Webinar:

EXPLORING INTELLECTUAL PROPERTY ADVANCEMENTS WITHIN USMCA:

WHAT LIES AHEAD FOR BOOSTING MEXICAN INNOVATION CAPACITY?

About this report

Fundación IDEA, Geneva Network, and Akron University, in collaboration with Basham, Ringe y Correa, S.C., and Asociación Mexicana de Industrias de Investigación Farmacéutica, A.C. (AMIIF), held the Webinar: ***"Exploring Intellectual Property Advancements within USMCA: What lies ahead for boosting Mexican innovation capacity?"***.

This event provided a dialogue space to identify and communicate the main challenges of the Mexican intellectual property system and compliance with Chapter 20 of the Treaty between Mexico, the United States, and Canada (USMCA). Similarly, it analyzed how gaps in this area could affect the potential for innovation and the attraction of investments in the life sciences sector in Mexico.

This report gathers the main ideas and findings generated during the Webinar held on June 6, 2024, via Zoom.

Fundación IDEA

It is a non-profit, independent, non-partisan organization whose main mission is to generate knowledge and provide technical advice to public and private organizations in the implementation, design, evaluation, and analysis of public policies. It operates under the think-and-do-tank model, meaning it engages in both the planning and implementation of ideas.

Geneva Network

It is a research organization focused on innovation, international markets, and development policies. Our main objectives include original research development, explaining complex public policy issues in the media, and providing a platform for discussion among experts, opinion leaders, and policymakers. We collaborate with think tanks, academics, and opinion leaders from around the world.

Universidad de Akron

Our mission is to promote justice, protect individual freedom, and uphold the rule of law through our commitment to excellence in teaching, scholarship, service, and our ongoing dedication to expanding opportunities for legal education. The University of Akron School of Law's commitment to this mission and to our students is strengthened by a distinguished community of faculty and scholars in leadership roles.

Basham, Ringe y Correa
It is one of the leading full-service legal firms in Latin America. Established in 1912, Basham has over a century of experience assisting clients in Mexico and abroad, founded on principles of ethics, quality, and professionalism.

La Asociación Mexicana de Industrias de Investigación Farmacéutica (AMIIF)
It represents more than 60 Mexican companies - both national and international with local and global presence - leaders in pharmaceutical research and biotechnology, medical devices, and clinical research. These companies are committed to developing new drugs and therapeutic options aimed at curing or altering the course of diseases, improving quality of life, and in some cases, enhancing survival chances against diseases that seriously threaten not only people's lives but also their relationships with work, family, and community.

We also appreciate the participation of the Asociación Mexicana para la Protección de la Propiedad Intelectual, A.C. (AMPPI), who collaborated in the event by providing final remarks summarizing the key points shared by the panelists.

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First Section: Panel dynamics

The panel showcased a wealth of expertise, with professionals from diverse fields such as public service, academia, public policy, research, chemistry and pharmaceuticals, intellectual property consulting, patent law advocacy, and international treaty negotiation.

The panelists presented their views on the current intellectual property situation in Mexico. They also reflected on the challenges and next steps to strengthen this field and promote an innovation ecosystem.

The webinar's primarily objectives were:

- Discuss Mexico's main advancements within the framework of the USMCA.
- Identify Mexico's pending tasks related to its commitments under the USMCA and the challenges in implementing institutional mechanisms to address these commitments.
- Reflect on the importance of intellectual property rights in scientific and social development.

The webinar was skillfully moderated by a facilitator who guided the discussion based on a comprehensive policy brief. This document provided a detailed report on Mexico's context and outlined the necessary actions to harness our country's technological potential in terms of innovation. Notably, the policy brief was shared in advance with the audience to establish a common ground of understanding and promote an open and inclusive dialogue.

Figure 1: Panel of experts at the Webinar

Second Section: Context, findings and thematic axes

This section consists of the following components: Initially, it provides **contextual information** that highlights the topic's relevance in alignment with the policy brief. Next, it presents **critical findings** based on questions posed by the moderator and the panelists' presentations. These findings are categorized and grouped into **thematic axes** to facilitate analysis. Finally, a **conclusion** synthesizes the significant ideas discussed during the panelists' interventions.

2.1 Context

Before the current regulatory framework, Mexico, the United States, and Canada ratified the North American Free Trade Agreement (NAFTA) in 1994. NAFTA included definitions and general regulations for the protection of intellectual property rights. This was part of its mission to establish a free market for exchanging ideas and technology among the three countries. These definitions encompassed points such as the concept of trademarks, the rights of use and registrability, and regulations on registration procedures, exceptions, and durations, among others[1] (Rosas 2003). This translated into modifications to the regulations in Mexico, such as the reform of the Industrial Property Law and the issuance of the Federal Copyright Law[2] (García 1998).

In 2020, Mexico, along with the United States and Canada, reached a new agreement, the Treaty between Mexico, the United States, and Canada (T-MEC). This modernization of NAFTA provides security and certainty for future investments and strengthens the regional market by including rules that protect SMEs, the environment, and labor rights. Mexico, as a key player in this agreement, is at a crucial moment and must take steps to attract investments in innovative and high-value industries, particularly in the life sciences sector. By strengthening its intellectual property framework, Mexico can create a more conducive environment for innovation and position itself as a leading destination for cutting-edge technology and research

Six years after the entry into force of the T-MEC, Mexico has made advances in intellectual property standards and regulations. This has been critical for developing technological markets and has driven progress in research, science, and innovation throughout the country. However,

[1] Rosas, Roberto (2003). *Las marcas en el Tratado de Libre Comercio de América del Norte.* Recovered from: https://www.scielo.org.mx/scielo.php?script=sci_arttext&pid=S0041-86332003000200008
[2] García, Victor (1998). *El Capítulo XVII Del TLCAN y su influencia en la Nueva Ley Mexicana Del Derecho De Autor*. Recovered from: https://archivos.juridicas.unam.mx/www/bjv/libros/1/164/9.pdf

there are still challenges regarding implementation, regulation, and norms to fulfill international commitments. Mexico can address these gaps by implementing its obligations under the USMCA on intellectual property (IP) and regulatory issues. Establishing an effective enforcement system for pharmaceutical patents under Article 20.50 and Annex 20-A of the USMCA is a priority in IP.

Protecting intellectual property rights is essential for maintaining a secure market for innovation, especially in industries like medicine and life sciences. Additionally, it provides an attractive environment for investment, strengthens economic development, and drives technological advancement in Mexico.

2.2 Findings and thematic axes

A. What have been Mexico's advances in implementing the USMCA regarding innovation and intellectual property? Also, what is the current situation regarding commitments under the USMCA?

The speakers' observations focused on four main axes:

- **Regulations for implementing the provisions of the USMCA on intellectual property**
  Intellectual property serves to achieve development, requiring clear rules that provide certainty to businesses and investors. After the USMCA negotiations, Mexico implemented 50% of the required provisions in its Intellectual Property System concerning:
  - Transparency
  - Cooperation in patent matters and shared work (e.g., Patent Prosecution Highway)
  - Patent revocation
  - Patent rights exceptions
  - Modifications, corrections, and observations
  - Publication of patent applications
  - Information on published patent applications and granted patents

  The remaining 50% required either amendments to national legislation (25%) or the creation of new regulations (25%).

- **Supplementary certificate and compensation for delays**
  In Mexico, industrial patents have a validity period of 20 years, starting from the grant of the patent by the Mexican Institute of Industrial Property (IMPI in Spanish). This period includes the entire processing period, extending up to five years. Due to this, the Federal Law on Protection of Industrial Property allows for issuing supplementary

certificates in cases where processing takes more than five years due to delays by the authority.

IMPI determines the processing time, excluding days of reasonable delays. Reasonable delays include actions attributable to the applicant, periods not attributable to actions or omissions of the institute, force majeure reasons, and others. Suppose the processing time exceeds five years after deducting reasonable delays. In that case, a supplementary certificate may be issued with a validity period of one day for every two days of unreasonable delay. This certificate comes into effect automatically after the patent expires 20 years later, grants the same rights, and is subject to the same limitations and obligations as the original patent. It is important to note that this regulation only applies to applications filed after the new law.

- **Protection of clinical data**

  One of the most crucial stages in the pharmaceutical development process is clinical trials, which ensure a drug's safety for consumption. Under Mexican legislation, for a new product to be authorized for commercialization, developers must present their tests and evidence within the patent application process. The regulations on the protection of clinical data aim to prevent practices where developers use shared data, presenting results from testing other biosimilar drugs. This can pose risks to consumers since two biosimilar drugs may have completely different adverse effects due to manufacturing differences.

  Mexican legislation has already incorporated this norm into the Federal Law on Protection of Industrial Property and in NAFTA. Additionally, within the new framework of the USMCA, rules have been updated to establish minimum protection periods for clinical data for different types of drugs. These include a three-year protection period for previously authorized products covering a new indication, five years for new products, and ten years for pharmaceutical products containing a biological component.

- **Bolar Clause**

  This clause refers to the historic Roche-Bolar case in the United States. This dispute arose from the unauthorized use of a patented drug in clinical trials to develop a biosimilar. The drug's patent was set to expire one year later, prompting the patent holder to sue for improper commercial use of their product. This case sparked a discussion on patent rights legislation and how such situations impact the early development of biosimilar generics.

  In Mexico, this concept is embodied in the Federal Law on Protection of Industrial Property, which allows third parties to conduct testing and experimental studies on

patented products throughout their term of validity. This facilitates and accelerates production and supply processes within the pharmaceutical market while promoting free market competition for medicines within the public domain.

B. What are the challenges for Mexico in terms of implementation?

The speakers' observations focused on three main axes:

- **Compensation for unreasonable delays**
  As mentioned earlier, Mexico already has a system that allows for extending the validity of a patent in cases of unjustified delays. However, there is potential to strengthen this instrument by offering other forms of compensation to developers affected by such delays. Different countries have implemented compensation systems; for instance, the United States has a Patent Term Extension system that adjusts the patent's validity period. Canada provides this compensation through a sui generis system that grants market exclusivity. Mexico could evaluate both systems, considering their advantages and disadvantages, as a reference for future modifications to current regulations. Additionally, institutional mechanisms could be encouraged to expedite application processes.

- **Discussion on the use of clinical data**
  The shared use of clinical data could significantly shorten the regulatory approval process for generic drugs. The processing time can vary considerably depending on the type of molecule under development. Therefore, different protection periods were considered for different types of molecules. Experts point out that a balance must be struck between protecting clinical records and using them for accelerated development. This balance ensures that ethical aspects, such as the need to avoid repeating examinations and clinical trials of biochemicals that have already been tested, are carefully considered and respected, providing reassurance about the moral integrity of the proposed changes.

- **Protection of cultural assets**
  One of the pending issues within regulation is the implementation of norms that protect the ownership of cultural and collective assets. Certain pharmaceutical products derive from raw materials from indigenous communities' herbal knowledge. Often, there needs to be more social or market recognition of these communities' contributions to scientific

research. In this context, it could be relevant to incorporate cultural and collective origin issues into the discussion on intellectual property in Mexico.

- **Promoting innovation and national scientific development**
  There is significant potential for innovation and technological development in Mexico. The country has achieved notable scientific and technological advancements in recent years. However, there remains a gap between the business sector and the scientific community, which has prevented fully harnessing this potential within the national market. Only about 3.5% of registered patents are held by Mexican citizens[3] (IMPI 2024). Furthermore, there is a gender gap within the industry, as in 2021, only 34% of trademark applications were filed by women, while 14% of invention applications were exclusively filed by women[4] (AMIIF 2022). It is crucial to bridge these gaps and promote innovation and national scientific development, inspiring and motivating all stakeholders to contribute to these important goals.
  Harmonizing intellectual property rights legislation provides a secure and accessible space for innovation. A joint effort among academic, governmental, and private entities is essential to channel these capabilities and use these advancements as instruments for social development.

Imagen 2: Panel of experts with the online audience

[3] Instituto Mexicano de la Propiedad Industrial (2024). *IMPI en Cifras.* Recovered from: https://www.gob.mx/impi/documentos/instituto-mexicano-de-la-propiedad-industrial-en-cifras-impi-en-cifras

[4] La Asociación Mexicana de Industrias de Investigación Farmacéutica (2022). *Las mujeres usan menos el sistema de propiedad intelectual que los hombres.* Recovered from: https://amiif.org/las-mujeres-usan-menos-el-sistema-de-propiedad-intelectual-que-los-hombres/

Third Section: Conclusions

Mexico has a solid regulatory framework regarding intellectual property rights, built upon previous international treaties such as the Trans-Pacific Partnership (TPP) and NAFTA and through laws like the Federal Law of Intellectual Property Protection. However, there is still room for improvement to further advance in this area, which would primarily benefit the technology sector and the development of science and innovation.

The USMCA provides critical guidelines for strengthening the regulatory framework. Many of Mexico's commitments under this treaty have already been fulfilled, such as establishing a system that guarantees patent term extensions as compensation for unjustified delays, clear timelines for clinical data protection, and permissions for early research of biosimilars under the Bolar clause. These advancements have created a secure space for developing new ideas and an attractive investment market.

Nevertheless, challenges exist in economic and social growth. For instance, a more advanced system of compensation for delays could further benefit the technology sector. Looking at models such as those in Canada and the United States could provide adequate references to adapt to the Mexican context. Advancing discussions on clinical data protection is also necessary to balance safeguarding this data and optimizing processing times without compromising fair market competition.

It is of utmost importance to recognize the contributions of communities in the origin of raw materials that lead to new biochemicals and pharmaceuticals. Therefore, clear and robust regulations are needed to protect the collective rights of these communities over the intellectual property of such drugs. This will ensure fairness and equity in the intellectual property system.

Lastly, it is crucial to emphasize the need for comprehensive efforts in designing and implementing public policies that protect intellectual property rights across all areas of science and innovation. This holistic approach can encourage broad participation from all sectors of the population in the continuous development of new ideas, ensuring that intellectual property rights are respected and upheld.

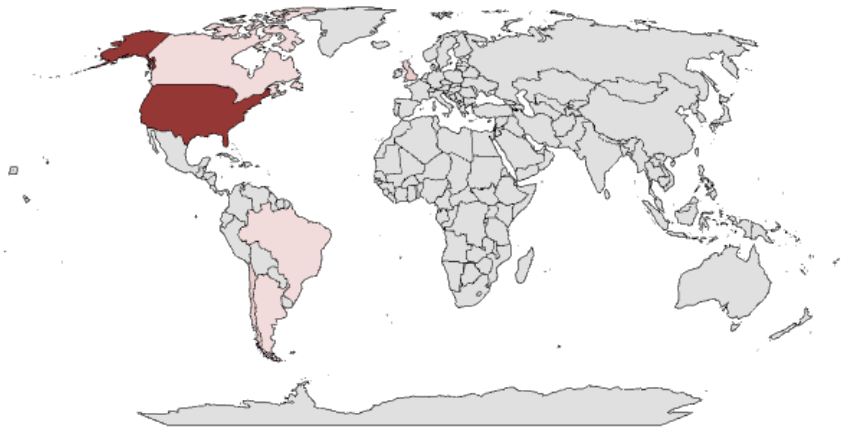
Annexes

Annex 1. Relevant Data about the *Webinar*

Within our audience, we had participation from 53 attendees from 8 countries across the Americas and Europe. The majority of our international audience joined us from the United States, Chile, and the United Kingdom.

Graph 1: Attendance by country of origin

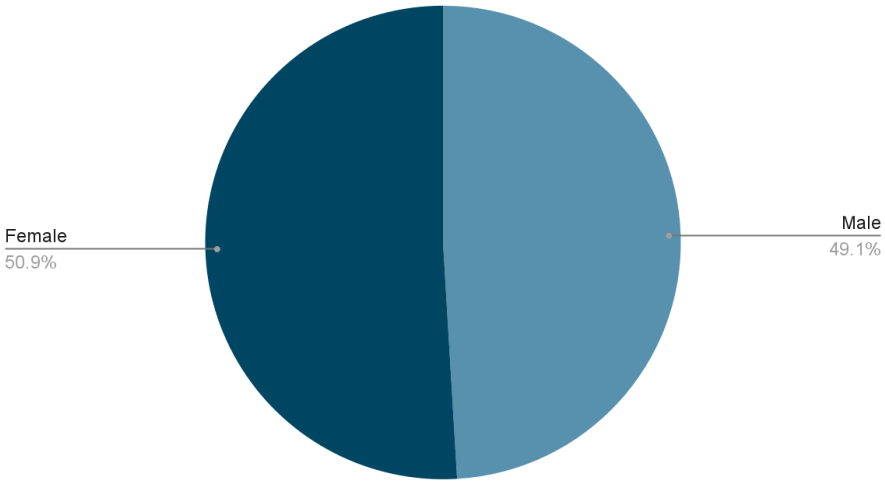
Argentina: 1 attendee
Belgium: 1 attendee
Brazil: 1 attendee
Canada: 1 attendee
Chile: 2 attendees
United States: 12 attendees
Mexico: 33 attendees
United Kingdom: 2 attendees



Attendees by gender

Additionally, we had a notable gender balance, which significantly enriched the discussion.

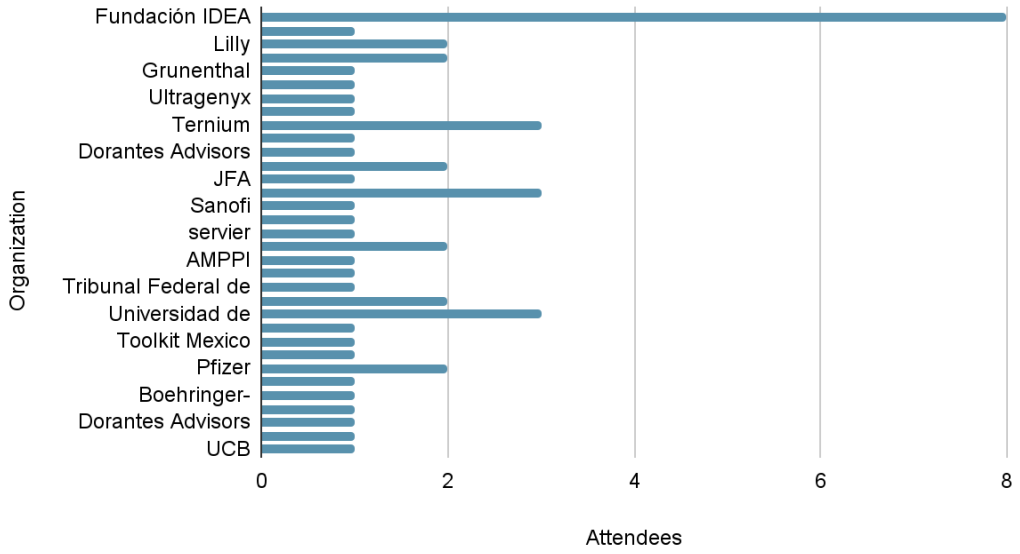
Graph 2: Gender distribution of attendees



Attendees by organization

Our attendees work in various companies and institutions involved in the pharmaceutical industry, technology development, and regulation and consulting on licenses and patents.

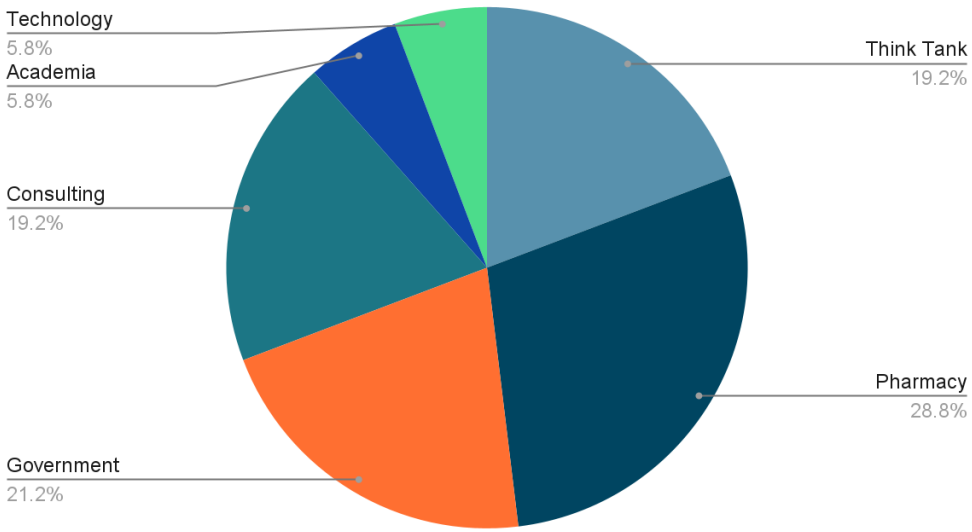
Graph 3: Attendees by organization



Attendees by expertise

Such companies and institutions represent the most important sectors related to work in intellectual property.

Graph 4: Attendees by field of expertise



Annex 2. *Webinar´s* Agenda

Hour	Activity
10:00 - 10:10 A.M.	**Welcome words and greetings** ● Carolina Agurto, Executive Director of Fundación IDEA ● Mark Schultz, Representative of Geneva Network
10:10 - 11:15 A.M.	**Panel** ● Moderator - Mariana González, *Partner at Basham, Ringe and Correa* ● Speakers 1. Francisco Medina, Head of the Third Panel of the Specialized Chamber in Intellectual Property Matters 2. Nahanny Canal, Intellectual Property Consultant 3. Héctor Chagoya, Founder of Mextrategy 4. Fernando Portugal, Director of Intellectual Property, Legal and International Affairs at AMIIF ● Panel Dynamic - Speakers' introduction (5 minutes) - Opening question and a round of a five-minute response starting with speaker 1, 2, 3, and 4(30 minutes) - Follow-up question and a round of a five-minute response starting with speaker 4, 3, 2 and 1 (30 minutes)
11:15 - 11:25 A.M.	**Questions and answers from the audience** ● Mariana González, Partner at Basham, Ringe and Correa
11:25 - 11:30 A.M.	**Closing remarks** ● Emily Morris, David L. Brennan Endowed Chair and Associate Professor at UAIP ● José Alejandro Luna, President of the Mexican Association for the Protection of Intellectual Property

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