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Patented Medicines (Notice of Compliance) Regulations

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Patented Medicines (Notice of Compliance) Regulations

- principal method of enforcing pharmaceutical patent rights in Canada.
- links the ability of Health Canada to approve a drug submission with the resolution of patent infringement issues.
- provides for "summary" proceedings by which patent issues are resolved.
- does not detract from other intellectual property rights or remedies.

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The Patent Register

- the core of the *PM(NOC) Regulations*.
- a product specific listing of eligible patents arranged by medicinal ingredient.
- "first persons" list eligible patents on the Patent Register in connection with their drugs.
- "second persons" must address each relevant patent on the Register before being eligible to receive a NOC.
- www.patentregister.ca

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Essential Responsibilities - First Persons

- Listing patents on the Patent Register (Form IV)
- Keeping Patent Register information current
- Responding to Notices of Allegations (NOA)

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First Persons - Listing Patents

- patents are listed by filing a Form IV with the Minister of Health
- Form IV patent lists contain patent information, drug submission information, and document service information
- each patent requires a separate Form IV
- patents are listed on the Register when the NOC is issued.

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First Persons - Listing Patents

- to be listed on the Register a patent must:
  - meet subject eligibility requirements (subject of patent); and
  - meet timing requirements (Form IV filing).

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Listing Patents - Patent Eligibility

- To be eligible, patent must contain "a claim to the medicine itself, or the use of a medicine" and be "relevant to the dosage form, strength and route of administration" of the drug for which the patent is being listed.
- includes claims to the "drug substance", formulations containing the medicine, and claims for the use of the medicine.
- does not include claims to devices, intermediates, metabolites.
- dosage forms?

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Listing Patents - Timing Requirements

- s.4(3) - file patent list with the drug submission.
  - NDS or SNDS
  - not every SNDS will support a patent listing
  - i.e., manufacturer name change, brand name change
  - product monograph updates?
- s.4(4) - a newly issued patent can be filed against a previously filed submission within 30 days of the patent issue *if* the patent application date precedes the submission application date.

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Listing Patents - the OPML Patent Audit Process

- Form IV's are reviewed by the OPML
- OPML will either accept the patent lists, or provide an initial statement of rejection.
- first person has an opportunity to respond within 30 days.
- OPML then takes these representations into consideration and issues final decision.
- to judicial review or not to judicial review?....(30 days)

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First Persons - Keep Information Current

- keep Form IV information current and consistent across all submissions for a particular product.
- contact information, product information.
- inform OPML of changes.
- implications for service of documents and determination of whether second person must address patents.
- monitor your patent listings from the website.

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First Persons - Responding to a NOA

- an NOA is a second person's challenge to a listed patent.
- the NOA must set out the details of the challenge.
- section 6 sets out the options for first persons
  - accept the NOA; or
  - initiate a prohibition proceeding in Federal Court within 45 days of receipt of NOA.
- filing in Federal Court triggers a 24 month stay during which Health Canada cannot issue a NOC to the seond person.

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Essential Responsibilities - Second Person

- File a Form V for each patent that must be addressed
- Serve a NOA on second person
- Provide Health Canada with copy of NOA and proof of service on first person

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Second Persons - Filing a Form V

- If there is a comparison to a drug for the purposes of demonstrating bioequivalence, second person must address (file a Form V) each patent on the Register listed against the drug which is the subject of the comparison. (s.5(1))
- Form V's also required when the second person submission contains the same medicine as a drug with a patent on the Register, in the same route of administration, and a comparable strength and dosage form. (s.5(1.1)

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Second Persons - Filing a Form V

- Form V indicates the intention of the second person with respect to each patent on the Patent Register which the second person must address.
- either that the second person will await patent expiry or intends to challenge the listed patent.
- challenge: the patent is invalid or the second person's drug will not infringe the patent.
- must file the Form V's with the submission, submission review will

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Second Persons - Serving a NOA

- if Form V indicates that the second person is challenging the listed patent, a NOA is required.
- must serve NOA on the first person
- a single NOA can deal with more than one patent.
- a copy of the NOA and accompanying proof of service on the first person must be provided to Health Canada.
- can be filed anytime, but NOC will not issue until the documents are received.

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Second Persons - Patent Hold

- when the review of a second person's submission is complete, but matters under the *PM(NOC) Regulations* are ongoing, the submission is placed on "patent hold".
- when requirements are met, submission comes off of hold.
- if it has been on hold for more than 6 months, the submission undergoes a safety update review.
- if there is new information, second person must amend submission before NOC can issue.

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PM(NOC) Regulations - Recent Developments

- Patent eligibility
  - formulations
  - uses
- s.5(1.1)
  - who must address listed patents

Developments - Patent Eligibility

- "rules" around patent eligibility evolve through judicial interpretation.
- *Eli Lilly v. Canada* - Federal Court of Appeal
  - a patent was found eligible for listing on the Register which claimed a formulation containing the medicine which differed from the formulation approved in the NOC issued for the submission against which the patent was listed.

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Developments - Patent Eligibility

- *Genpharm v. Minister of Health*
- indicated a patent which claimed an unapproved use of the medicine was eligible for listing.
- Other ongoing cases re: patents for patches, implants, sustained release dosage forms

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Developments - s. 5(1.1)

- *s.5* specifies which submissions are "caught" by the *Regulations*
- s.5(1) - submission makes a comparison with a drug for which a patent is listed (i.e. ANDS)
- s.5(1.1) - *Bristol-Myers Squibb v. the AG and Biolyse Pharma*
  - does submission contain the same medicine, same route, in comparable strength and dosage form as a drug for which a patent is listed on the Register?
  - all such submissions must file Form V's and serve NOA, if

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Developments - s. 5(1.1)

- s.5(1.1) - *Bristol-Myers Squibb v. the AG and Biolyse Pharma*
  - s.5(1.1) will apply to brand name companies filing supplemental or administrative new drug submissions.
  - must file Form V's re: patents listed by other brand name companies, if applicable.

The *PM(NOC) Regulations* Process