research while minimizing the risk inherent in research.

Secondly, when it comes to the regulatory process for new drugs the current process delays the approval of new medicines and hinders innovation in this sector. Concerning this matter, participants pointed out the lack of coordination between the boards of the National Institutes of Health and the Federal Commission for the Protection Against Sanitary Risks (COFEPRIS), when the researcher obtains approval from the internal boards, COFEPRIS slows down the process of obtaining research permits with requirements that the researchers have already submitted before.

Participants agreed that both issues are the perfect storm as the lack of technical knowledge by government officials affects an effective regulatory process for the approval of new drugs.

Best practices

Participants identified three possible solutions to foster technical knowledge for government officials and achieve a more effective regulatory process.

- The first possible solution is based on the experience of the Food and Drug Administration (FDA) regarding the development of **clinical trials in collaboration with industry**. This promotes innovation because the regulatory agency adapts the timing or requirements of clinical trials to the specifications of each new drug. In this way, the

United States can approve new drugs in record time; for example, new cancer treatments are approved 10 months earlier than in Europe.

- The second good practice of the FDA is that it **modifies the duration of the patent according to the time of the clinical trials**. In this way, the regulatory agency can carry out exhaustive tests on new treatments without this representing a loss for the company because it has less time to market its product.

- The third good practice is aimed at addressing the lack of technical capacity of Mexican regulatory authorities. This practice is focus in **promoting international cooperation to acquire training**. Participants emphasized that an applied example is **TEC 21 Model** of the Tecnológico de Monterrey which encourages collaboration between hospitals in Monterrey, Mexico and Houston, Texas. Originally the model began working with nurses from two cities, but the model has grown to encompass collaboration between doctors and researchers to increase the transfer of technical knowledge between the two cities. It was comment that the model could be expanded to include regulatory authorities obtaining technical expertise from their U.S. counterparts.

Picture 2: Participants during Roundtable's sessions

Session 3: Importance of the effectiveness and efficiency of the pharma and regulatory sector to the development and access to medicines.

The third session dealt with the obstacles to innovation posed by the lack of efficiency of Mexican authorities in regulating the pharmaceutical sector. Specifically, the participants identified three problems that will be detailed in the following paragraphs: **international obligations**, **national obligations**, and **perception of regulation.**

Challenges

Regarding Mexico's **international regulatory obligations**, participants mentioned two issues. The first is the obligations derived from the Free Trade Agreement between the United States, Mexico, and Canada (USMC) which requires that Mexico complies with its obligations before the renegotiation of the treaty in 2026. However, industry perception is that the Mexican government might not comply the obligations and will be sanction. The second problem is the inclusion of U.S. patents in the IP Gazette because the Mexican Institute of Industrial Property (IMPI) does not automatically add U.S. trademarks to it. Consequently, foreign trademarks must challenge this decision in the legal system. The underlying problem is that resorting to the legal system implies a waste of time and resources that makes it difficult for U.S. companies to operate in Mexico.

Concerning **national obligations**, the source of discord is the lack of coordination between IMPI and COFEPRIS to sanction patent violations. The issue stems from the fact that the technical capacity to define a patent violation resides within IMPI, but the technical capacity in the pharmaceutical sector is in COFEPRIS; therefore, these two institutions collaborate. The second problem lies in that as of 2018 the government defined a conflict of interest to include industry-related experts in COFEPRIS technical committees. Consequently, these committees experience a deficiency of capacity and function with a lack of transparency.

Lastly, the differences in the **narrative between pro-access and pro-innovation**. In the Mexican context, society perceives prioritizing access to medicines or innovation by pharmaceutical companies as opposites. This false dichotomy hinders the implementation of a regulatory framework that protects IP and promotes innovation.

Best practices

Participants identified two solutions to increase Mexico's regulatory capacity in the pharmaceutical sector and to reduce the tension between access and intellectual property protection in the drug regulatory process.

- The first is Mexico's intention to **seek technical guidelines on regulation in Europe**. It is important to mention that Mexico cannot adopt European standards on IP protection, however proposing to adopt those standards is a roadmap to follow.

- Another good practice discussed was the **Bollard clause** that allows pharmaceutical companies to start developing the studies necessary to approve a generic drug before the patent expires. This good practice is important because it balances the conflict between pro-access and pro-innovation. Just as the Bollard clause is a good practice to favor access to medicines, it is vital to adapt the regulatory framework to favor innovation too.

Picture 3: Participants during Roundtable's sessions

Third Section: Next Steps

Participants celebrated the Roundtable initiative as the three sectors —academia, industry, and civil society— together for dialogue. They agreed that the fora provided a perfect opportunity to discuss intellectual property and innovation prospects in Mexico and to examine the actions that can be taken to address the regulatory challenges, technology transfer, and cooperation in the national pharmaceutical sector.

Finally, the experts explicitly expressed their intention to continue with this initiative that promotes dialogue and cooperation in the life sciences innovation sector, as well as their willingness to participate in future events.

Picture 4: Participants at the end of the Roundtable

Annexes

Annex 1. Roundtable Agenda

Date: August 8, 2023
Place: Library Room 201, Tecnológico de Monterrey, Mexico City Campus

Time	Description
08:30 – 9:00	**Registration**
09:00 - 10:00	**Welcome word and working session instructions.** **Format:** Working breakfast
10:00 – 11:00	**Discussion Session One: The importance of effective IP institutions to innovation in Mexico.**
11:00 – 11:15	*Break*
11:15 – 12:15	**Discussion Session Two: The role of the IP system and institutions to develop Mexico's innovative industries.**
12:15 – 12:30	*Break*
12:30 - 13:30	**Discussion Session Three: Importance of the effectiveness and efficiency of the pharma and regulatory sector to the development and access to medicines.**
13:30 – 13:45	*Break*
13:45 – 14:30	**Conclusion and research proposals**

Annex 2. Relevant data

Attendees by Organization

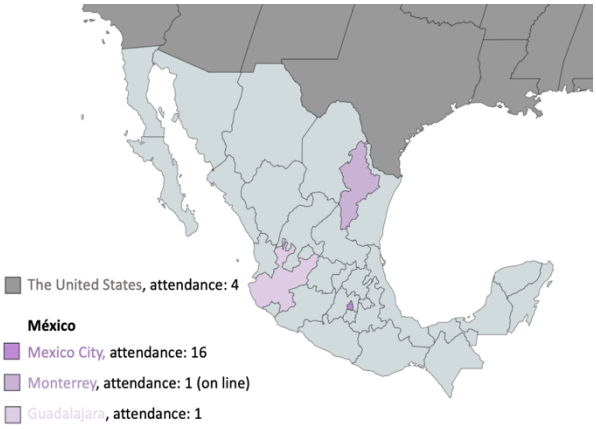
The Roundtable brought together 22 national and international researchers, policy experts, and industry representatives. The participation of *Tecnológico de Monterrey,* and the University of Akron was noteworthy at the event.

By Origin of attendance

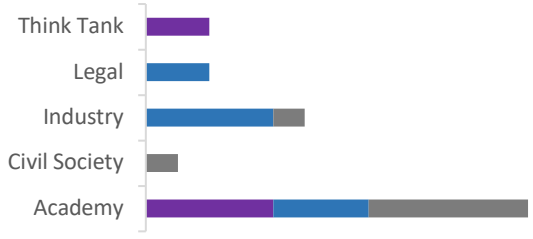
Four foreign experts and 18 national experts participated in the event.

- Of the foreign participants, three attended in person and one online.
- Of the national participants, 17 attended in person and one online.

National experts attended from Mexico City and from innovation and development hubs in the country, such as Monterrey and Guadalajara.



By Area of Expertise



In addition, the experts belonged to academia; civil society or Think Tanks; Industry or Legal sector. This allowed for a multidisciplinary discussion because the participants were experts in the areas of innovation, Intellectual Property and Life Sciences.

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