"Evergreening" under the *Patented Medicines (Notice of Compliance) Regulations*

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Because the term "evergreening" implies perpetual renewal, it is sometimes used to describe various strategies involving the use of the automatic stay in the *Patented Medicines (Notice of Compliance) Regulations* ("*PM (NOC) Regulations*") to prevent competition after basic patent protection on a drug product has expired.

The *PM (NOC) Regulations* are regulations under the *Patent Act.* They link the granting of a Notice of Compliance (NOC) to a generic drug to the patent status of the Canadian reference product, the brand product with which the generic product is compared for regulatory purposes. The *PM (NOC) Regulations* give pharmaceutical patentees remedies in addition to those available to patentees in other sectors of the economy.

The Regulations are more fully described in Appendix A. For the purposes of a discussion of evergreening, the main points are:

- A 24 month stay on approval of a generic drug occurs automatically if a "first person," a patentee name drug company, commences a prohibition proceeding within 45 days of receiving a notice of allegation (NOA) from a "second person," usually, though not always, a generic drug company.

- Even if a generic company is subject to the 24 month stay as a result of such a prohibition proceeding, it must still address any other patents that the patentee may list on the patent register. [1]

- If the second person addresses other patents by serving further NOAs, prohibition proceedings start the 24 month stay again.

This process can be repeated, allowing a patentee to use weak patents claiming coatings, crystalline forms, manufacturing processes, new uses etc. to prevent competition.

The resulting delay in the market entry of a generic drug can be considerable, as can be shown from the following chronology in respect of paroxetine, an anti-depressant:

- Apotex filed an abbreviated submission for Apo-paroxetine on August 29, 1997, and served Notices of Allegation to the four patents listed on the patent register at the time.

- 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[2] i.e. the court found Apotex's allegations of invalidity and non-infringement 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 (i.e. TPD's health and safety approval process was complete.)

- Apotex served an allegation that the '637 patent was invalid. SmithKline commenced a new application (T-677-99), re-triggering the stay. This application

[1] *PM(NOC) Regulations*, s. 5(2).
[2] *SmithKline Beecham v. Apotex* (1999) 1 C.P.R. (4th) 99, affirmed (2001) 10 C.P.R. (4th) 338 (F.C.A).

was dismissed on July 6, 2001[3]; the Court found Apotex's allegation of invalidity was justified.

- While the litigation on the '637 patent was pending, SmithKline added more patents to the register.

- Apotex served an allegation to the '575 patent, resulting in a new prohibition application (T-1059-01), triggering a further automatic stay. That case was dismissed on May 30, 2003; the court found Apotex's allegation of double patenting to be justified.[4]

- However, another prohibition proceeding had meanwhile been commenced against Apotex concerning 3 further patents on "Form A" (T-876-02).[5]

- Several generic parties finally received NOCs in October 2003, when Genpharm, another generic company, also won prohibition proceedings on some of the same patents already litigated by Apotex,[6] and GSK seems to have decided that the risk of damages outweighed the benefit of continuing to litigate.

Note that the delay in market entry the Apotex product was about four years after the health and safety approval process was complete, yet the generic manufacturers' NOAs were found to be justified in every case that went to a hearing.

At least 75% or the prohibition applications decided by a court since 1988 have been dismissed. But, as the above example shows, even when a generic manufacturer "wins" several times with respect to a particular drug, further automatic stays may still keep its product off the market.

The 75% figure is about the same as in the US. The Federal Trade Commission studied equivalent litigation in the US in 2002, and found "The data in the [FTC] study suggest that the generic applicants have brought appropriate patent challenges: generic applicants prevailed in nearly 75% of the patent litigation ultimately resolved by a court decision."[7]

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[3] *SmithKline Beecham v. Apotex* (2001) 14 C.P.R. (4th) 76, affirmed (2002) 21 C.P.R. (4th) 129 (F.C.A.)
[4] *GlaxoSmithKline v. Apotex* 2003 FCT 687.
[5] A motion to get this case dismissed on the grounds the patents were not eligible for listing was dismissed *GlaxoSmithKline v. Apotex* 2003 FC 1055.
[6] *GlaxoSmithKline* v. Genpharm 2003 FC 1248.
[7] Generic Drug Entry Prior to Patent Expiration, an FTC Study, Federal Trade Commission, July, 2002, p. viii.

As discussed below, the FTC study led to recent amendments to permit only one stay in the US.

Eligibility: what patents can be listed?

Given the extraordinary 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. A summary of the rules as they stand follows:

Section 4 of the *PM (NOC) Regulations* governs the filing of patent lists. An excerpt is set out below, with the more important phrases highlighted.

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
>
> …
> (b) set out any Canadian patent that is owned by the person, … 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;
>
> ….
>
> (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).
>
> …
>
> (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).*

Broadly speaking, the restrictions, such as they are, can be divided into two categories which might be termed “subject matter” and “timing” restrictions. Both can be circumvented easily by the patentee.

Subject matter restrictions

Under section 4(2)(b), the patent must contain a claim for the medicine itself or a claim for the use of the medicine.

“Pure” process claims are not claims for the medicine itself (although product-by-process claims are), nor are claims to intermediates i.e. substances used in the manufacturing

process,[8] claims to metabolites, [9] claims to medical devices such inhalers, patches, or kits.[10]

Claims to compositions are claims to the medicine itself.[11]

Starting about 1999, the Minister took the position that patents claiming formulations that the brand is not itself approved to sell could not be listed.[12] However, the Federal Court of Appeal, in *Eli Lilly*, a 2 to 1 decision, held that patents on non-approved formulations could be listed.[13]

The Eli Lilly case greatly increased the class of patents that could be listed because the patentee can potentially obtain many patents for formulations containing the active ingredient; there is no end to the excipients, coatings, solvents and other variants that might be claimed as novel.

The Courts have also said that a patent on a non-approved use is eligible for listing.[14] In reaching that decision, Justice Blais commented that the Regulations are ambiguous with respect to patent eligibility, and that although he was bound to apply the *Eli Lilly* majority decision, he found it "opposite" to "logic". He stated: "No doubt clearer language in the *PM (NOC) Regulations* would go a long way to dispel the fog we find ourselves in, and prevent the abundant litigation which is sure to continue as long as the ambiguity remains."

Timing restrictions

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[8] *Deprenyl v. Apotex* (1995), 60 C.P.R. (3d) 501(F.C.A.), *Eli Lilly v. Apotex* (1996) 68 C.P.R. (3d) 126 (F.C.A.)
[9] *Merck v. Minister of Health* (2001), 12 C.P.R. (4th) 383.
[10] *Glaxo Group Ltd. v. Novopharm Ltd*. (1999), 87 C.P.R. (3d) 525 (F.C.A.), *Novartis v. Minister of Health* 2003 FCA 299, *Procter & Gamble v. Genpharm* 2004 FC 204.
[11] *Hoffman-La Roche Ltd. v. Canada (Minister of National Health and Welfare)*(1995), 62 C.P.R. (3d) 58 at 72, aff'd (1995), 67 C.P.R. (3d) 25, leave to appeal to SCC dismissed, [1996] 3 S.C.R. xi
[12] *Warner Lambert v. M. of H.* [2001] F.C.J. No. 801, *Eli Lilly v. M. of H*., T-1212-00, January 10, 2002.
[13] *Eli Lilly v. Minister of Health*, 2003 FCA 24
[14] *Genpharm v. M.O.H*. 2003 FC 1148.

There are also timing rules, but again they are so easily surmounted as to be effectively meaningless.

Under s. 4(4), a patent resulting from an application filed prior to the first person's submission for a notice of compliance can be listed, if the first person submits the patent within 30 days after the patent issues. A “supplement to a new drug submission” (SNDS)[15] has been held to be a "submission" for the purposes of this section.[16]

This broad reading of “submission” opens the door widely because a patentee can file an SNDS when it wishes; for most drugs new SNDSs will be submitted routinely from time to time to change the information filed with the TPD.

Section C.08.003(2) of the *Food and Drug Regulations* lists the circumstances when an SNDS can be filed by a sponsor, and contains a long list of potential changes than can be effected by filing an SNDS, such as a change in the “description of the drug,” the “brand name” of the drug, the “specifications of the ingredients,” the “plant and equipment used in manufacturing,” etc.

In *Bristol Myers*, a case involving a SNDS for a name change, the Federal Court of Appeal held that if the SNDS does not “change the drug,” then the SNDS cannot be used to list a patent.[17] A subsequent trial level decision refused to apply the *Bristol Myers* case,[18] but was overturned on appeal.[19]

The question therefore arises when does an SNDS “change the drug” or not do so?

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[15] *Food and Drug Regulations*. C.08.003.
[16] *Apotex v. Minister of Health* (1999), 87 C.P.R. (3d) 271, affirmed (2001) 11 C.P.R. (4th) 538.
[17] *Bristol Myers Squibb v. Canada (A.G.)* 2002 FCA 32.
[18] *Ferring v. Apotex* 2003 FCT 293.
[19] 2003 FCA 274.

At present, the practice of the TPD is that patents can be listed with *any* SNDS except one for a mere product name change[20] or company name change.[21]

The question whether a patent can be listed with an SNDS for a brief product monograph revision was argued before Madam Justice Simpson in May, 2003 by various generic manufacturers and Abbot Labs in various prohibition cases involving clarithromycin.[22] Justice Simpson issued an order that the patent in question was not eligible for listing on January 29, 2004, but so far as I know she has not yet issued reasons. While her decision was under reserve, seven other patents were listed by the patentee for clarithromycin.

There seems be no need for the subject matter of the patent to correspond with that of the SNDS with which it is listed, as long as they both somehow refer to the same drug. For example, a patent on a crystalline form may be listed with a SNDS for an unrelated product monograph revision.

In late February 2002, the Minister of Health commenced a "Reference by Federal Tribunal" under Rule 18.3(1), as to whether patents must be “relevant” to the SNDS with which it is submitted. However, the Reference was struck out on the grounds the facts put to the court by the Minister were in dispute.[23]

As noted above, the “filing date” of the patent must be prior to the “submission.” Patentees argued that the words "filing date" in section 4(4) include a priority date, and initially convinced TPD to adopt that position. But TPD then changed its mind, and refused to list various patents where the priority date, not the filing date, was prior to the submission, including a patent for azithromycin submitted by Pfizer. In the *Pfizer* and *Schering* case, the courts held that "filing date" does not include a priority date.[24]

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[20] *Bristol Myers v. Canada*, (2001) 10 C.P.R. (4th) 318, affirmed (2002) 16 C.P.R. (4th) 425.
[21] *Toba Pharma Inc. v. A.G. Canada*, see above
[22] In T-1035-02, T-1133-02 and T-1847-02.
[23] *Patented Medicines (Notice of Compliance) Regulations (Reference)*, (2003), 22 C.P.R. (4th) 62.
[24] *Pfizer, Schering v. Canada* 2002 FCT 706, affirmed 2003 FCA 138, leave to appeal to SCC refused, [2003] S.C.C.A. No. 224.

However, this restriction makes no real difference. Pfizer simply listed the azithromycin patent at issue with a later SNDS, thus circumventing the restriction. This illustrates that, as a result of the various cases mentioned above, the time limits have little practical effect. If a patentee misses one time limit, all it has to do is file an SNDS, and its gets the benefit of a later time limit.

The register includes patents on both approved and non-approved formulations and uses, products-by-process, variants as allegedly new coatings or dosage forms, manufacturing methods using, for example, particular solvents or temperatures, dosing regimes, allegedly new crystalline forms etc. There are as many as eleven patents on the register for some products. A generic manufacturer never knows when more patents will be added to the register for a given drug.

Entering any important drug as a search term in the CIPO patent database will typically turn up dozens of patents or open-to-the public applications. For example, a search of the term "omeprazole" on March 11, 2004 turned up 192 patents or applications.

The question arises: is this chaotic and unpredictable system what the regulator intended when it passed the *PM (NOC) Regulations*.

Policy-makers' concerns

The Romanow Report of November 28, 2002 referred to evergreening as a particular concern affecting the cost of drugs:

> **Recommendation 41:**
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> **The Federal government should immediately review the pharmaceutical industry practices related to patent protection, specifically, the practices of *evergreening* and the notice of compliance regulations. The review should ensure that there is an appropriate balance between the protection of intellectual property and the need to contain costs and provide Canadian with improved access to non-patented prescription drugs**. (Italics in original)[25]

[25] Romanow Commission: "Building on Values; the Future of Health Care in Canada," p. 208.

The reference to evergreening in the recommendation is elaborated as follows:

> A particular concern with current pharmaceutical industry practice is the process of "evergreening," where manufacturers of brand name drugs make variations to existing drugs in order to extend their patent coverage. This delays the ability of generic manufacturers to develop cheaper products for the marketplace and is a questionable outcome of Canada's patent law.

The Report comments specifically on the Regulations as follows:

> Furthermore, regulations under the patent law require generic drug manufacturers to demonstrate that their product is not infringing on a patent held by another drug manufacturer rather than putting the onus of the patent drug manufacturer to show that their patent has been infringed - what is referred to as the notice of compliance regulations. Suggestions have been made that this leads to "pre-emptory" lawsuits from patented drug manufacturers was a way of delaying the approval of generic drugs. Clearly, if this is the case, the practice is not in the public interest. The federal government should review this issue, determine what constitutes a legitimate extension of patent protection, and also consider ways of streamlining approval of generic drugs…[26]

In response, the House of Commons Standing Committee on Industry, Science and Technology conducted hearings into the Regulations in early June 2003.

At the hearings, the brand and generic industies expressed opposing views about the Regulations. Industry Canada was, as usual, supportive of the Regulations in general, but also suggested recent court decisions dealing with the timing of the listing of patents and the relevance of the patents "require the balance to be looked at carefully."[27]

However, the Committee had not issued a report when Parliament rose for the summer of 2003. During the summer, the government's agenda on drug patents suddenly shifted and became completely focused on what is now known as Bill C-9, the Access to Medicines legislation.

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[26] Romanow Report, p. 208 - 209.

[27] Summary of evidence and submissions, *Patented Medicines (Notice of Compliance) Regulations*, Parliamentary Research Branch, 28 August 2003.

The Senate expressed dissatisfaction with the Regulations in its Observations on Bill S-17 (the most recent amendment to the *Patent Act*). On April 5, 2001, the Senate Banking Committee commented the Regulations "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."

Comparable legislation in the US

Canada's *PM (NOC) Regulations* are loosely modeled on the Hatch-Waxman amendments of 1984,[28] the equivalent US legislative scheme.[29]

In 2003, the US amended the scheme to permit only one automatic stay, per generic submission. The amendments were in response to concerns raised by anti-trust authorities about the anti-competitive effect of multiple stays.

In the summer of 2002, as mentioned above, the US antitrust authority, the Federal Trade Commission, released a report[30] dealing with, among others things, the anti-competitive effect of listing multiple patents for a single drug in the Orange Book (equivalent to the patent register in Canada). The Report found multiple stays had extended the patentees' monopolies in certain drugs improperly, an example being paroxetine (the US situation was not dissimilar to the Canadian chronology set out above).

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[28] *Drug Price Competition and Patent Term Restoration Act, 1984*, Public Law 98-417 [S.1538]; September 24, 1984, known as the Hatch-Waxman Act After the sponsors of the bill, Representative Henry Waxman, and Senator Orrin Hatch.
[29] See Hore, E. "*A Comparison of United States and Canadian Laws as They Affect Generic Pharmaceutical Entry*," 55 Food and Drug Law Journal 2 2000 at 373.
[30] *Generic Drug Entry Prior to Patent Expiration: An FTC Study, Federal Trade Commission*, July, 2002.

The FTC's primary recommendation was:

> Recommendation 1: Permit only one automatic 30-month stay [equivalent to Canada's 24 month stay] per drug product per ANDA [generic submission] to resolve infringement disputes over patents listed in the Orange Book prior to the filing date of the generic applicant's ANDA.[31]

On October 21, 2002, in response to the FTC Report, President George W. Bush proposed a new FDA regulation in draft, intended to impose a limit of one automatic stay per generic submission. President Bush expressed concerns about evergreening strategies.

> When a drug patent is about to expire, one method some companies use is to file a brand new patent based on a minor feature, such as the color of the pill bottle or a specific combination of ingredients unrelated to the drug's effectiveness. In this way, the brand name company buys time through repeated delays, called automatic stays, that freeze the status quo as the legal complexities are sorted out. In the meantime, the lower-cost generic drug is shut out of the market.These delays have gone on, in some cases, for 37 months or 53 months or 65 months. This is not how Congress intended the law to work. Today, I'm taking action to close the loopholes, to promote fair competition and to reduce the cost of prescription drugs in America.[32]

After consultations, FDA issued a "final rule" on June 12, 2003, effective August 18, 2003. The rule limited a brand drug company to only one 30-month stay.[33] It was estimated the change would save consumers $35 billion over ten years.[34]

The FDA Final Rule was somewhat awkwardly drafted, so as not to step outside the existing statutory wording of the 1984 Waxman-Hatch Act. The Final Rule said a generic need serve a paragraph IV certification (equivalent to a Canadian NOA) on the brand

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[31] FTC Report p. ii.
[32] Remarks by the President on Prescription Drugs, The Rose Garden, October 21, 2002. See http://www.whitehouse.gov/news/releases/2002/10/20021021-2.html
[33] *Federal Register*, June 18 2003 (68 FR 36676).
[34] Statement of FDA counsel Daniel Troy to the Committee on the Judiciary, US Senate, August 1, 2003.

only if it was an initial certification, or if a previous certification did not result in a 30 month stay. For later patents, the generic need only file a certification with the FDA, but did not have to serve it on the brand. The effect was that the brand company no longer had the opportunity to obtain a second 30 month stay.

On December 8, 2003, the President signed the *Medicare Prescription Drug, Improvement, and Modernization Act* into law. This omnibus bill made changes to the Medicare system in the US, but also included in Title XI amendments to the Waxman-Hatch Act to limit the brand to one automatic stay per ANDA, retroactive to August 18, 2003, the effective date of the FDA Final Rule. The FDA has just revoked its Final Rule as unnecessary in light of this new statutory language.[35]

Why not use the ordinary patent litigation system for drugs?

The arguments usually put forward as to why a special patent-enforcement regime is required for pharmaceuticals are (a) patent litigation is lengthy, and interlocutory injunctions are difficult to get in such litigation, and (b) pharmaceuticals spend many years in the regulatory process before they can get on the market, reducing their period of effective exclusivity, so quick remedies are required, and (c) generic companies have the benefit of the "early working" exception in section 55.2(1) of the *Patent Act*.

Are the remedies available in ordinary patent litigation sufficient for pharmaceutical patentees? A patentee who establishes that its patent is valid and infringed is entitled to relief under section 57 of the *Patent Act*, which "gives the trial judge in an action for infringement of a patent a wide discretion to make such order as the judge sees fit."[36] Such an order will typically grant the plaintiff damages, or an accounting of the defendant's profits, as the patentee may elect, delivery up of any infringing goods, a

[35] *Federal Register*, March 10, 2004 (69 FR 11309).
[36] *Bayer AG et al. v. Apotex Inc*. (2002), 16 C.P.R. (4th) 417 (Ont. C.A.) at paragraph 11.

permanent injunction until patent expiry, and court costs. Punitive damages may be available in an appropriate case.[37]

These remedies have existed for many decades in Canada and elsewhere and it is difficult to see why they are inadequate in the pharmaceutical industry alone.

Are the Regulations necessary because interlocutory injunctions are too hard to get? The Regulations effectively eliminate the discretion of the court over the granting of interlocutory relief in patent disputes about drugs. They impose an automatic injunction until the hearing, analogous to an interim injunction, and then provide for an order of prohibition at trial, analogous to an interlocutory injunction, but without regard to the normal test.

The three part test that must normally be satisfied before an interim or interlocutory injunction is granted is well-known: the moving party must establish (1) a *prima facie* case on the merits, (2) that it will suffer irreparable harm if the injunction is not granted, and (3) that the balance of convenience favours the granting of the interlocutory injunction. The moving party must give an undertaking as to damages. [38]

Interlocutory injunctions are rarely granted in patent cases (nor in other intellectual property cases, nor civil litigation of any kind), because the courts have long regarded it as unfair to enjoin the defendant before trial, except in extraordinary circumstances.

However, patentees and litigants in all industries are subject to the same constraints in attempting to get interlocutory relief, and are faced with the same challenges in getting cases to trial expeditiously. The appropriate response to delays in getting trial dates is to increase court resources by, for example, hiring more judges, which the Federal Court seems to be doing.

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[37] *Lubrizol Corp.* v. *Imperial Oil Ltd.* (1996) 67 C.P.R. (3d) 1 (FCA). *Apotex v. Merck* (2002), 19 C.P.R. (4th) 460.

[38] *RJR-Macdonald Inc. v. Canada*, [1994] 1 S.C. R. 311.

Are the Regulations necessary because of long regulatory delays for drug approvals? Many patentees outside the pharmaceutical industry make a large investment in research and may have a short window of opportunity in which to sell a new product, due to technological advances by competitors (the computer and electronics industries, for example). It is unclear why the pharmaceutical industry should be treated differently from the others. The best way to minimize regulatory delays would appear to be to accelerate the drug approval process.

Are the Regulations needed because of the "early working" exception? The "early working" provision creates an exception available to any patentee, in any industry. The exception provides:

> **55.2 (1) Exception** - 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, a province or a country other than Canada that regulates the manufacture, construction, use or sale of any product.

The subsection of the *Patent Act* that authorizes the *PM (NOC) Regulations* makes reference to the early working provision:

> **(4) Regulations** - The Governor in Council may make such regulations as the Governor in Council considers necessary for preventing the infringement of a patent by any person who makes, constructs, uses or sells a patented invention in accordance with subsection (1)…

The *PM (NOC) Regulations* are not necessary to determine whether the exception applies in any particular case, nor to impose remedies if not. The usual remedies for infringement can be pursued against a defendant in any patent action who raises the early working exception as a defence, and the court can determine at trial if the defence applies.

The "early working" exception has been upheld by a dispute panel of the World Trade Organization as a reasonable "limited exception" under Article 20 of the TRIPS

agreement on its own merits, and not because the *PM (NOC) Regulations* exist.[39] The "early working" exception in any event existed at common law before the passing of ss. 55.2(1) or (4).[40]

All of this must be weighed against the cost of the Regulations to society. The automatic injunctions have an obvious downside: non-infringing products are inevitably kept off the market. This raises drugs costs. It also creates an economic disincentive to the challenging of potentially invalid patents, although such challenges have the potential to benefit the public at large, and are indeed essential if the patent system is to function as intended.

Conversely, the Regulations create an obvious incentive to litigate weak patent claims, and engage in practices designed to re-start the stay and extend the monopoly indefinitely.

As well, the issue between the parties (is the patent valid and infringed?) is not, and cannot be, determined under the *PM (NOC) Regulations*, defeating the normal purpose of the courts: to resolve civil disputes.

Finally, anecdotal evidence suggests the sheer volume of pharmaceutical judicial review applications have led to long delays in getting trial dates for non-pharmaceutical cases.

Conclusion

The normal litigation process should be used to resolve patent disputes in the pharmaceutical industry, as in all other industries.

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[39] *Canada - Patent Protection of Pharmaceutical Products*, WT/DS/114 (March 17, 2000)
[40] *Micro Chemicals Ltd. v. Smith Kline & French Inter-m. Corp*. [1972] S.C.R. 506, 520.

The courts can determine what interlocutory relief or other procedural measures are appropriate in any given case, and determine the patent issues at trial.

If the *PM (NOC) Regulations* are retained, there should be a limit of one automatic stay per generic submission. Disputes over later patents can be litigated using the normal court procedure.

Appendix A

The *PM (NOC Regulations* were enacted under s. 55.2 of the *Patent Act* in 1993.[41] They were amended in 1998,[42] and again in 1999.[43]

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

The procedure under the *Regulations*, in short, allows a patentee to 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.[44]

The procedure under the Regulations

The procedure under the Regulations, in brief, is as follows:

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[41] SOR/93-133

[42] SOR/98-166. The amendments included the following: the 30 month stay became 24 months, the damages section was amended (section 8), the right to serve a notice of allegation of non-infringement prior to filing the ANDS was removed, the Minister's authority to audit the patent register was confirmed, an early dismissal section was added (6(5)), disclosure of relevant potions of second person submission was provided for (6(7)), and section 4 was amended, possibly with the intent of limiting to some extent the patents that can be listed on the register.

[43] SOR/DORS/99-379. The effect of these amendments was to add s. 5(1.1), the intent of which seems to have been to ensure that the regulations applied even if the generic submission compared itself to an existing generic product. Section 5(1.1) has been held to bring a non-abbreviated submission based on clinical trials within the scope of the Regulations: *Bristol-Myers v. Biolyse*, 2003 FCA 180, leave to appeal to Supreme Court of Canada granted, November 20, 2003, SCC No. 29823.

[44] *Merck Frosst v. Canada (Minister of National Health and Welfare)*, (1998), 80 C.P.R. (3d) 368 (S.C.C.) at 384, para. 32, 33.

The register: Patentees, referred to as "first persons," may list patents on a patent register in connection with drug products for which they hold regulatory approval.[45] The health and safety regulator at Health Canada, Therapeutic Products Directorate (TPD), maintains the register.

Allegation: 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 (i.e. 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,[46] or serve an "allegation" on the first person that the listed patent or patents are invalid or are not infringed by its submission,[47] together with a detailed statement of the legal and factual basis of the allegation.[48]

Judicial review application: 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.[49]

Automatic stay: If the application is commenced, the NOC may not be issued for 24 months,[50] or until the court hearing or patent expiry.[51] 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

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[45] *PM(NOC) Regulations*, s. 3, 4.
[46] *PM(NOC) Regulations*, s. 5(1)(a).
[47] *PM(NOC) Regulations*, s. 5(1)(b).
[48] *PM(NOC) Regulations*, s. 5(3)(a).
[49] *PM(NOC) Regulations*, s. 6(1).
[50] *PM(NOC) Regulations*, s. 7. If litigation was commenced prior to March 12, 1998, the automatic stay is 30 months as in Hatch-Waxman.
[51] *PM(NOC) Regulations*, s. 7.

having satisfied any of the criteria a court would require before enjoining issuance of an NOC."[52]

Prohibition order: 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.[53] If the court 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.)

Litigation does not determine patent issue: The litigation started by the first person after receiving an allegation is not an action for patent infringement, but a judicial review proceeding.[54] 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 may take years 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."[55] Therefore, the remedies under the Regulations are in addition to the remedies available under the *Patent Act*; either party can also commence a patent action on the same patent.[56] As the Federal Court of Appeal observed, "patent invalidity, like patent infringement, cannot be litigated in this type of proceeding [i.e. an application under the *Regulations*]. I can only think that the draftsperson had in mind the possibility of there being parallel proceeding instituted by

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[52] *Bayer A.G. v. Canada (Minister of National Health and Welfare)* (1993), 163 N.R. 183 at 189-90, 51 C.P.R. (3d) 129 (F.C.A.)
[53] *PM(NOC) Regulations*, s. 6(1).
[54] *Eli Lilly & Co. et al. v. Apotex Inc. et al*. (1997), 76 C.P.R. (3d) 1 (F.C.A.) at 5 - 6.
[55] *Merck Frosst v. Minister of National Health & Welfare* (1994), 55 C.P.R. (3d) 302 at 319 (F.C.A.)
[56] *Pharmacia Inc. v. Canada (Minister of National Health and Welfare)*(1994), 58 C.P.R. (3d) 209 (F.C.A.) at 217

the second person which might give rise to such a declaration [of invalidity or non-infringement] and be binding on the parties."[57]

The odd result is that a second person might lose the prohibition proceedings under the *Regulations*, i.e. 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.[58]

Damages: If a generic product is delayed by the Regulations, the generic may be able to claim damages from the first person.[59] However, there is no provision in the Regulations for damages to payers such as provincial governments, private benefit plan operators or the public.

[57] *Merck*, supra. at 320.
[58] After being prohibited in several NOC cases with respect to naproxen SR, Apotex obtained a declaration that the patent was not infringed and invalid at trial, *Apotex v. Hoffmann La Roche*, F.C.T.D. Court File no. T-2870-96, Reasons, April 23, 1999. The prohibition order granted years earlier was set aside, *Hoffman La Roche Limited v. Apotex Inc.* File no. T-1898-93, April 30, 1999, but only after the generic NOC had been delayed for years.
[59] The damages section, section 8, was amended in 1998. There are now several cases on-going seeking damages, but none have yet reached trial.