The *Patented Medicines (Notice of Compliance) Regulations:* What patents are eligible to be listed on the register?

Edward Hore
Hazzard & Hore
141 Adelaide Street West, Suite 1002
Toronto, ON M5H 3L5
(416) 868-1340
edhore@ hazzardandhore.com

Pharma Patents Conference: October 24, 2002, Marriott Bloor Yorkville Hotel

Introduction: Overview of PM (NOC) Regulations

The *Patented Medicines (Notice of Compliance) Regulations* (the "Regulations") were enacted under s. 55.2 of the *Patent Act* in 1993, creating a scheme roughly modeled on the US Hatch-Waxman amendments of 1984. They were amended in 1998, and again in 1999.

The Regulations give pharmaceutical patentees (but not other patentees) powerful remedies in a patent dispute, in addition to the normal civil remedies.

The procedure under the *Regulations*, in short, allows a patentee keep a generic competitor out of the market merely by *asserting* that a patent, or several patents, would be infringed by the generic product.

The Regulations have been described as "draconian" in their effect on generic manufacturers by the Supreme Court of Canada.

The procedure under the Regulations, in brief, is as follows: Patentees, referred to as "first persons," may list patents on a patent register in connection with drug products for which they hold regulatory approval. The register is maintained by the health and safety

regulator at Health Canada, Therapeutic Products Directorate (TPD).

If a generic manufacturer, referred to as a "second person," files a submission that makes a comparison or reference to the first person's drug (ie. is an Abbreviated New Drug Submission (ANDS)), the Minister of Health (in practice, Therapeutic Products Directorate (TPD), the federal health and safety regulator) may not issue regulatory approval under the *Food and Drug Regulations* (a notice of compliance or NOC) to the generic drug until the second person has addressed all listed patents. The second person must either accept that it will not get regulatory approval until expiry of all listed patents, or serve an "allegation" on the first person that the listed patent or patents are invalid or are not infringed by its submission, together with a detailed statement of the legal and factual basis of the allegation.

The first person, or originator company, on being served with such an allegation, may within 45 days commence a judicial review application for an order that the NOC not be issued to the generic drug.

If the application is commenced, the NOC may not be issued for 24 months, or until the court hearing or patent expiry. As the Federal Court of Appeal stated, "By merely commencing the proceeding, the applicant obtains what is tantamount to an interlocutory injunction for up to 30 months [as the time frame then was] without having satisfied any of the criteria a court would require before enjoining issuance of an NOC."

At the hearing of a judicial review application under the *Regulations* the court must determine whether the generic manufacturer's allegation is "justified." If the court finds the allegation is not justified, the court must issue an "order of prohibition", preventing the Minister from issuing the NOC until patent expiry. If it finds the allegation is justified, the application is dismissed, and health and safety approval may be granted once the TPD's regulatory review is complete (assuming no other prohibition applications have been commenced in respect of the same generic drug submission, and no other patents are listed.)

The litigation started by the first person after receiving an allegation is not an action for patent infringement, but a judicial review proceeding. Procedurally, the litigation consists of an exchange of affidavit evidence and cross-examination, followed usually by a one to three day hearing. Although such judicial review proceedings are theoretically "summary" in nature, they typically take at least a year and often much longer to get to a hearing.

The issue of patent infringement or validity cannot be determined in NOC proceedings; "their object is solely to prohibit the issuance of a notice of compliance under the Food and Drug Regulations." Therefore, either party can also commence a parallel patent action on the same patent. As the Federal Court of Appeal observed, "patent invalidity, like patent infringement, cannot be litigated in this type of proceeding [ie. an application under the *Regulations*]. I can only think that the draftsperson had in mind the possibility of there being parallel proceeding instituted by the second person which might give rise to such a declaration [of invalidity or non-infringement] and be binding on the parties."

The odd result is that a second person might lose the prohibition proceedings under the *Regulations*, ie be unable to enter the market due to a prohibition order, yet later establish at a full trial under the *Patent Act* that the patent is both not infringed and invalid.

Although the generic may be able to claim damages from the first person, payers such as provincial governments, insurers and the public cannot.

Many have questioned the need for such extreme remedies against an alleged infringer, unique to one segment of the economy. For example, in its Observations on Bill S-17 (the most recent amendment to the *Patent Act*), released April 5, 2001, the Senate Banking Committee called for a full parliamentary review of the Regulations on the grounds they "may not be working in the manner that Parliament originally anticipated."

The Committee was concerned the Regulations had resulted in "higher prices" for pharmaceuticals, and commented that "the court's are fully capable of determining

appropriate procedures [in patent disputes], which should not differ substantially from one industry to another."

The Standing Committee on Industry recently voted to hold hearings to review the Regulations.

Why patent eligibility matters - restarting the automatic stay

The automatic stay can be repeatedly re-started for a single generic submission. First persons may list a succession of patents claiming variants on its manufacturing process (product-by-process claims), crystalline forms, formulations, method of use claims etc. expiring long after any basic patent on the medicine.

A second person already in litigation under the *Regulations* on a patent must address any other patent that may appear on the register for that drug.

For example, consider the chronology in respect of paroxetine, an anti-depressant:

- Apotex filed an abbreviated submission for Apo-paroxetine on August 29, 1997, and served allegations to the four patents listed on the patent register at the time, asserting no valid claim of those patents would be infringed by Apotex making constructing, using or selling its product.
- SmithKline Beecham commenced two applications in response to the allegations (T-2660-96 and T-2230-97), triggering the stay.
- While those cases were before the court, SmithKline listed a further patent (the '637 patent), on February 17, 1998.
- SmithKline's two earlier applications were dismissed April 20, 1999 ie. the court found Apotex's allegations were justified, but Apotex was unable to obtain its NOC because the '637 patent had meanwhile been listed.
- Apotex's submission entered "patent hold" status on October 9, 1999 (ie. TPP's health and safety approval process was complete.)

- Apotex served an allegation saying the '637 patent was invalid. SmithKline commenced a new application (T-677-99), re-triggering the stay. This application was dismissed on July 16, 2001; the Court again found Apotex's allegation of invalidity was justified.

- However, while the litigation on the '637 patent was pending, SmithKline added four *further* patents to the register, relating to various tablet formulations, preventing the issuance of an NOC to Apotex.

- Two further judicial review applications have been commenced in response to allegations to those patents (T-1059-01, commenced June 15, 1002, and T-876-02, commenced June 6, 2002). Those cases have not yet been heard

Note that the delay in market entry for this drug alone has been more than two and a half years after the health and safety approval process was complete, yet Apotex's "allegation" of invalidity or infringement has been found to be justified in the applications that have come to a hearing so far. Yet the automatic stay continues to block competition as more patents are added to the register.

What patents are eligible to be listed?

Given the dramatic benefit to the first person of listing as many patents as possible over time, the rules governing the eligibility of patents for listing are of critical importance.

Section 4 of the Regulations states:

Patent List

4.(1) A person who files or has filed a submission for or has been issued, a notice of compliance in respect of a drug that contains a medicine may submit to the Minister a patent list certified in accordance with subsection (7) in respect of the drug.

(2) A patent list submitted in respect of a drug must

(a) indicate the dosage form, strength and route of administration of the drug;

(b) set out any Canadian patent that is owned by the person, or in respect of which the person has an exclusive license or has obtained the consent of the owner of the patent for the inclusion of the patent on the patent list, that contains a claim for the medicine itself or a claim for the use of the medicine and that the person wishes to have included on the

register;

(c) contain a statement that, in respect of each patent, the person applying for a notice of compliance is the owner, has an exclusive licence or has obtained the consent of the owner of the patent for the inclusion of the patent on the patent list;

(d) set out the date on which the term limited for the duration of each patent will expire pursuant to section 44 or 45 of the *Patent Act*; and

(e) set out the address in Canada for service on the person of any notice of an allegation referred to in paragraph 5(3) (b) or (c), or the name and address in Canada of another person on whom service may be made, with the same effect as if service had been made on the person.

(3) Subject to subsection (4), a person who submits a patent list must do so at the time the person files a submission for a notice of compliance.

(4) A first person may, after the date of filing a submission for a notice of compliance and within 30 days after the issuance of a patent that was issued on the basis of an application that has a filing date that precedes the date of filing of the submission, submit a patent list, or an amendment to an existing patent list, that includes the information referred to in subsection (2).

(5) When a first person submits a patent list or an amendment to an existing patent list in accordance with subsection (4), the first person must identify the submission to which the patent list or the amendment relates, including the date on which the submission was filed.

(6) A person who submits a patent list must keep the list up to date but may not add a patent to an existing patent list except in accordance with subsection (4).

(7) A person who submits a patent list or an amendment to an existing patent list under subsection (1) or (4) must certify that

(a) the information submitted is accurate; and

(b) the patents set out on the patent list or in the amendment are eligible for inclusion on the register and are relevant to the dosage form, strength and route of administration of the drug in respect of which the submission for a notice of compliance has been filed.

[Transition:] Subsection 4 (4) does not apply to an allegation if, before the coming into force of these Regulations [March 12, 1998], it was served on the first person, if proof of that service was served on the Minister and if the first person has commenced a proceeding under subsection 6 (1).

Section 4 has been vigorously litigated. Broadly speaking the restrictions, such as they are, can be divided into two categories: subject matter restrictions and timing restrictions.

Subject matter restrictions

- Under section 4(2)(b), the patent list must set out claims containing a claim for the

medicine itself or a claim for the use of the medicine.

- Process claims are not claims for the medicine itself, nor are claims to intermediates ie. substances used in the manufacturing process. (However, it appears this restriction can be circumvented simply by drafting a method claim as a product by process claim.)

- Claims to compositions, ie. where the invention is alleged to be the formulation of an old active ingredient with specified excipients, have been held to be claims to the medicine itself.

- Claims to medical devices are not claims to the medicine.

- The patent must be "relevant" to the dosage form, strength and route of administration of the first person's product. Patents claiming non-approved formulations therefore may not be listed.

Timing restrictions

- Section 4(3) provides a patent list must be submitted at the time the first person files its initial new drug submission (NDS).

- There is an exception under s. 4(4) where a patent application has been filed prior to the first person's filing of a submission for a notice of compliance, but the patent issues after the submission is filed. In that event the first person may submit a patent list containing the patent within 30 days after the patent issues.

- In the *Apotex* decision, which dealt with a decision of the Minister under the pre-1998 Regulations, a supplemental submission (SNDS) was held to be a "submission" for the purposes of the predecessor of section 4(4). As the sponsor of

a drug submission files an SNDS any time it wishes to make even a very minor change in the material submitted to the Minister to obtain its initial NOC, that seemed to open the door to a wide variety of multiple patent listing strategies.

- The March 1998 amendments amended, *inter alia* section 4, in order to "make the Regulations fairer and more effective, and reduce unnecessary litigation." For example, section 4(6) was added to overcome practices that would inhibit the entry of generics on to the market place. Courts have not followed the *Apotex* case in interpreting the post-1998 Regulations.

- At present, the practice of the Minister appears to be that patents can be listed with a supplemental submissions except for SNDS for a mere product name change or company name change.

- The Minister has recently listed numerous patents submitted with supplementary submissions, where the subject matter of the patent does not correspond with the subject matter of the supplementary submission.

- In late February, 2002, the Minister of Health commenced a "Reference by Federal Tribunal" under Rule 18.3(1), as to whether such patents are properly listed. However, the Reference was struck out on the grounds the facts put to the court by the Minister were in dispute. At time of writing, it is not clear how the Minister will respond.

- What is does "filing date" in s. 4(4) mean? First persons argue that the words "filing date" in section 4(4) include a priority date, which would mean many more patents could be listed, since most Canadian pharmaceutical patents claim priority to a previously regularly filed application filed in a treaty country approximately a year before the filing date in Canada. The courts recently held that "filing date" does not include a priority date.

US situation.

Similar issues have arisen under the US scheme. The US Federal Trade Commission recently released a report dealing with, among others things, the possible anti-competitive effect of listing more than one patent for a single drug in the Orange Book (equivalent to the patent register in Canada). The FTC's primary recommendation was:

> Recommendation 1: Permit only one automatic 30-month stay per drug product per ANDA to resolve infringement disputes over patent listed in the Orange Book prior to the filing date of the generic applicant's ANDA.

Are the Regulations "working"?

A system for resolving civil disputes can be said to be working if it is (a) fair, (b) gets disputes resolved fairly quickly, and (c) at reasonable cost. The Regulations fail on all three; they are unfair, they do not resolve the civil dispute, and they impose enormous costs on the parties and on society by keeping products which may be non-infringing off the market.

The Regulations can be said to be "working" only in the sense that they undeniably prevent patent infringement. If no competing product is allowed on the market, then of course no patent will be infringed.

They achieve this result at great cost: they also keep products that *do not* infringe patents off the market. This confers a windfall on a privileged industry sector, at the expense of all payers for prescription drugs.

The Regulations also discourage what would seem to be a desirable activity, the challenging of invalid patent monopolies. The equivalent scheme in the US rewards a generic manufacturer that is first to challenge an invalid patent, by giving the

manufacturer exclusivity on the very large US market from other generic competition for 180 days, in order to give them an incentive them to challenge patent monopolies.

The problem is particularly acute because the automatic injunction can be restarted through listing a succession of patents. The complex and ever-shifting rules described above seem to have done little to prevent this.