



# Canada Patent Legislation Update

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# Overview

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- Legislation, treaties, trade agreements affecting Canadian patent law:
  - *Economic Action Plan 2015 Act, No. 1*
  - Canada/European Union Comprehensive Economic and Trade Agreement
  - *Budget Implementation Act, 2018, No. 2*
  - Patent Law Treaty
  - “NAFTA 2.0”

## *Economic Action Plan 2015 Act, No. 1*

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- *Patent Act* and *Trade-marks Act* amended effective June 24, 2016
- Statutory privilege for communications between patent agent or trademark agent and client
- Applies also to communications between client and foreign agent if privileged under law of that country
- Applies to communications before coming-into-force that were still confidential on June 24, 2016, but not in respect of actions commenced before that day

# CETA

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- Canada-European Union Comprehensive Economic and Trade Agreement (CETA) in force September 21, 2017
- Changes to pharmaceutical litigation and introduction of Certificate of Supplementary Protection (CSP) system

# CETA - Pharmaceutical litigation

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- **Before CETA:** two branches – ‘dual litigation’
  1. Patented Medicines (Notice of Compliance) (“NOC”) Regulations
  2. Separate action for infringement/validity
- **After CETA:** actions on all patents/CSPs

# CETA - Old v. new NOC Regulations

<b>Old Regulations</b>	<b>New Regulations</b>
Summary proceeding (application), hearing based on written record	Action, trial with live witness testimony
No discovery; limited disclosure	Up front disclosure + discovery
No patentee appeal if NOC issues	Appeal on the merits as of right
Outcome does not bind parties on infringement/validity	Binding decision, subject to appellate review (end of dual litigation)
24 month stay, can be extended on consent	24 month stay, no consent extensions; may be waived to avoid s. 8
Validity - Patentee bears burden	Validity - Generic bears burden

# CETA - Old v. new NOC Regulations

Old Regulations	New Regulations
Section 8 <ul style="list-style-type: none"><li>• Damages limited to delay period</li><li>• Only 1<sup>st</sup> person liable</li></ul>	Section 8 <ul style="list-style-type: none"><li>• No specified end date</li><li>• All plaintiffs liable</li></ul>
Generic limited to issues in NOA	Pleadings define issues

# CETA – Certificates of Supplementary Protection

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- Available only if:
  - Medicinal ingredient (MI) or combination thereof first approved in CA by Notice of Compliance (NOC) issued on or after September 21, 2017
  - no prior NOC for MI or combination thereof
  - no prior CSP – one patent per product
- New Drug Submission (NDS) must have been filed **within 12 months after first regulatory filing** in any of EU or a country thereof, US, AU, CH, and JP
- Patent must claim MI, combination of MI, or *any* use of MI or combination thereof
- Applicant can be patentee, or NOC holder authorized by patentee
- Priority regime of competing CSP applications based on patent grant date
- Term = (NOC date – patent filing date) – 5 years, with maximum 2 year term



## *Budget Implementation Act, 2018, No. 2*

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- In force December 13, 2018
- Licensing commitments on standard-essential patents bind subsequent patent owners<sup>†</sup>
- Prosecution history admissible in evidence to construe patent claims<sup>†</sup>
- Experimental use exception to infringement<sup>†</sup>
- Scope of prior user rights has been expanded<sup>‡</sup>
- Regulation-making authority concerning the requirements for cease and desist letters established

<sup>†</sup>In proceedings not finally disposed of as of December 13, 2018

<sup>‡</sup>in proceedings commenced on or after October 29, 2018

# Patent Law Treaty

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- Changes to *Patent Act* / Rules possibly in force late 2019
- Restoration of priority introduced
- National phase entry after 30 months from priority date only on “unintentional” standard
- Certified copy of priority document required
- Complicated new notice provisions for maintenance fees and examination request—“due care” reinstatement standard, and third party rights
- Shortened prosecution timelines (4 months to request examination, respond to Office Action, pay issue fee)

# “NAFTA 2.0”

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- Various called CUSMA, USMCA, or T-MEX
- Signed November 30, 2018
- Ratification uncertain—e.g. Canada concerned about ongoing steel and aluminum tariffs
- Would require Canada to:
  - provide patent term adjustment to account for Patent Office delay in issuing patents
  - extension of the data protection term for biologics from the current 8 years to 10



# THANK YOU

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