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 **NORTON ROSE FULBRIGHT**

FICPI World Congress – Trade Related Aspects of IP

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Toronto, June 7, 2018

Outline

- 1. IP Related Trade Disputes**
- 2. Trade Agreement Impact on Canadian IP Practice**
- 3. Future Trade Agreement IP Impact?**

1. IP Related Trade Disputes

TRIPS – Tobacco Plain Packaging Dispute

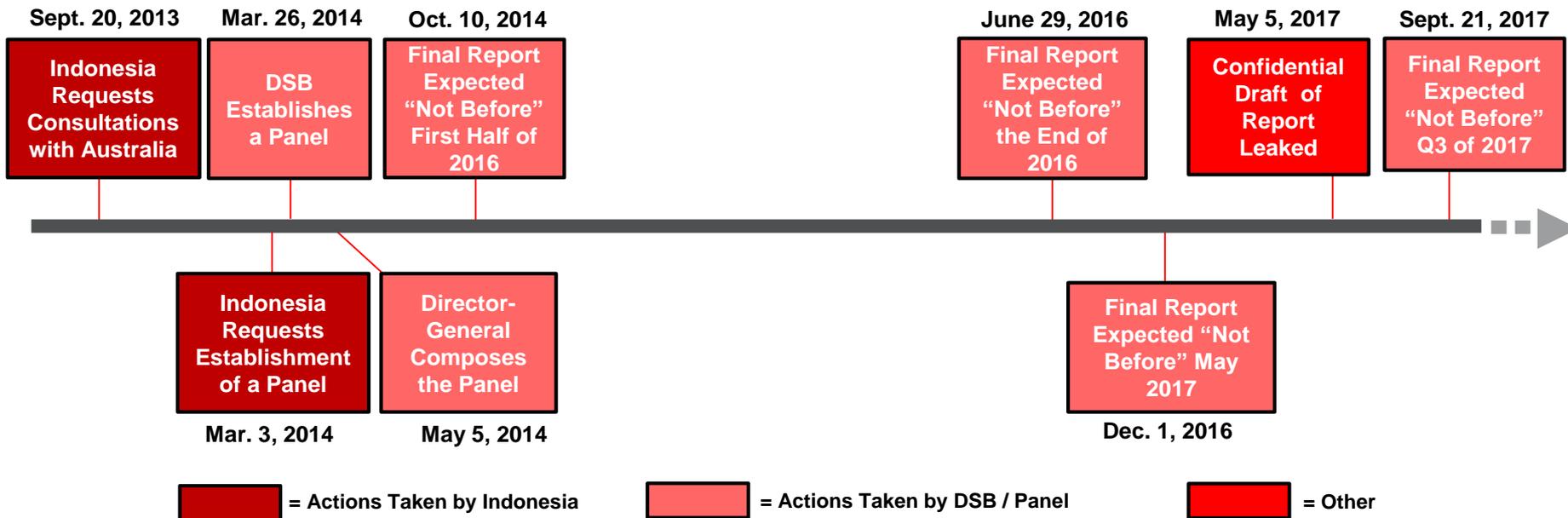
Background

- Australian laws imposed plain packaging requirements and restrictions on trademarks and geographical indications on tobacco products and packaging
- Complaints by Indonesia, Honduras, Dominican Republic, Cuba and Ukraine (suspended) against Australia
- Allegations that measures were inconsistent with Australia's obligations under GATT 1994, TRIPS agreement and TBT agreement



TRIPS – Tobacco Plain Packaging Dispute

Timeline*



* Timeline for Indonesia's complaint. The timelines for the other complaints are similar, except for Ukraine's complaint which was suspended in May 2015.

TRIPS – Tobacco Plain Packaging Dispute

Examples of Australia's Plain Packaging Laws

- Prohibition on trademarks and marks generally appearing on retail packaging [*Tobacco Plain Packaging Act 2011* (No. 148,2011), s. 20]
- The surfaces of the packaging must not have any decorative ridges, embossing, bulges or other irregularities of shape or texture, or any other embellishments [s. 18(1)(a)]
- All outer surfaces of primary packaging and secondary packaging must be the colour known as Pantone 448C [*Tobacco Plain Packaging Regulations 2011*, Division 2.2.1(2)]

TRIPS – Tobacco Plain Packaging Dispute

Relevant TRIPS Agreement Provisions

- The nature of the goods or services to which a trademark is to be applied shall in no case form an obstacle to registration of the trademark. [*TRIPS*, Art. 15.4]
- The use of a trademark in the course of trade shall not be unjustifiably encumbered by special requirements, such as...use in a special form...[*TRIPS*, Art. 20]
- ...a Member shall not diminish the protection of geographical indications that existed in that Member immediately prior to the date of entry into force of the WTO Agreement. [*TRIPS*, Art. 24.3]

TRIPS – Tobacco Plain Packaging Dispute

Resolution

- May 4, 2017 – Bloomberg reports an unidentified source indicated that the WTO upheld Australia's right to impose plain packaging label restrictions on the sale of tobacco products as a legitimate public health measure
- Panel has not released its report



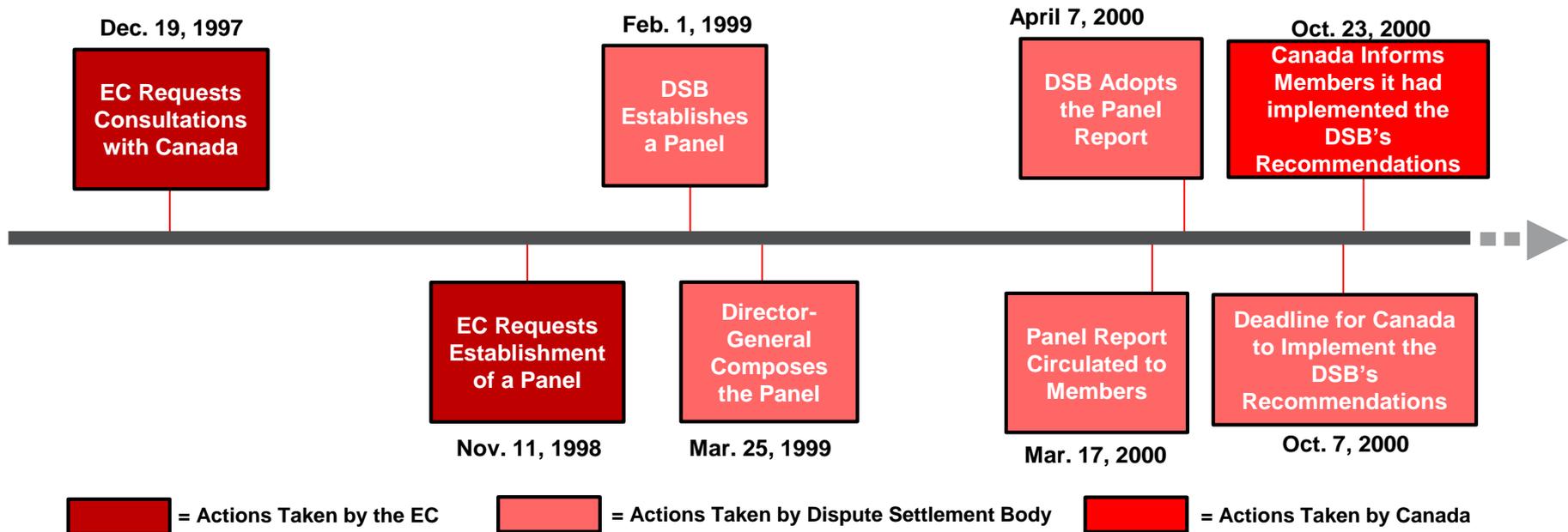
TRIPS – Pharmaceutical Patents Dispute (DS114)

Background

- Complaint by the European Communities and their member states against Canada
- Allegations that s. 55.2(1) (the “**Regulatory Review Exception**”) and s. 55.2(2) (the “**Stockpiling Exception**”) of the *Patent Act* were not compatible with Canada’s TRIPS obligations

TRIPS – Pharmaceutical Patents Dispute (DS114)

Timeline



TRIPS – Pharmaceutical Patents Dispute (DS114)

Relevant Legislation (*Patent Act*)

- The Canadian *Patent Act* provided that:

55.2(1) It is not an infringement of a patent for any person to make, construct, use or sell the patented invention solely for uses reasonably related to the development and submission of information required under any law of Canada...that regulates the manufacture, construction, use or sale of any product (**Regulatory Review Exception**); and

55.2(2) It is not an infringement of a patent for any person who makes, constructs, uses or sells a patented invention in accordance with subsection (1) to make, construct or use the invention, during the applicable period provided for by the regulations, for the manufacture and storage of articles intended for sale after the date on which the term of the patent expires. (**Stockpiling Exception**)

TRIPS – Pharmaceutical Patents Dispute (DS114)

Relevant TRIPS Agreement Provisions

- A patent shall confer on its owner the following exclusive rights:
 - (a) where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing for those purposes that product... [Art. 28.1(a)]
- Members may provide **limited exceptions** to the exclusive rights conferred by a patent, provided that such exceptions do not **unreasonably conflict with a normal exploitation of the patent** and do not **unreasonably prejudice the legitimate interests of the patent owner**, taking account of the legitimate interests of third parties. [Art. 30]

TRIPS – Pharmaceutical Patents Dispute (DS114)

TRIPS Agreement Article 30

- Three criteria required to be met to qualify for an exception:
 - (i) the exception must be “**limited**”;
 - (ii) the exception must not “**unreasonably conflict with normal exploitation of the patent**”; and
 - (iii) the exception must not “**unreasonably prejudice the legitimate interests of the patent owner**.”

TRIPS – Pharmaceutical Patents Dispute (DS114)

Stockpiling Exception - s. 55.2(2)

➤ Panel Report

- ✘ i) **The exception must be limited.** - The right to exclude “making” and “using” provides protection during the entire term of the patent by cutting off the supply of competing goods at the source. s. 55.2(2) removes that protection entirely during the last six months of the patent term
- ii) and iii) – In light of the finding concerning i), the panel did not consider parts ii) and iii) to an Art. 30 exception

TRIPS – Pharmaceutical Patents Dispute (DS114)

Resolution - Stockpiling

- Panel concluded that the stockpiling exception constitutes a substantial curtailment of the exclusionary rights required to be granted to patent owners under Art. 28.1 of TRIPS
- Canada was given until October 7, 2000 to implement the recommendations and rulings of the DSB
- On October 7, 2000, the Governor General in Council revoked the *Manufacturing and Storage of Patented Medicines Regulations*
- s. 55.2(2) of the *Patent Act* was repealed by Bill S-17 (*An Act to amend the Patent Act*) on June 14, 2001

TRIPS – Pharmaceutical Patents Dispute (DS114)

Resolution – Regulatory Review Exception

- Panel found that s. 55.2(1) satisfies all three conditions of Art. 30 and thus is not inconsistent with Canada's obligations under Art. 28.1 of the TRIPS Agreement
- The Regulatory Review Exception is still in force today

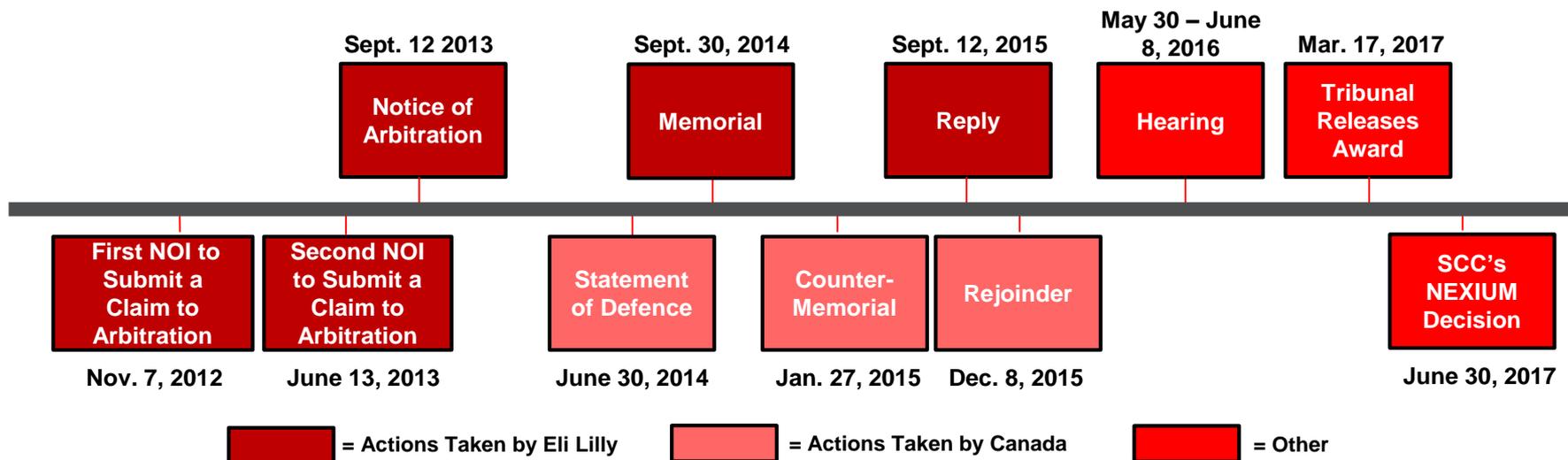
NAFTA - Eli Lilly v. Canada

Background

- Eli Lilly owns Canadian patents relating to atomoxetine (STRATTERA®) and olanzapine (ZYPREXA®)
- Patents invalidated for lack of utility / failing to fulfill the “promise” of the patent
- Claim for \$500 million against Canada for violating obligations to foreign investors under NAFTA
- Application of the “promise doctrine” by Canadian Courts is “arbitrary in its application” and “discriminatory in its effects”

NAFTA - Eli Lilly v. Canada

Timeline



NAFTA - Eli Lilly v. Canada

Promise Doctrine

“Where the specification does not promise a specific result, no particular level of utility is required; a “**mere scintilla**” of utility will suffice. However, where the specification sets out an explicit “promise”, **utility will be measured against that promise**. The question is whether the invention does what the patent promises it will do.

– *Layden-Stevenson J.A.*”

Eli Lilly Canada Inc. v. Novopharm Ltd. (olanzapine), 2010 FCA 197

NAFTA - Eli Lilly v. Canada

Relevant NAFTA Provisions

- No Party may directly or indirectly nationalize or expropriate an investment of an investor of another Party in its territory or take a measure tantamount to nationalization or expropriation of such an investment... [Art. 1110]
- Each Party shall accord to investments of investors of another Party treatment in accordance with international law, including fair and equitable treatment and full protection and security [Art. 1105]
- ...[E]ach Party shall make patents available for any inventions, ...provided that such inventions are new, result from an inventive step and are **capable of industrial application**. [Art. 1709]

NAFTA - Eli Lilly v. Canada

Resolution

- Claimant's claim is dismissed in its entirety
- i) No Dramatic Change in Law
- ii) Promise Doctrine Applied by Courts not Arbitrary
- iii) Promise Doctrine Applied by Courts not Discriminatory Against Pharmaceutical Patents

NAFTA - Eli Lilly v. Canada

Promise Doctrine

“

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“

The **Promise Doctrine is not the correct method** of determining whether the utility requirement under s. 2 of the *Patent Act* is met. **First**, courts must identify the subject-matter of the invention as claimed in the patent. **Second**, courts must ask whether that subject-matter is useful — is it capable of a practical purpose (i.e. an actual result)



– Rowe J.J.

”

AstraZeneca Canada Inc. v. Apotex Inc. (esomeprazole), 2017 SCC 36

2. Trade Agreement Impact on Canadian IP Practice

Trade Agreement Impact on Canadian IP Rights

- **Extension of patent term** (17 years from date of issue → 20 years from date of filing)
- **Compulsory licensing abolished** (Bill C-91 – Feb. 15, 1993)
- ***PM(NOC) Regulations* introduced** (SOR/93-133 – Mar. 12, 1993)
- **Pharmaceutical data protection** (*Food and Drug Regulations*, s. C.08.004.1)

Comprehensive Economic and Trade Agreement

CETA (2017 - provisionally)

- Bilateral trade agreement between Canada and the EU
- Significant changes relating to pharmaceutical patents

CETA – Key Reforms

1) Patent Term Restoration:

- *via* Certificates of Supplementary Protection (“**CSP**”)
- Capped at 2 years

2) “Single Track” Patented Medicines (Notice of Compliance) Regulations [PM(NOC):

- *In rem* litigation by way of action in 24 months

3) Data Protection:

- Minimum 6 year no-filing period
- Minimum of 8 year market exclusivity

CETA – CSP Eligibility (Overview)

CSP eligibility based on 3 key components:

- ✓ **Timing**
- ✓ **Medicinal Ingredient**
- ✓ **Patent**

CETA – “Single Track PMNOC” (Overview)

Before CETA

- Summary proceedings under the *PM(NOC) Regulations*
- No *in rem* patent findings
- Alternative remedies under the *Patent Act*
- Innovators lack effective appeal rights
- S. 8 liability limited to generic damages suffered during specified period

After CETA

- Full actions under the *PM(NOC) Regulations*
- Patent findings *in rem*
- Action estoppel, subject to lack of “reasonable basis”
- All litigants provided with “equivalent and effective” rights of appeal
- S. 8 liability for damages suffered after specified start date

3. Future Trade Agreement IP Impact?

NAFTA Re-negotiation

IP Negotiating Objectives?

- **July 17, 2017** – Office of the United States Trade Representative releases list of NAFTA negotiation objectives. IP objectives include:
 - i) ensuring provisions governing IP rights reflect a standard of protection similar to that found in U.S. law;
 - ii) preventing the improper use of a country's system for protecting or recognizing GIs
 - iii) provide strong civil, administrative, and criminal enforcement mechanisms

- **August 14, 2017** – Foreign Affairs Minister Chrystia Freeland releases Canada's list of key demands. IP demands include:
 - i) none!

NAFTA Re-negotiation

Potential Differing Standards of IP Protection?

- **Patent term restoration**
- **Data protection**
- **Orphan drug legislation**
- **Geographical indications**

NAFTA Re-negotiation

Upcoming Events

- 8th Round of Formal Talks – **on hold**
- Recent high level talks occurred in Washington D.C.
- Officials expected to reconvene in early May
- **November 2018** – U.S. midterm elections
- **July 2018** – Mexican presidential election

CP-TPP

Background

- **Original TPP** – Multilateral agreement between 12 Pacific Rim countries (Canada, U.S., Japan, Australia, New Zealand, Peru, Chile, Mexico, Singapore, Brunei, Vietnam, Malaysia)
- **February 4, 2016** – TPP signed (never ratified)
- **January 23, 2017** - President Trump withdraws U.S. from the TPP
- **Late 2017** – Remaining countries attempt to salvage TPP without U.S. involvement
- **January 2018** – CP-TPP negotiations conclude with agreement. Various IP provisions added at the U.S.'s request are suspended
- **March 8, 2018** – CP-TPP signed

CP-TPP

Examples of IP Provisions - TPP vs. CP-TPP

TPP

- Extension of copyright term
- Patent term adjustment
- Patent grace-period
- 8-year biologic protection (with flexibility)
- Limitations on GI rights
- Stronger trade secret protection

CP-TPP

- Patent grace-period
- Limitations on GI rights
- Stronger trade secret protection

U.S. Returning to TPP?

- **April 12, 2018** – President Trump asks trade officials to explore the possibility of the U.S. rejoining the TPP



Donald J. Trump ✓
@realDonaldTrump

Follow



Would only join TPP if the deal were substantially better than the deal offered to Pres. Obama. We already have BILATERAL deals with six of the eleven nations in TPP, and are working to make a deal with the biggest of those nations, Japan, who has hit us hard on trade for years!

8:15 PM - 12 Apr 2018

CP-TPP

U.S. CP-TPP Concession Targets?

Suspended Provisions include:

- **Extension of Copyright Term** – i) Natural persons = life of author + 70 years; ii) Otherwise = 70 years from publication or 70 years from creation (if no publication within 25 years of creation)
- **Patent Term Adjustment** – Means to adjust the term of the patent to compensate for unreasonable granting authority delays
- **Biologic Data Protection** – 8 years of protection, or 5 years plus “other measures”

The logo consists of a stylized, upward-pointing chevron shape in a gold color, positioned above the first letter of the text.

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