

**UNITED STATES
PATENT AND TRADEMARK OFFICE**



Patent Public Advisory Committee
Quarterly Meeting

IP Provisions of the
**United States-Mexico-Canada
Agreement (USMCA)**

Shira Perlmutter

Chief Policy Officer and Director for International Affairs

Mary Critharis

Senior Patent Counsel

Office of Policy and International Affairs

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AGENDA

- Goals of the USMCA, IP Chapter
- Multilateral Treaties
- Patents
- Pharmaceutical and Agro-Chemical Products
- Industrial Designs
- Other Provisions
 - Trade Secrets
 - Enforcement

Goals of IP Chapter of USMCA

- The IP Chapter of the USMCA modernizes and improves upon the IP commitments under NAFTA & the TRIPS Agreement
- The IP chapter seeks to:
 - Establish enhanced IP standards;
 - Improve transparency in the region;
 - Balance the development of innovative, life-saving drugs with affordable access to generic medicines;
 - Establish a common regional standard of industrial design protection;
 - Establish a federal cause of action for trade secret protection; and
 - Improve on existing IP enforcement mechanisms.
- Implementation does not require changes to U.S. law.

Multilateral Treaties

- **Mandates adherence to modern multilateral treaties**
 - Plant Varieties (the International Convention for the Protection of New Varieties of Plants, UPOV 91)
 - Industrial Designs (the Geneva Act of the Hague Agreement Concerning the International Registration of Industrial Designs, 1999)
- **Encourages adoption of the Patent Law Treaty, 2000**
- ***Benefits***
 - A cutting-edge framework to harmonize patent procedures and simplify patent filing procedures in the region.

Patents

- **Summary of Patent Obligations**
 - Patent Standards
 - Patentable Subject Matter
 - 12 Month Grace Period
 - Transparency
 - Amendments, Corrections, and Observations
 - Publication of Patent Applications
 - Information Relating to Published Patent Applications
 - Patent Revocation
 - Patent Term Adjustment

Patents – Patent Standards

- **Patentable Subject Matter**
 - Ensures a broad scope of patent protection.
 - Requires Parties to provide patents for new uses of a known product, new methods of using a known product, or new processes of using a known product.
 - Confirms that all plant-derived inventions, except for plants *per se*, are eligible for protection.
- **Benefits**
 - Ensures that innovators are properly incentivized to explore novel and nonobvious uses of existing medicines
 - Agricultural and biotechnology industries will enjoy protection of plant-derived inventions.

Patents – Patent Standards

- **Grace Period**
 - A patent applicant's public disclosures of an invention that occur within 12 months from the filing date will not be used as prior art against the applicant.
- ***Benefits***
 - A more robust and harmonized standard across North America that acknowledges certain disclosures in academic settings, professional environments, and commercialization discussions will not prevent them from obtaining patent rights.

Patents – Transparency

- **Amendments, Corrections, and Observations**
 - Requires Parties to provide at least one opportunity to make amendments, corrections, or observations to a patent application.
 - *Benefits*
 - Ensures due process during patent examination in the region.
- **Publication of Patent Applications**
 - Parties shall endeavor to publish patent applications at 18 months from the earliest filing date. Patent applications or corresponding patents that are not published at 18 months should be published as soon as practicable.
 - *Benefits*
 - Enriches the body of prior art; facilitates higher quality examination; enhances certainty and predictability for businesses

Patents – Transparency

- **Information Relating to Published Patent Applications**
 - Parties agree to make available:
 - Search & examination results;
 - Non-confidential applicant communications; and
 - Relevant prior art citations.
- *Benefits*
 - Facilitates patent work sharing
 - Ensures transparency in patent examination

Patents – Revocation

- **Patent Revocation**
 - Parties may only revoke a patent on grounds that would have been available to refuse a patent grant.
 - Exceptions:
 - Fraud, misrepresentation, or inequitable conduct may be a basis for patent revocation.
 - Revocation is permitted if consistent with Article 5A of the Paris Convention (failure to work) .
- *Benefits*
 - Prevents unjust revocation on grounds not related to patentability

Patents – Term Adjustment

- **Patent Term Adjustment (for office delays)**
 - Parties agree to adjust the patent term to compensate for unreasonable delays in the issuance of a patent.
 - Unreasonable delay defined as delay in the issuance of a patent of more than 5 years from the date of filing, or 3 years after a request for examination has been made, with some exceptions (e.g., applicant delays).
- ***Benefits***
 - Ensures that patent holders can have their patent term restored for delays attributed to an IP office.

Pharmaceutical & Agro-Chemical Products

- Summary of Pharmaceutical and Agro-Chemical Product Obligations
 - Regulatory Data Protections (RDP)
 - Exclusivity Periods
 - Common Definition for Biologics
 - Additional Provisions for Pharmaceutical Products
 - Regulatory Review (*Bolar*) Exception
 - Patent Term Adjustment (Regulatory Delays)
 - Patent Resolution Mechanism
 - Public Health Considerations

Pharmaceutical & Agro-Chemical Products – Regulatory Data Protection

- *Exclusivity Periods*
 - Parties agree to protect innovators against unfair competition by providing periods of exclusivity for test data submitted to health authorities to obtain marketing approval. During the periods of exclusivity, third parties may not enter the market with a same or similar product.
 - Obligations
 - Pharmaceutical Products: at least 5 years from approval in Party
 - **Biologics: at least 10 years from approval in the Party**
 - Agricultural Products: at least 10 years from approval in the Party
- *Benefits*
 - Ensures innovators are rewarded for the lengthy, costly, and risky process of obtaining marketing approval.

Pharmaceutical Products – Biologics

- **Common Definition for Biologics**
 - Parties agree that a biologic is, or contains, a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein, or analogous product.
- ***Benefits***
 - Aligns the region with United States standards and increases the scope of biological products covered by the agreement
 - Increases innovation of a broad spectrum of biological products

Pharmaceutical Products- Permissible Uses

- **Regulatory Review (*Bolar*) Exception**
 - Parties agree to provide an exception to the patent right by allowing third parties to engage in activities related to obtaining marketing approval, without being liable for patent infringement.
- ***Benefits***
 - Allows generic/biosimilar companies to perform necessary tests for marketing approval during the term of a patent covering the innovative product.
 - Ensures that generic/biosimilar products can enter the market immediately after the patent expires on the pioneer drug product.

Pharmaceutical Products – Patent Term Adjustments

- **Patent Term Adjustment (regulatory delays)**
 - Parties agree to provide restoration of the patent term to compensate for unreasonable curtailments of the patent term due to the marketing approval process.
- ***Benefits***
 - Ensures that patent holders can have their patent term restored for delays associated with the regulatory approval process to ensure a meaningful period of exclusive patent rights.

Pharmaceutical Products- Patent Resolution Mechanism

- **Patent Resolution Mechanism**
 - System to provide notice to patent holders that a third party is seeking to market a product during the term of a patent covering an approved product or its method of use
 - Adequate time and opportunity for a patent holders to seek remedies, e.g., injunctions, in conjunction with the timely resolution of patent disputes OR
 - System that prevents marketing approval during the term of a patent covering an approved product.
- ***Benefits***
 - Ensures patent holders are protected against patent-infringing products.

Pharmaceutical Products- Public Health

- **Public Health Considerations**
 - Parties may take measures to protect public health in accordance with:
 - the Declaration on the TRIPS Agreement and Public Health;
 - Any waiver of any provision of the TRIPS Agreement granted by WTO; and
 - Any amendment of the TRIPS Agreement to implement the Declaration that enters into force with respect to the Parties..
- **Benefits**
 - Provides Parties with sufficient flexibility to ensure access to medicines in a public health crisis.

Industrial Designs

- **Summary of Industrial Designs Obligations**
 - Scope of Protection
 - Grace Period
 - Electronic Systems
 - Term of Protection

Industrial Designs

- **Scope of Protection**
 - Parties agree to ensure that industrial design protection is available for partial designs.
 - *Benefits*
 - Aligns the region under a common standard, ensures that design owners can have more comprehensive protection over their creations
- **Grace Period**
 - Parties agree that public disclosures of an industrial design occurring 12 months prior to the filing date may not be used to reject a design application.
 - *Benefits*
 - Provides a harmonized standard across the region on design disclosures prior to filing

Industrial Designs

- **Electronic Systems**
 - Parties agree to provide an electronic application system, and a publicly available electronic information system for industrial designs.
 - *Benefits*
 - Ensures that design rights can be more easily obtained, and facilitates greater transparency in design rights.
- **Term of Protection**
 - Parties agree to provide a term of protection for industrial designs of at least 15 years.
 - *Benefits*
 - Harmonizes the term of protection across North America

Trade Secrets

- **Trade Secrets Protection**
 - Civil Protection & Remedies
 - Parties agree to provide a civil cause of action for misappropriation of trade secrets.
 - Misappropriation means the acquisition, use, or disclosure of a trade secret in a manner contrary to honest commercial practices.
 - Criminal Procedures & Penalties for Unauthorized and Willful Misappropriation

Enforcement

- **Presumption of Validity**
 - Parties agree to afford *prima facie* presumption of validity to an issued patent being enforced in a civil or administrative enforcement proceeding.
- **Remedies**
 - Parties agree to provide their respective judicial authorities the power to provide:
 - injunctive relief, including preventing goods from entering channels of commerce;
 - adequate compensation for infringement (e.g., lost profits, market price value, suggested retail price); and
 - provisional measures to safeguard against infringement during the course of litigation.

QUESTIONS???

USPTO USMCA Lead

Shira Perlmutter, shira.perlmutter@uspto.gov

USPTO USMCA Patent Team

Mary Critharis, mary.critharis@uspto.gov

Charles Eloshway, Charles.elsohway@uspto.gov

Jesus Hernandez, jesus.hernandez@uspto.gov

David Gerck, david.gerk@uspto.gov

Questions and Comments

Shira Perlmutter

Chief Policy Officer and Director for International Affairs

(571) 272-9300

Shira.Perlmutter@USPTO.GOV

Mary Critharis

Senior Patent Counsel

Office of Policy and International Affairs

(571) 272-8839

Mary.Critharis@USPTO.GOV



