Are the *Patented Medicines (Notice of Compliance) Regulations* Working?

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Introduction

The *Patented Medicines (Notice of Compliance) Regulations* (the "Regulations") were enacted under s. 55.2 of the *Patent Act* in 1993,[1] creating a scheme roughly modeled on the US Hatch-Waxman amendments of 1984.[2] They were amended in 1998,[3] and again in 1999.[4]

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*.

[1] SOR/93-133
[2] *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.
[3] 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.
[4] 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 recently been held to bring a non-abbreviated submission based on clinical trials within the scope of the Regulations: *Bristol-Myers v. Biolyse*, T-1898-01, November 22, 2002.

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.[5]

The procedure under the Regulations

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

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.[6] 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,[7] or serve an "allegation" on the first person that the listed patent or patents are invalid or are not infringed by its submission,[8] together with a detailed statement of the legal and factual basis of the allegation.[9]

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[5] *Merck Frosst v. Canada (Minister of National Health and Welfare)*, (1998), 80 C.P.R. (3d) 368 (S.C.C.) at 384.
Supreme Court of Canada File No. 25419, July 9, 1998, para. 32, 33.
[6] *PM(NOC) Regulations*, s. 3, 4.
[7] *PM(NOC) Regulations*, s. 5(1)(a).
[8] *PM(NOC) Regulations*, s. 5(1)(b).
[9] *PM(NOC) Regulations*, s. 5(3)(a).

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.[10]

Automatic stay: If the application is commenced, the NOC may not be issued for 24 months,[11] or until the court hearing or patent expiry.[12] 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."[13]

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.[14] 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.[15] 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

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[10] *PM(NOC) Regulations*, s. 6(1).
[11] *PM(NOC) Regulations*, s. 7. If litigation was commenced prior to March 12, 1998, the automatic stay is 30 months as in Hatch-Waxman.
[12] *PM(NOC) Regulations*, s. 7.
[13] *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.)
[14] *PM(NOC) Regulations*, s. 6(1).
[15] *Eli Lilly & Co. et al. v. Apotex Inc. et al*. (1997), 76 C.P.R. (3d) 1 (F.C.A.) at 5 - 6.

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."[16] 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.[17] 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 the second person which might give rise to such a declaration [of invalidity or non-infringement] and be binding on the parties."[18]

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.[19]

Damages: If a generic product is delayed by the Regulations, the generic may be able to claim damages from the first person.[20] However, there is no provision in the Regulations for damages to payers such as provincial governments, private benefit plan operators or the public.

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[16] *Merck Frosst v. Minister of National Health & Welfare* (1994), 55 C.P.R. (3d) 302 at 319 (F.C.A.)
[17] *Pharmacia Inc. v. Canada (Minister of National Health and Welfare)*(1994), 58 C.P.R. (3d) 209 (F.C.A.) at 217
[18] *Merck*, supra. at 320.
[19] 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.
[20] The damages section, section 8, was amended in 1998. There are now several cases on-going seeking damages.

Questions about the Regulations by policy makers

As the Regulations impose additional remedies against an alleged infringer beyond those normally available under the *Patent Act*, but available only to patent-holders in one segment of the economy, some policy makers have questioned why the Regulations are needed.

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."

More recently, the Romanow Report recommended that the Regulations be reviewed:

> **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)[21]

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

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

> 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…[22]

As the Report said that the review should take place "immediately," it appears that Parliament's Standing Committee on Industry will review the Regulations in the spring of 2003, although the date and format of the review have not yet finalized as of the date of writing.

Why not use the ordinary patent litigation system for drugs?

The arguments usually put forward as to why additional remedies are 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

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

infringement of a patent a wide discretion to make such order as the judge sees fit."[23] 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 permanent injunction until patent expiry, and court costs. Punitive damages may be available in an appropriate case.[24]

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. [25]

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

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[23] *Bayer AG et al. v. Apotex Inc*. (2002), 16 C.P.R. (4th) 417 (Ont. C.A.) at paragraph 11.
[24] *Lubrizol Corp*. v. *Imperial Oil Ltd.* (1996) 67 C.P.R. (3d) 1 (FCA). *Apotex v. Merck* (2002), 19 C.P.R. (4th) 460.
[25] *RJR-Macdonald Inc. v. Canada*, [1994] 1 S.C. R. 311.

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.

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 (eg. the computer industry) for example. Thus it is unclear why the pharmaceutical industry should be treated differently from the others. The remedy to 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.[26] The "early working" exception existed at common law long before the passing of s. 55.2(1) or (4).[27]

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.

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

Multiple patents - restarting the stay

An outcome of the Regulations that is attracting particular attention is what the Romanow Report referred to as "evergreening." This term essentially refers to the practice of re-starting the automatic stay, through listing and litigating additional patents after the main patent on the active molecule has expired, in order to prolong the patentee's period of exclusivity

If the second person is already in litigation under the *Regulations* on one patent in connection with a particular drug product, and another patent appears on the register in connection with the drug, the second person must address the new patent.[28] If it does so by serving a notice of allegation, the second person can commence another application and the 24 months starts again. This may happen several times. There may be several applications between the first person and the second person relating to a single drug product.

The delay in the approval of generic caused by the Regulations can be very considerable, particularly due to the effect of multiple patents, 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, 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.

[28] *PM(NOC) Regulations*, s. 5(2).

- SmithKline's two earlier applications were dismissed April 20, 1999[29] i.e. 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 (i.e. TPD'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 again dismissed on July 6, 2001[30]; the Court 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.

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 the three applications that have come to a hearing so far. Yet the automatic stay remains in place.

Eligibility: what patents can 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. A summary of the rules as they stand follows:

Section 4 of the Regulations governs the filing of patent lists:

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

[29] *SmithKline Beecham v. Apotex* (1999) 1 C.P.R. (4th) 99, affirmed (2001) 10 C.P.R. (4th) 338 (F.C.A).
[30] *SmithKline Beecham v. Apotex* (2001) 14 C.P.R. (4th) 76, affirmed (2002) 21 C.P.R. (4th) 129 (F.C.A.)

(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 i.e. substances used in the manufacturing process.[31]

- Claims to metabolites are not claims for the medicine itself.[32]

- Claims to compositions, i.e. 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.[33]

- Claims to medical devices are not claims to the medicine.[34]

- Under amendments made in 1998, the patentee must certify that the patent is "relevant" to the dosage form, strength and route of administration of the first person's drug.[35] The Minister interpreted this to mean that any patent claiming non-approved formulations could not be listed,[36] but the Federal Court of Appeal in the recent *Eli Lilly* case, in a split 2 to 1 decision, overturned the lower court and held the Minister should have listed the patent on the register.[37]

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[31] *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.)
[32] *Merck v. Minister of Health* (2001), 12 C.P.R. (4th) 383.
[33] *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
[34] *Glaxo Group Ltd. v. Novopharm Ltd*. (1999), 87 C.P.R. (3d) 525 (F.C.A.), *Novartis v. Minister of Health* (T-193-01), October 7, 2002.
[35] s. 4(7)(b).
[36] *Warner Lambert v. M. of H.* [2001] F.C.J. No. 801, *Eli Lilly v. M. of H.*, T-1212-00, January 10, 2002.
[37] *Eli Lilly v. Minister of Health*, 2003 FCA 24

As there is no real limit to the number of patents for non-approved formulations of any given drug that may be obtained, the *Eli Lilly* case may open the door to many imaginative evergreening strategies, particularly if the timing restrictions are not strictly enforced.

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.

- A supplemental submission (SNDS) [38] has been held to be a "submission" for the purposes of the predecessor of section 4(4),[39] but the Federal Court of Appeal has not followed that interpretation in applying the post-1998 Regulations.[40] More recently, it has been held that an SNDS is not an opportunity to list a patent.[41]

- At present, the practice of the Minister appears to be that patents can be listed with a supplemental submission except for SNDS for a mere product name change[42] or company name change.[43]

- 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

[38] *Food and Drug Regulations*. C.08.003.
[39] *Apotex v. Minister of Health* (1999), 87 C.P.R. (3d) 271, affirmed (2001) 11 C.P.R. (4th) 538.
[40] *Bristol Myers Squibb v. Canada (A.G.)* 2002 FCA 32.
[41] *Toba Pharma v. Canada (A.G.)* (2002) 21 C.P.R. (4th) 232
[42] *Bristol Myers v. Canada*, (2001) 10 C.P.R. (4th) 318, affirmed (2002) 16 C.P.R. (4th) 425.
[43] *Toba Pharma Inc. v. A.G. Canada*, see above

the Minister were in dispute.[44] The Minister of Health then sent out question for comment on November 9, 2002, and held a "meeting" or informal hearing on the issue on December 2. At time of writing, there has been no decision or other action from the Minister in response.

- 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.[45]

These ever-changing rules have proved virtually impossible to administer, and have done nothing to prevent evergreening strategies, and continual litigation.

Changes in the US

As noted above, the Canadian PM (NOC) Regulations are loosely modeled on the equivalent US legislative scheme known as the Waxman-Hatch Act.
The US Federal Trade Commission recently released a report[46] 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.[47]

[44] *Patented Medicines (Notice of Compliance) Regulations (Reference)*, (2003), 22 C.P.R. (4th) 62.
[45] *Pfizer, Schering v. Canada* 2002 FCT 706, appeal currently under reserve.
[46] *Generic Drug Entry Prior to Patent Expiration: An FTC Study, Federal Trade Commission*, July, 2002.

On October 21, 2002, in response to FTC Report, and various bills in the Senate and House of Representatives, President George W. Bush announced that he is taking action to close loopholes in U.S. drug patent laws (the Hatch-Waxman Act), which grant an automatic stay similar to that under the *Regulations* in Canada.

In his October 21 statement Bush said that:

> 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.

The President's proposed to amend the regulations under Hatch-Waxman to provide that there can only be one automatic stay per generic submission.

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 in that they impose automatic remedies on one side of a civil dispute regardless of the merits, they do not resolve the civil dispute, and they impose enormous costs on the parties and on society by keeping low-cost drug 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.

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[47] FTC Report p. ii.

The normal litigation process should be used to resolve patent disputes in the pharmaceutical industry, as in all other industries. The courts can then determine what interlocutory relief or other procedural measures are appropriate in any given case, and determine the patent issues at trial.