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Examining the United States – Mexico – Canada Agreement (USMCA):

A Closer Look at Patent Term Adjustment and Test Data Exclusivity

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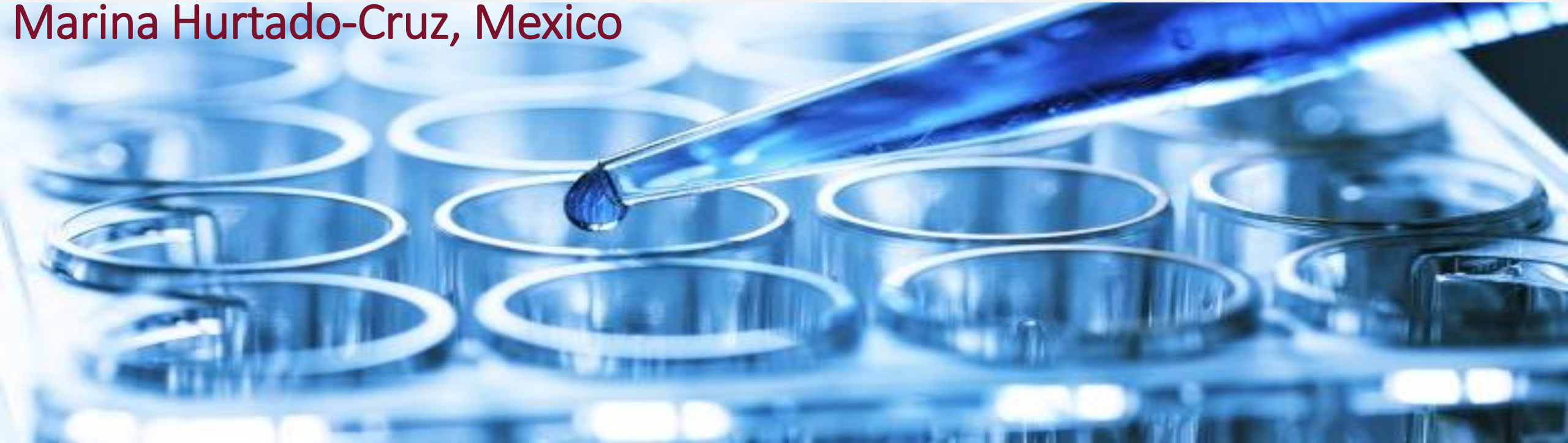


Overview

1	Mexico Before NAFTA
2	From NAFTA to USMCA
3	Patent Term Adjustment in the USMCA
4	Test Data Exclusivity Protection in the USMCA
5	Patent Linkage Changes in Mexico
6	Conclusions

Mexico Before NAFTA

- Economic crisis in the 80's
- International Monetary Fund (IMF) recommended Mexico to accede to GATT
- Negotations began for a Free Trade Agreement with USA and Canada
- Beginning of economic liberalism for Mexico

From NAFTA to USMCA: General Overview

January 1st, 1994
North American Free Trade Agreement (NAFTA) between Canada, Mexico and the United States.

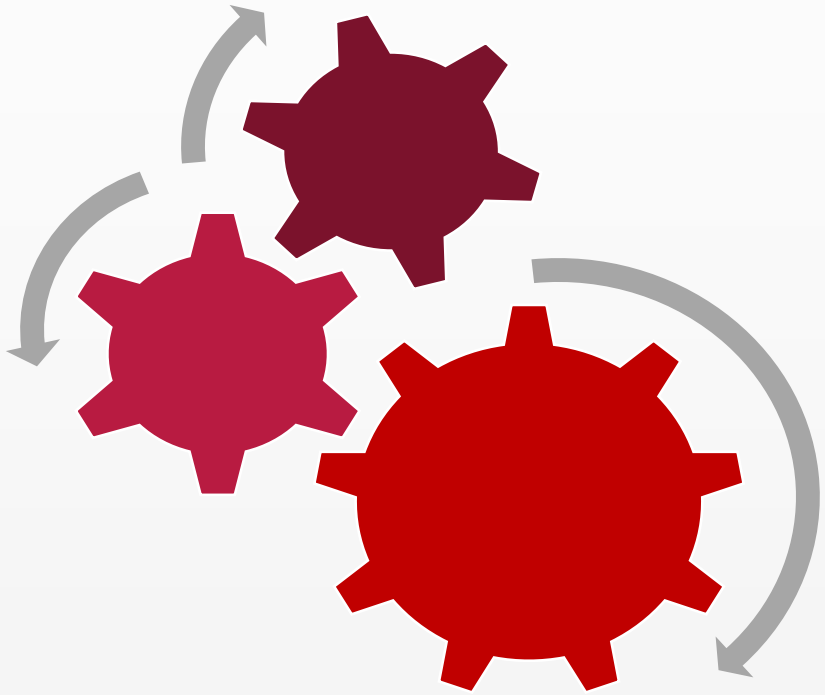
- From 1993-2017 trade under NAFTA increased almost four times from 297 billion to 1.17 trillion USD
- Each day, the US conducts more than US $ 3.6 billion in trade with Canada and Mexico

From NAFTA to USMCA: General Overview

- USMCA negotiations concluded on September 30, 2018.
- Agreement signed on November 30, 2018.
- Currently being ratified by all parties.
- USMCA reinforces regulatory systems, e-commerce and protection of intellectual property.

Patent Term Adjustment in the USMCA

USMCA: Impact on the Pharmaceutical Industry



Patent Term Adjustment - In general

Each country shall:

- **Process patent applications** in an efficient and timely manner, avoiding unreasonable or unnecessary delays.

- Provide procedures for a patent applicant to request to **expedite the examination of its patent application**.

- If there are unreasonable delays in the issuance of a patent, that Party shall provide the **means to adjust the term of the patent to compensate for those delays**.

An **unreasonable delay** shall include (at least) a delay in the issuance of a patent of more than:

5 years from the date of filing of the application or

3 years after a request for examination of the application, whichever is later.

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USMCA: Impact on the Pharmaceutical Industry

Additional Patent Term Adjustment for Pharmaceutical Products

Each country shall

- Process applications for **marketing approval** of pharmaceutical products in an **efficient and timely manner**, **avoiding unreasonable or unnecessary delays**.
- Make **an adjustment** of the **patent term** for unreasonable curtailment of the effective patent term **as a result of the marketing approval process**.

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Patent Term Adjustment - Mexico

CURRENT LEGISLATION

Non-renewable term of 20 years, starting from the date on which the application is filed.

No provision of patent term adjustment to compensate the patent owner for unreasonable delay to obtain **marketing approval by the Health Authority**.

CHANGES TO BE IMPLEMENTED

Patent term adjustment process may be implemented to compensate Mexican Patent Office (MPO) delays.
No announcement yet on this point.

Patent term adjustment process may be implemented to compensate the patent owner for unreasonable delay to obtain **marketing approval**.
No announcement yet on this point.

Time allowed for adjustments is 4.5 years.

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Patent Term Adjustment - Canada

CURRENT LEGISLATION

Some human and veterinary drugs patents qualify for up to **two additional years of patent protection** from expiry of original patent via Certificate of Supplementary Protection (CSP) under CETA

Issuance of a CSP will grant the same rights as a patent, but only as they relate to a drug that contains a medicinal ingredient.

CHANGES TO BE IMPLEMENTED

No change in relation to pharmaceutical patents.

No announcement on patent term adjustment about non-pharmaceutical patents.

Patent Term Adjustment - United States

CURRENT LEGISLATION

If the issue of a patent is delayed to more than 3 years after filing date of the application, the term of the patent shall be extended 1 day for each day of delay.
35 U.S.C. § 154(b)(1)(B).

U.S. law currently provides term extensions for pharmaceutical patents to compensate for marketing time lost after the patent has issued, but before receiving FDA marketing authorization.
35 U.S.C. § 156.

CHANGES TO BE IMPLEMENTED

No changes to patent term adjustment.

Test Data Exclusivity Protection

USMCA: Impact on the Pharmaceutical Industry

Test Data Exclusivity Protection

Undisclosed test or other data concerning the safety and efficacy of the product filed as a condition for granting **marketing approval for a new pharmaceutical product or biologic,** shall not be used by third persons on the basis of that information for:

NEW PHARMACEUTICAL PRODUCT

(a chemical entity that has not been previously approved)

- **At least 5 years** from the date of marketing approval.
- **At least 3 years** with respect to new clinical information submitted as required in support of a marketing approval covering new indication, new formulation, or a new method of administration.

BIOLOGIC

("A product that is produced using biotechnology processes and that is, or alternatively, contains, a virus, therapeutic serum, toxin, antitoxin, vaccine blood, blood component", among others).

- **At least 10 years**

Test Data Exclusivity - Mexico

CURRENT LEGISLATION

No current laws. However, recent internal guidelines, encouraged by NAFTA and TPP, cover small molecule drugs for 5 years.

Biologics also have a 5 year protection, but only through litigation.

CHANGES TO BE IMPLEMENTED

Small molecules will have 5 years protection.

Biologics will have 10 years protection .

Time allowed for adjustments is 5 years.

Test Data Exclusivity - Canada

CURRENT LEGISLATION

The Food and Drugs Act, currently has an 8-year data protection term for pharmaceutical products that contain new chemical entities, which includes biologics.

CHANGES TO BE IMPLEMENTED

No change for small molecule pharmaceuticals .

Upon implementation of the USMCA, Canada's 8 year term will be extended to 10 years for biologics.

Time allowed for adjustments is 5 years.

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Test Data Exclusivity - United States

CURRENT LEGISLATION

The United States currently provides a 5-year data exclusivity period for new pharmaceutical chemical entities and a 3-year data exclusivity period for new indications of pharmaceutical drugs.
21 USC § 355(c)(3)(E)(ii,iii).

The law currently includes a 12-year data protection term for biologics.

CHANGES TO BE IMPLEMENTED

No changes are required.

Possible Patent Linkage Changes in Mexico

Patent Linkage in Mexico

Marketing approval application

Cofepris
Comisión Federal para la Protección contra Riesgos Sanitarios

Health authority

Resolution

IMPI sends report to COFEPRIS

Gazette
Mexican Institute of Industrial Property
(IMPI)

IMPI
INSTITUTO MEXICANO DE LA PROPIEDAD INDUSTRIAL

Is the information sufficient?

NO

COFEPRIS requests information to IMPI

Possible Patent Linkage Changes in Mexico

USMCA states that if a Party permits third parties to rely on the safety and efficacy information that was previously approved by a reference medicinal product, that Party shall provide:

- A system to provide notice to a patent holder, prior to the marketing of such pharmaceutical product, that a third person is seeking the marketing approval for that product.

- Adequate time for the patent holder to seek remedies prior to the marketing of the product that may infringe a patent.

Conclusions

Patent Term Adjustment **Test Data Exclusivity Protection**

Main changes to be implemented in local legislation derived from the USMCA

Mexico	Canada	USA
• Patent term adjustment to compensate Mexican Patent Office (MPO) delays. • Patent term adjustment to compensate for unreasonable delay to obtain marketing approval. • 10 years Test Data Exclusivity protection for biologics. • Possible changes to the Patent Linkage to provide notice to a patent holder about an application for marketing authorization that may infringe a patent.	• Patent term adjustment for non-pharmaceutical patents. • Canada's 8 year Test Data Exclusivity term will be extended to 10 years for biologics.	No changes are required.

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THANK YOU