Early Resolution Mechanism for Patent Disputes Regarding Approved Drug Products - Canada

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Presentation Overview

- The Pharmaceutical Regulatory Regime in Canada
- The Drug Approval Process in Canada
- The *Patented Medicines (Notice of Compliance) Regulations*
- The *Canada-European Union Comprehensive Economic and Trade Agreement (CETA)*
The Pharmaceutical Regulatory Regime in Canada

• 1. *The Food and Drugs Act and Regulations*
  • Governs the approval and sale of drugs
  • Governs the evaluation of drug effectiveness and safety

• 2. *The Patent Act*
  • Provides a period of market exclusivity for an invention in exchange for the disclosure of the invention to the public

• 3. *The Patented Medicines (Notice of Compliance) (“PM(NOC)”)* *Regulations*
  • Provides a “linkage” mechanism between the drug approval system and the patent system
  • Attempts to strike a balance between effective patent enforcement for new and innovative drugs and the timely entry of their lower priced generic competitors
  • Replaced compulsory licencing system
The Drug Approval Process in Canada

• All drugs must be approved for sale and marketing by Health Canada.
• Any manufacturer seeking approval of a "new" drug must submit a New Drug Submission ("NDS") to Health Canada which sets out evidence of efficacy and safety.
• Once approved, Health Canada issues a Notice of Compliance ("NOC"), which allows the drug to be marketed and sold in Canada.
The Drug Approval Process in Canada

• A manufacturer seeking approval of a generic drug can submit an Abbreviated New Drug Submission ("ANDS") to Health Canada which demonstrates that the generic formulation is "bioequivalent" to the brand formulation.

• Once approved, Health Canada issues an NOC, which allows the drug to be marketed and sold in Canada.
The PM(NOC) Regulations

- *PM(NOC) Regulations* enacted in 1993
- “Summary” proceedings – not a trial and no right to oral or documentary discovery
- An application based on affidavit evidence and cross-examination (outside of court – no live testimony)
- Patentee retains the right to commence infringement action if unsuccessful in a *PM(NOC)* proceeding
- Generic manufacturer retains the right to commence impeachment action/declaration of non-infringement if unsuccessful in a *PM(NOC)* proceeding
The PM(NOC) Regulations

• ss. 3 and 4 - Patent List and Register
  • Establishes the linkage between drug patents and the NOC system

• s. 5 – Notice of Allegation (“NOA”)
  • Provides the procedure for the generic drug manufacturer to address the listed patents of the brand-name drug

• ss. 6 and 7 – Proceedings Under the Regulations
  • Describes the procedure for PM(NOC) proceedings

• s. 8 – Damages
  • Establishes a generic manufacturer’s right to damages from PM(NOC) proceedings
The **PM(NOC) Regulations**

The Patent List and Register (ss. 3 and 4)

- The Minister of Health is required to maintain a public register of patents that pertain to drugs for which NOCs have been issued.
- These patents are submitted by the patentee (or party having consent of patentee) when an NDS is filed or within 30 days of the grant of the patent.
- Patents which are listed on the register are entitled to “protection” under the **PM(NOC) Regulations**.
The PM(NOC) Regulations

The Patent List and Register (ss. 3 and 4)

- In order to be listed on the patent register the patent must contain:
  
  (a) a claim for the medicinal ingredient;
  
  (b) a claim for the formulation;
  
  (c) a claim for the dosage form; or
  
  (d) a claim for the use of the medicinal ingredient,

  and the medicinal ingredient, formulation, dosage form or use has been approved through the issuance of a notice of compliance in respect of the submission.
The PM(NOC) Regulations

Notice of Allegation Procedure (s. 5)

• When a generic manufacturer files a drug submission that references a drug which has patents listed on the register, the PM(NOC) Regulations are activated.

• Before a generic manufacturer may obtain an NOC for their drug, they must make an allegation of invalidity or non-infringement against each patent on the register in a “Notice of Allegation” (“NOA”).

• Otherwise, the generic manufacturer needs to wait until all patents on the register that relate to the reference brand-name drug have expired.
Notice of Allegation Procedure (s. 5)

• The NOA is a “letter” from the generic manufacturer served on the patent holder (or the person who files the patent list) and filed with Health Canada.

• The NOA sets out the allegations of non-infringement and/or invalidity relied on by the generic manufacturer.

• The NOA cannot be amended
Proceedings Under the Regulations (ss. 6 and 7)

• Within 45 days of receiving an NOA, the patentee may commence an application in the Federal Court for an order prohibiting the Minister of Health from issuing an NOC to the generic manufacturer.

• The patentee must argue that the generic manufacturer’s allegations of invalidity and/or non-infringement as set out in its NOA are “not justified”.
Proceedings Under the Regulations (ss. 6 and 7)

- After a proceeding has been initiated under the *PM(NOC) Regulations*, the Minister may not issue an NOC for the generic drug until the expiry of 24 months unless:
  
  1. The patent(s) listed on the register have expired; or
  2. The court has found the allegations of non-infringement and/or invalidity in the NOA to have been justified.

- This mechanism effectively provides for an automatic injunction preventing the generic manufacturer from marketing or selling the drug in Canada.
The PM(NOC) Regulations

Proceedings Under the Regulations (ss. 6 and 7)

• The proceedings under the PM(NOC) Regulations are intended to be summary in nature and must be completed within the 24 month period.

• These proceedings do not allow for oral or documentary discovery or live testimony. Evidence is tendered in the form of affidavits and cross-examination transcripts.
The PM(NOC) Regulations

Proceedings Under the Regulations (ss. 6 and 7)

• At the conclusion of the PM(NOC) proceeding, the court will either:

  1. grant a prohibition order preventing the issuance of an NOC for the generic drug until the expiry of the patent(s); or

  2. dismiss the application for the prohibition order, allowing for the issuance of an NOC for the generic drug.
The PM(NOC) Regulations

After the *PM(NOC) Proceeding*

- If unsuccessful in the *PM(NOC) proceeding*, the *patentee*:
  - can appeal the decision to the Court of Appeal prior to the issuance of an NOC to the generic manufacturer (once the NOC issues the appeal is considered moot);
  - can commence an infringement action once the generic manufacturer obtains its NOC and makes, uses or sells the infringing product.
The PM(NOC) Regulations

After the PM(NOC) Proceeding

• If unsuccessful under the PM(NOC) Regulations, the generic manufacturer:
  - has a right to appeal to the Court of Appeal; and
  - has the right to commence an impeachment action/or an action for a declaration for non-infringement.
The PM(NOC) Regulations

After the PM(NOC) Proceeding

As stated by the Court of Appeal:

“The basic principle is that the extraordinary procedures provided by the Regulations are for the public law purpose of enabling the Trial Division to prevent a public officer from issuing a Notice of Compliance, designed for the protection of the public's health, if the patentee can show that the patents, as referred to by a generic company in its notice of allegation seeking a Notice of Compliance, ... are not invalid and would be infringed. This is a finding of the Court for the limited purpose of deciding whether or not the Minister can issue a Notice of Compliance: no one could suppose that this is a scheme designed for *res judicata* determinations of the scope or validity of patents.”
The PM(NOC) Regulations

Damages (s. 8)

• If the patentee (applicant) is unsuccessful in the PM(NOC) proceeding, it will be liable to the generic manufacturer for damages.

• These damages compensate a generic manufacturer for lost profits on sales it would have made during the period it was prohibited from selling its product due to the PM(NOC) proceedings.
The Patented Medicines (Notice of Compliance) Regulations

Damages (s. 8)

• the patentee is liable to the generic for any loss suffered from (1) the date it received Health Canada’s approval to sell its product (subject to PM(NOC) Regulations) to (2) the date the proceeding instituted under s. 6 is dismissed by the court, reversed on appeal, or otherwise discontinued or withdrawn.
The Patented Medicines (Notice of Compliance) Regulations

**Damages (s. 8)**

- The generic manufacturer must commence an action to recover damages from the patentee.
- The generic manufacturer must establish sales it would have made and its profits during the period it was excluded from the market.
Damages (s. 8)

• In the past few years there have been damages awarded to generic companies in the 100s of million dollars.

• Even so, not a significant deterrent to patent holders in commencing PMNOC proceedings

• Patentee Profits >> Generic Profits
  (generic product ≤25% of selling price of patentee)
The Canada-European Union Comprehensive Economic and Trade Agreement (CETA)

• A comprehensive free trade agreement between Canada and the European Union that has been the subject of ongoing negotiation for many years.

• It was announced that the agreement had been agreed to “in principle” in October 2013, and last month it was officially confirmed that the text of CETA had been finalized.

• The final text of CETA has not been released.
CETA will require Canada to make two significant changes to its patent law:

1. providing an effective right of appeal from PM(NOC) decisions for patentees; and
2. an extension of patent term for basic patents to compensate for delay in obtaining market authorization (maximum of 2 years)
The Canada-European Union Comprehensive Economic and Trade Agreement (CETA)

• Canada will likely implement changes under CETA late in 2015.

• In order to provide patent holders with an effective right of appeal, Canada may provide for an action (similar to US model) or if a PM(NOC) decision is appealed the right to commence a subsequent action is forfeited.
Thank you

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