

PATENTLY ABSURD:

**Evergreening of pharmaceutical patent
protection under the *Patented Medicines
(Notice of Compliance) Regulations
of Canada's Patent Act***

By
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Table of Contents

| | |
|------------------------------------|-----------|
| Executive Summary | 3 |
| Highlights | 5 |
| Part I | 6 |
| Part II | 20 |
| Conclusion | 28 |
| Footnotes | 29 |
| Appendix A | 32 |
| Appendix B. | 33 |
| Appendix C | 34 |
| Appendix D | 34 |
| Appendix E. | 35 |
| Appendix F. | 36 |

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Executive Summary

THE *PATENTED MEDICINES (NOTICE OF COMPLIANCE) REGULATIONS* are regulations under Canada's *Patent Act* that apply only to pharmaceutical products. They give pharmaceutical patentees, i.e. brand-name drug companies, extra remedies in a patent dispute, far beyond the normal remedies available to patentees in other industries. The *Regulations* have been described as "a draconian regime" by the Supreme Court of Canada in their effect on generic manufacturers

The *Regulations* allow brand-name drug companies to keep a generic competitor out of the market automatically for 24 months, without a court hearing, merely by starting a court case asserting that a patent, or several patents, would be infringed by the generic product.

The *Regulations* have enabled many abusive strategies, which allow patentees to prolong their market monopolies at the expense of all purchasers of prescription medicines in Canada, including provincial governments, employers that sponsor drug plans and the public. Unfortunately, brand-name companies now find it more lucrative to litigate than to innovate. Examples of these strategies are described in detail in Part II.

The *Regulations* give patentees every incentive to litigate patents as long as possible, keeping non-infringing, lower-cost generic pharmaceutical products off the market. Generic drug companies win most of the cases eventually, but only after years of delays.

The automatic stay under the *Regulations* is particularly problematic because loopholes in the wording of the *Regulations* allow brand-name drug companies to obtain several automatic stays in a row, as new patents are listed under the scheme, a practice known as "ever-greening."

Health-care commissioner Roy Romanow called on the federal government to review this practice in his November 2002 report. In February 2004, the Competition Bureau made the same recommendation.

In April 2001, the Senate Standing Committee on Banking, Trade and Commerce noted that the *Regulations* may not be working as Parliament originally anticipated and that the courts are fully capable of determining appropriate procedures in patent disputes, which should not differ substantially from one industry to another.

In December 2003, the United States amended its drug patent scheme to limit brand-name drug companies' ability to employ ever-greening strategies to keep generic competition off the market.

Repealing the *Regulations* would not violate Canada's international obligations; patent disputes would simply be litigated via the normal court process used in patent disputes in all other industries.

In short, brand-name drug companies should not be granted automatic extensions of their market monopolies simply because they decide to sue a generic pharmaceutical manufacturer.

Highlights

- Pharmaceutical products with annual sales totalling nearly \$1-billion in Canada have had their market monopolies extended by evergreening strategies under the *Patented Medicines (Notice of Compliance) Regulations*.
- Brand-name drug companies have employed strategies under the *Regulations* to extend their exclusive marketing rights on blockbuster drugs such as anti-depressant Paxil, heartburn drug Losec and Taxol, the leading treatment for breast, ovarian and lung cancer.
- Since 1998, generic pharmaceutical manufacturers have won at least 75% of the cases under the *Regulations*. However, even when the generic firm wins the court cases, the brand-name drug company has successfully extended its market monopoly, sometimes for years after the expiry of the basic patents.
- Multiple-patent strategies are increasingly used by brand-name companies to extend their market monopolies beyond the expiry of the patent on the basic medicine. As evidence of this, Health Canada approved only 16 new active substances in 2003, yet brand-name drug companies added 103 patents to Health Canada's Patent Register in that same year.
- Under the *Regulations*, brand-name drug companies are allowed to list patents for uses of a drug, even though the drug is not approved for that use by Health Canada. Patents can be listed to restart the automatic stay even years after the basic patent on the drug has expired.

Absurd Practices: Constructing the thicket of patents

Part I

The Patented Medicines (Notice of Compliance) Regulations

THE *PATENTED MEDICINES (NOTICE OF COMPLIANCE) REGULATIONS* give pharmaceutical patentees (brand-name drug companies) powerful remedies in a patent dispute, in addition to the normal remedies under the *Patent Act* available to patentees in other industries.

The *Regulations* were enacted under section 55.2 of the *Patent Act* in 1993.¹ They were amended in 1998² and again in 1999.³

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

The *Regulations* were originally enacted for the dual purpose of protecting legitimate patent rights and accelerating the market entry of affordable generic drugs. Rather than protecting legitimate

patent rights, however, the *Regulations* have enabled a host of abusive strategies that allow patentees to prolong their market monopolies at the expense of the Canadian public. Examples of such strategies are described in detail in Part II.

In practice, the *Regulations* do not facilitate the market entry of affordable generic drugs, but rather tie up generic manufacturers in years of wasteful and ineffectual litigation over dubious

p a t e n t s .
Throughout the litigation, the generic manufacturer is subject to automatic injunctions preventing its lower-cost product from entering the market, long past the time when its drug

has been found safe and effective by Health Canada.

The *Regulations* give patentees every incentive to litigate meritless patent claims as long as possible, keeping affordable, generic products off the market. The public pays higher drug prices

"The anti-generic strategy by pharmaceutical companies has probably the highest rate of return of any business activity they do right now."

Stock Analyst Hemant K. Shah,
Wall Street Journal, July 12, 2001.

as a result.

The *Regulations* have been described as “a draconian regime” by the Supreme Court of Canada in their effect on generic manufacturers.⁴

The *Regulations* could be eliminated without violating any of Canada’s treaty obligations. If the *Regulations* were abolished, pharmaceutical patentees would still have all the legal rights that other patentees do, but they would no longer have an automatic right to keep competitors off the market.

Brand-name drug companies should not be granted automatic extensions of their market monopolies simply because they decide to sue a generic firm.

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.⁵ 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,⁶ or serve an “allegation” on the first person that the listed patent or patents are invalid or are not infringed by its submission,⁷ together with a detailed statement of the legal and factual basis of the allegation.⁸

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.⁹

Automatic stay: If the application is commenced, the NOC may not be issued for 24 months,¹⁰ or until the court hearing or patent expiry.¹¹ 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.”¹²

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.¹³ 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.¹⁴ 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*."¹⁵ 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.¹⁶ 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 proceedings instituted by the second person which might give rise to such a declaration [of invalidity or non-infringement] and be binding on the parties."¹⁷

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.¹⁸

Damages: If a generic product is delayed by the *Regulations*, the generic may be able to claim damages from the first person.¹⁹ However, there is no provision in the *Regulations* for damages to payers such as provincial governments, private benefit plan operators or the public.

No damages have ever been awarded to any generic party under this section. There are now at least 12 section 8 cases before the courts, in which generics seek damages resulting from delays to market entry of generic drugs. It may take many years for these cases to be resolved. Many other generic drugs are now delayed by the *Regulations*, at great cost to the public, but the delay is ongoing. Litigation for damages cannot be commenced until an NOC is obtained, which may not occur for many years.

It is unlikely that the damages section will ever be a disincentive to the abusive use of the *Regulations* because generic prices are much lower than the patentee's prices. Therefore any damages or profits that generic parties are awarded are likely to be far less than the windfall the patentee earned from using the stay to keep competition off the market. Furthermore, patentees argue in these cases that section 8 is unconstitutional, and are seeking to have the courts strike out the section so that they never have to pay any damages.

As the Competition Bureau noted on February 27, 2004: "Furthermore, I note

there is no ready mechanism for compensating consumers affected by these delays in the introduction of generic drugs, thereby creating a possible incentive for brand-name pharmaceutical companies to strategically use the *NOC Regulations* to improperly delay generic drug entry."

Evergreening: 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.

For the purposes of addressing evergreening, the main points about the procedure described above are:

- A 24-month stay on approval of a generic drug occurs automatically if a

"first person," a brand-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.²⁰
- 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.

A Case Study

The Paroxetine Prognosis: Take nine patents and call me in 8 years

THE DELAY IN THE MARKET ENTRY OF A GENERIC DRUG can be considerable, as illustrated by the following chronology in respect of paroxetine, an anti-depressant sold under the trade name Paxil.

- Generic pharmaceutical manufacturer 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, 1999,²¹ 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 was dismissed on July 6, 2001;²² 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.²³
- However, another prohibition proceeding had meanwhile been commenced against Apotex concerning three further patents on “Form A” (T-876-02).²⁴
- Several generic companies 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,²⁵ and GlaxoSmithKline seems to have decided that the risk of damages outweighed the benefit of continuing to litigate.

A diagram of this chronology is set out in Appendix F.

Note that the delay in market entry of 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. In the third case mentioned above, T-1059-01, the court commented on the patentee’s multiple-patent strategy as follows:

The effect of [the 24-month automatic stay] is to put in place a mandatory injunction that remains in force until either the case is disposed of or the 24-month stay expires. The addition of additional patents allows the patent-holder to bring additional applications, thereby obtaining multiple injunctive periods. There is no need to look further than the case at bar for an excellent example of this practice. Even though Apotex successfully invalidated the ‘637 patent in 2001, the filing of this application by GSK has prohibited Apotex from bringing its product to market

for the past two years.²⁶

Similar evergreening strategies used for omeprazole capsules, citalopram tablets, diltiazem capsules and omeprazole tablets, are illustrated through diagrams provided in the appendices.

At least 75% of the prohibition applications decided by a court since 1998 have been dismissed; that is to say, the generic won. But, as the above examples show, 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 United States. The Federal Trade Commission studied equivalent litigation in the U.S. 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.”²⁷

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

Eligibility:

What patents can be listed?

Given the extraordinary benefit to the first person (brand-name drug company) 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.

Broadly speaking, the restrictions on listing patents in the case law, 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,²⁸ claims to metabolites,²⁹ claims to medical devices such inhalers, patches or kits.³⁰

Claims to compositions are claims to the medicine itself.³¹ A composition patent, also known as a formulation patent, is a patent claiming the active ingredient combined with one or more inactive ingredients, for example a coating. Such patents typically issue after the active ingredient itself is old, and no longer patentable. There can be many composition patents for a particular drug product.

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.³² However, the Federal Court of Appeal, in *Eli Lilly*, a 2 to 1 decision, held that patents on non-approved formulations could be listed.³³

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.³⁴ 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 “oppo-

site” 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.”

The register includes patents on both approved and non-approved formulations and uses, products-by-process, variants such 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 11 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.

Timing restrictions

There are also timing rules on when new patents can be listed, 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)³⁵ has been held to be a “submission” for the purposes of this section.³⁶

This broad reading of “submission” opens the door widely because a patentee can file an SNDS when it chooses; for most drugs new SNDSs will be submitted routinely from time to time to update

the information filed with Health Canada.

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 Squibb*, a case involving an 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.³⁷ A subsequent trial level decision refused to apply the *Bristol-Myers* case,³⁸ but was overturned on appeal.³⁹ A more recent case has held that an SNDS for an additional manufacturing site cannot support the listing of a patent.⁴⁰

Because the wording of the *Regulations* is unclear, the courts have said in effect that a patent can be listed with any SNDS not for a name change. The Federal Court of Appeal recently held that even a seemingly minor product monograph revision (an addition of a sentence indicating that the drug clarithromycin is also available packaged together with two other drugs) can be used to list an unrelated patent for a method of crystallizing clarithromycin in a solvent.⁴¹ The patentee, Abbott Laboratories, has now listed eight more patents for clarithromycin,⁴² and will no doubt continue to list more. Several automatic stays have been commenced against various generic manufacturers.

The Minister of Health has tried unsuccessfully to get the courts to provide clarification as to the meaning of the wording in s. 4 of the *Regulations*. In late February 2002, the Minister commenced a “Reference by Federal Tribunal” under Rule 18.3(1), asking the courts to rule to whether a patent must be “relevant” to the SNDS with which it is submitted. However, brand-name drug companies moved successfully to strike out the Reference on the grounds the facts put to the court by the Minister were in dispute.⁴³

As noted above, the “filing date” of the patent must be prior to the “submission.” Brand-name drug companies argued that the words “filing date” in section 4(4) include a priority date,⁴⁴ 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. Brand-name drug firms then commenced litigation against the Minister attacking this position, but the courts held that “filing date” does not include a priority date.⁴⁵ Pfizer’s azithromycin patent, the court said, was therefore out of time to be listed.

However, Pfizer simply listed the azithromycin patent with a later SNDS, thus circumventing the time limit.

This example shows that if a patent-ee misses one time limit to list its patent, all it need do is file an SNDS, and its gets the benefit of a later time limit. In short, nothing prevents brand-name drug companies from listing new patents for a

drug, and starting the automatic stay again and again. All listed patents must be addressed by the generic company, regardless of what SNDS they were listed with.⁴⁶

Brand-name drug companies generally file many patent applications, so as to have a steady supply of new patents to list for any particular drug. Entering any important drug as a search term in the CIPO patent database⁴⁷ will typically turn up dozens of patents or open-to-the-public applications. For example, a search of the term “omeprazole” on October 1, 2004 turned up 210 patents or applications.

The number of patents listed on Health Canada’s Patent Register under the *Regulations* far exceeds the number of new pharmaceutical products approved in any given period of time. For example, only 16 “new active substances,” meaning new drugs, were approved by Health Canada in 2003⁴⁸ but 103 patents were added to the patent register in the same year.⁴⁹

The question arises: does this chaotic and unfair system serve the public interest in access to non-infringing, affordable drugs?

Policymakers’ concerns

Various policymakers have expressed concerns about the *Regulations*.

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

Recommendation 41:

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.⁵⁰

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

A particular concern with current pharmaceutical industry practice is the process of “evergreening,” whereby manufacturers of brand name drugs make variations to existing drugs 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 as 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...⁵¹

At the resulting hearings before the House of Commons Standing Committee on Industry, Science and Technology in early June 2003, Industry Canada (which drafted the *Regulations*) 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 patents “require the balance to be looked at carefully.”⁵²

Throughout late 2003 and early 2004, the government’s agenda on drug patents became exclusively focused on Bill C-9, *The Jean Chrétien Pledge to Africa*. The worthy objectives of that legislation, however, did nothing to resolve the mounting problems with the *Regulations*.

More recently, the Commissioner of Competition commented that the Government may wish to review the *Regulations*:

... a number of court decisions over the last several years regarding what constitutes a relevant patent and the time period during which such a patent can be added have somewhat altered the balance contained in the *NOC Regulations* between the competing interests of the brand-name pharmaceutical patent holders and generic drug companies. Furthermore, I note there is no ready mechanism in the

NOC Regulations for compensating consumers affected by delays in the introduction of generic drugs, thereby creating a possible incentive for brand name pharmaceutical companies to strategically use the *NOC Regulations* to improperly delay generic drug entry.

Therefore, from a competition policy perspective in particular, the Government may wish to review the current regulatory process established by the *NOC Regulations* to ensure that an appropriate balance be maintained between protecting intellectual property rights and encouraging a competitive supply of pharmaceutical products for consumers.⁵³

The Senate has also expressed concern about the *Regulations*. On April 5, 2001, the Senate Banking Committee commented in its Observations on Bill S-17 that 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 1984,⁵⁴ the equivalent U.S. legislative scheme.⁵⁵

Unlike Canada’s *PM (NOC) Regulations*, the U.S. scheme rewards the

generic manufacturer that is first to challenge the brand patent monopoly. The first generic manufacturer to file a regulatory submission in the U.S. challenging a patent obtains a 180-day exclusivity.⁵⁶ This gives it a “head start” on other generic manufacturers so it can earn higher returns on its product during the 180-day period. The 180-day exclusivity is a recognition of the public interest in encouraging generic manufacturers to challenge improper drug patent monopolies as early as possible.

In 2003, the U.S. 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 U.S. antitrust authority, the Federal Trade Commission (FTC), released a report⁵⁷ 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 U.S. situation was not dissimilar to the Canadian chronology set out above).

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.⁵⁸

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 remarkably similar to concerns raised here in Canada.

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.⁵⁹

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.⁶⁰ It was estimated the change would save consumers \$35 billion over ten years.⁶¹

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 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 then revoked its Final Rule as unnecessary in light of this new statutory language.⁶²

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;
- b) pharmaceuticals spend many years in the regulatory process before they can get on the market, reducing their period of effective exclu-

sivity, 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.”⁶³ 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.⁶⁴

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 the hearing, 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.⁶⁵

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.

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.⁶⁶ The "early working" exception in any event existed at common law before the passing of subsection 55.2(1) or (4).⁶⁷

Part II

How the *Regulations* Foster Abuse

“...society would be deprived of the benefit of new methods of using existing pharmaceutical medicines at a lower cost.”

Federal Court of Appeal ruling

ABUSIVE STRATEGIES fall under 10 interrelated categories:

1. Multiple stays.
2. Listing patents for non-approved formulations and uses.
3. Listing of inappropriate and irrelevant patents.
4. Late listing of patents after generic submission filed.
5. Employing “use” patents to prevent sale for non-patented uses.
6. Litigation solely to trigger the automatic stay.
7. Use of the *Regulations* to stop non-generic products: Biolyse case.
8. Litigating NOC revoked.
9. Litigating to delay payment of damages indefinitely.
10. Double jeopardy: if generic wins NOC case, it's still sued for patent infringement.

1. *Multiple stays: Generic wins in court, but can't get on the market because new patents are listed following dismissal of prohibition proceedings*

Diagrams at Appendices A and B summarize the multi-patent strategy used by the brands for several “blockbuster” drugs. These include paroxetine (PAXIL, for treatment of depression) and omeprazole (LOSEC, for treatment of ulcers).

In both cases, the automatic injunction kept the generic version off the market for years after the basic patent had expired.

Multi-patent strategies were also used for other best-selling drugs, including fluconazole (DIFLUCAN, an antifungal agent), diltiazem (TIAZAC, a calcium channel blocker used in treatment of cardiovascular disease), citalopram (CELEXA, a selective serotonin re-uptake inhibitor (SSRI) used in the treatment of depression) and norfloxacin (NOROXIN), an antibiotic.

The litigation for these blockbuster drugs typically lasted 3-4 years on average, with court proceedings relating to paroxetine taking 7 years, and those for diltiazem ongoing since January 2001. All

involved multiple automatic injunctions per drug relating to several listed patents.

Similar multi-stay strategies are being used in the U.S. for these drugs. The FTC Report used paroxetine as a key example of abuse.¹

As indicated by the above examples, the use of multiple-patent strategies to keep generic products off the market in Canada and the U.S. has been employed increasingly for blockbuster drugs whose basic patents have expired, to extend market exclusivity as long as possible.

2. Listing patents on non-approved formulations and uses: Eli Lilly and Genpharm cases

Multiple-patent strategies recently became much easier to carry out, to the point that it may become very difficult to bring out any new generic products.

In *Eli Lilly v. Minister of Health*,² the Federal Court of Appeal decided by a 2 to 1 margin (with a strong dissent) that patents on non-approved formulations can be listed on the patent register. Previous case law³

"Nothing drug companies do is as profitable as stretching out monopoly rights on their blockbusters. Extending that privileged time by a variety of stratagems is the most innovative activity of big pharma. For blockbuster drugs, it is certainly the most lucrative."

Former editor-in-chief of the New England Journal of Medicine Dr. Marcia Angell in her book *The Truth About Drug Companies* page 173-174.

had upheld the Minister in refusing to list such patents; a patent could only be listed if it claimed the version of a drug for which the patentee had marketing approval from Health Canada.

A "formulation patent" is a patent on the

active ingredient in combination with various fillers or coatings, or formulated into a dosage form in a certain way. Such patents are usually granted long after the active ingredient is too old to be patentable on its own.

The *Lilly* decision on non-approved formulations was recently extended by the Federal Court to non-approved uses in *Genpharm v. Canada*.⁴

The result of these cases is that a patent on a non-approved formulation or use can now be listed by a brand for a drug. It is unlikely a generic would infringe such patents since they do not apply even to the brand's own drug. An endless succession of such patents can be listed, and used to re-start the automatic stay.

3. Listing of inappropriate and irrelevant patents through supplemental submissions, etc.

Brands litigate continually to list as many patents as possible. The effect is that there are now no effective limits on listing patents sequentially over time, in order to re-start the automatic stay. Neither the 1998 amendments nor efforts by Health Canada to police the register prevent new patents from being listed. The following is a summary of strategies used by the brands to list as many patents as possible on the patent register.

Patents filed with a supplemental submission, but not relevant to the supplemental submission: Brand-name companies can list patents with minor supplementary new drug submissions (SNDS) which merely amend the brand's drug approval information filed with Health Canada, even if the patent is unrelated to the amendment. For example, the Court of Appeal recently held that Abbott Laboratories could list a patent on a formulation of clarithromycin, an antibiotic, with even a minor "supplemental" submission dealing with an unrelated addition to the approved labeling information for its clarithromycin product BIAXIN BID.⁵

This opened the floodgates. Abbott has now added eight more patents to the register for BIAXIN BID.

Product Name Change: Patentees have even attempted to list patents with submissions for mere changes in the name of the product. Brand company Ferring

listed patent '296 for desmopressin acetate (CONCENTRAID, for dehydration and other symptoms). The patent was out of time to be listed under the *Regulations*. However, Ferring was able to list it anyway by filing a supplemental submission for a change to the product name. This filing restarted the time limit, said the lower court. The Federal Court of Appeal overturned,⁶ holding that the name change was clearly part of a strategy designed to overcome the time limitation.

Manufacturer Name Change: Patent '436 was submitted for sevoflurane (SEVORANE, a general anesthetic) with annual sales of \$12 million, in connection with a supplemental change seeking a change in the manufacturer's name. The court upheld the Minister in refusing to list this patent.⁷ Brand giant AstraZeneca recently tried the same strategy with its blockbuster ulcer drug omeprazole.⁸

Priority date v. "filing date": In order to be eligible for listing, the filing date of a patent must be prior to the submission date. Brand companies sued the Minister of Health asserting the "filing date" means the patent priority date, usually approximately a year earlier. This would greatly expand the class of patents that can be listed.

This argument was rejected by the courts.⁹ Among the patents at issue was one for azithromycin (ZITHROMAX, an antibiotic). However, even though the court

held the patent was out of time to be listed, the azithromycin patent was then listed with a later supplementary submission, and used to trigger automatic injunctions against several generic companies.¹⁰ This shows the time limit for listing a patent under the *Regulations* is meaningless.

Listing patents for non-marketed products: Brand-name drug companies remove products from the market as their patent expiry draws near and replace them with slightly different dosage forms, against which more patents can be listed.

For example, omeprazole capsules were removed from the market by AstraZeneca in 1996 and replaced with tablets. The change did not benefit patients in any way. In 2000 AstraZeneca listed an additional patent ('762) for the capsules¹¹ (at least four were already listed) and the courts held that generics must address the patent.

AstraZeneca listed still other patents for omeprazole capsules that were not even applied for until years after its capsules were removed from the market in 1996. AstraZeneca argued such patents can be used to revoke an NOC issued by Health Canada to a generic firm in Canada, although generic versions of omeprazole were already on the market in the U.S. and Europe. The courts dismissed the argument, noting that there had already been 11 years of litigation over omeprazole between the generic and brand under the *Regulations*.¹²

4. Late listing of patents: Patent listed after generic files its submission

Brand-name drug companies often list "later issued" patents after a generic submission has been submitted to Health Canada. For clarithromycin, Abbott Laboratories listed a patent ('732) on the register in February 2002, even though its product had been on the market since 1992. Various generic submissions for clarithromycin had already been submitted to Health Canada by generic manufacturers before the patent was listed. Generic manufacturers had to serve NOAs, triggering the 24-month stay.

Although the generics' submissions compared their versions of the drug with what Abbott Laboratories had been selling since 1992 (technology that existed before the '732 patent application was even filed), they were nevertheless subject to the automatic stay resulting from serving NOAs to the '732 patent. Abbott then listed 8 more patents between 2002 and 2004, triggering further automatic stays.

Patents have been listed in this manner right up to one day prior to the hearing of prohibition proceedings¹³ where the generic has completed its Health Canada approval process, and has won all of the prohibition cases up to that point (as for diltiazem in *Biovail*) or was on the eve of a hearing on the only patent listed to that point (as for citalopram in *Genpharm*).

5. 'Use' patents

Brand-name drug companies can sometimes extend their market monopoly after expiry of the basic patent by obtaining patents claiming the use of the drug in treatment of allegedly new diseases.

Even if the generic states it will not seek approval for the patented use, the brand company can use the *Regulations* to prevent the generic manufacturer from receiving approval for its drug so that it cannot be sold, even for non-patented uses.¹⁴ Use patents have been held invalid¹⁵ yet still trigger the automatic stay until the hearing.

Recent cases involving a use patent for omeprazole highlight the unpredictable nature of litigation about use patents under the *Regulations*. In one case¹⁶ the court rejected the brand company's submission that a generic manufacturer should be prohibited unless it can prove that no one in the world would ever use the generic drug for the patented use. However, in another case involving omeprazole,¹⁷ the court granted prohibition even though the case involved the same drug and patent.

In the former case, the Federal Court of Appeal commented:

"Thus Apotex cannot be prevented from obtaining an NOC solely on the basis that it will sell omeprazole. If it were otherwise, then serious policy issues would arise. If there was any likelihood that a patient would consume a generic product for a patented use, then the generic product would not be

approved. This would prevent new uses from being approved for existing drugs because there is always the possibility that someone somewhere will use the drug for the prohibited, patented purpose. This would result in a real injustice: since a generic company cannot possibly control how everyone in the world uses its product, the prevention of the generic from marketing the product would further fortify and artificially extend the monopoly held by the patent holders. The patent holder would, therefore, effectively control not just the new uses for the old compound, but the compound itself, even though the compound itself is not protected by the patent in the first place. The patent holders, as a result, would obtain a benefit they were not meant to have. In the end, society would be deprived of the benefit of new methods of using existing pharmaceutical medicines at a lower cost."¹⁸

Yet if use patents are listed, the automatic 24-month stay is nevertheless in effect, at least until the hearing.

6. *Delays/Abuses of litigation process solely to trigger automatic stay*

Brand-name drug company patentees frequently start cases under the *Regulations*, even when there is clearly no real patent issue, solely in order to obtain the stay. Some examples:

Cefuroxime: The brand name of this drug is CEFTIN, an antibiotic with annual sales of \$11 million. GlaxoSmithKline lost a court case under the *Regulations*.¹⁹ Generic drug company Apotex then made a

minor variation to its submission, and had to file a new notice of allegation. Although all the patent issues had been litigated in the previous proceeding, GSK still commenced a proceeding, raising the same issues. It is clear that it did so solely to trigger the automatic stay and block the generic from coming to market. The case was eventually struck out as an abuse of process.²⁰

Lovastatin: MEVACOR is a lipid-lowering agent with annual sales of \$98 million. Generic versions of this blockbuster cholesterol drug were kept off the market for many years by litigation under the *Regulations*. The proceedings were eventually dismissed long after Health Canada's health and safety approval process for the generic products was complete. For example, one prohibition case kept Apotex's generic product off the market for years but brand company Merck Frosst never even asserted in the proceeding that its patent was in fact infringed.

Simvastatin: ZOCOR, a lipid-lowering agent with annual sales of \$267 million. Merck Frosst obtained a stay by commencing litigation but never argued that the patent was in fact infringed. Apotex served its allegation of non-infringement prior to serving its submission, as it was permitted to do under the pre-1998 *Regulations*. When the case got to a hearing more than two years later, Merck Frosst did not argue that the patent was infringed, but that Apotex's allegation was "premature"

and not allowed under the post-1998 amendments.²¹ Apotex served a new notice of allegation. Merck Frosst started new prohibition proceedings, but again did not even argue its patent was infringed. Merck's second case was also dismissed.²²

7. Preventing market entry of non-generic products: The Biolyse case

The *Regulations* are now applied by the Minister to impose an automatic stay even against brand companies. For example, Bristol-Myers Squibb used the *Regulations* to have an NOC revoked after it was issued to Biolyse, a small company that had approval to sell a low-cost version of paclitaxel (TAXOL), a cancer drug.

Biolyse's product was approved based on its own clinical trial. However BMS sued Health Canada and Biolyse saying the NOC should not even have been issued, basing its argument on a poorly worded amendment (s. 5(1.1)), passed in 1999. The Court found Biolyse should have served a notice of allegation on BMS and ordered the NOC revoked.²³

8. Litigating NOC revoked

A new strategy of brand companies is to attack the NOC issued by Health Canada to the generic product on the grounds that patents listed on the register were not addressed.

AstraZeneca recently went to court to argue unsuccessfully that an NOC issued to Apotex's omeprazole

capsule should be revoked, because of Apotex's alleged failure to address certain evergreening patents listed years after AstraZeneca removed its own capsules from the market.²⁴ The court noted that there had already been 11 years of litigation before Apotex obtained its NOC.

GlaxoSmithKline attempted to argue in the courts recently that Apotex's NOC for CFC-free salbutamol, an asthma drug, should be revoked due to Apotex's alleged failure to address patents listed for its salbutamol product VENTOLIN, although Apotex's version was not based on the GlaxoSmithKline product.²⁵

Bristol-Myers Squibb was successful in arguing that an NOC issued to Biolyse should be revoked, due to alleged failure to address BMS's listed patents, as discussed above. This issue was heard by the Supreme Court of Canada in November 2004.

9. *Delayed payment of damages: s. 8 cases*

Section 8, added in the 1998 amendments to the *Regulations*, states that the brand company may be liable to the generic manufacturer for damages suffered as a result of the delay in obtaining an NOC due to the *Regulations*.

Brand-name drug companies have vigorously opposed any s. 8 cases, and claim the damages section itself is unconstitutional. Brand companies typically bring many motions to delay cases proceeding to trial,

including motions for summary dismissal, removal of the brand companies' corporate parents as parties, amending statements of defence and counterclaims, particulars, compelling attendance of witnesses, striking portions of damages and extensions of time. As of June 2004, there were 13 s. 8 cases proceeding to trial, five of which were started as far back as 2001, but it will years before any of these cases get to trial.

As the Commissioner of Competition pointed out on February 27, 2004, Canadian citizens and governments are not entitled to damages under s. 8. Thus the people of Canada will never receive compensation, even though they paid more for drugs due to the improper monopoly during the delay. The table on the facing page sets out drugs that were delayed from reaching the market and are currently the subject of s. 8 proceedings.

Many other major drugs are still caught up in litigation under the *Regulations*, and delays may continue for years due to the relative ease with which the automatic stay can be restarted. Section 8 cases seeking damages can only be commenced once an NOC is issued to the generic product.

| Generic Name | Brand Name | Indication/ Treatment | Regulatory Process Complete | Date of Notice of Compliance From Health Canada | Annual Sales (000s) in final year prior to first generic entry <small>(Source: IMS HEALTH)</small> |
|--------------|-------------|--------------------------|-----------------------------------|--|---|
| Acyclovir | ZOVIRAX | Antiviral | 15/02/96 | 21/08/97 | \$22 (1996) |
| Cetirizine | ZYRTEC | Allergies | 15/06/97 | 21/10/98 | \$586 (1997) |
| Citalopram | CELEXA | Depression | 24/07/02 | 04/01/04 | \$153,918 (2003) |
| Fluconazole | DIFLUCAN | Antifungal | 08/12/93 | 09/10/98 | \$14,107 (1997) |
| Lovastatin | MEVACOR | Cholesterol-lowering | 26/04/96 | 26/03/97 | \$94,941 (1996) |
| Nizatidine | AXID | Ulcer | 30/04/96 | 30/04/97 | \$14,518 (1996) |
| Norfloxacin | NOROXIN | Antibiotic | 31/05/93 | 16/07/98 | \$17,202 (1997) |
| Naproxen SR | NAPROSYN SR | Anti-inflammatory | 04/07/95 | 04/05/99 | \$2,182 (1998) |
| Omeprazole | LOSEC | Ulcer | 04/01/02 | 27/01/04 | \$411,880 (2003) |
| Paroxetine | PAXIL | Depression | 05/10/99 | 23/10/03 | \$227,517 (2002) |
| Terbinafine | LAMISIL | Antifungal | 28/03/99 | 16/05/00 | \$25,693 (1999) |

10. Double jeopardy: if generic wins NOC case, it can still be sued for infringement of the same patent

The generic faces double jeopardy under the *Regulations*. Even if it “wins” litigation under the *Regulations* and gets its product on the market, it can still be sued again on the same patents it has already spent years litigating. This is because litigation under the *Regulations* does not result in a final determination by the court whether the patent in question is valid or infringed.

The *Regulations* in other words lead to complex and expensive litigation which does not resolve the issue in dispute between the parties: is the patent valid and infringed or not?

There are several instances where generics have spent years in litigation under the *Regulations* in order to get their product on the market, only to be sued again and face further litigation once the product enters the market. AstraZeneca recently sued Apotex in respect of omeprazole capsules when they finally went on the market after eleven years of litigation under the *Regulations*.²⁶ Other generic products on the market now involved in patent litigation, which were also litigated under the *Regulations*, include lisinopril,²⁷ nizatidine,²⁸ and lovastatin.²⁹

Conclusion

All of this must be weighed against the cost of the *Patented Medicines (Notice of Compliance) Regulations* to Canadian society. Brand-name drug companies' evergreening strategies under the *Regulations* have an obvious downside: non-infringing lower-cost generic products are inevitably kept off the market.

This raises drug costs for Canadian governments, employers and consumers. 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 automatic 24-month stay and extend the monopoly indefinitely. As mentioned earlier, an unfortunate result of the *Regulations* is that brand-name drug companies now find it more lucrative to litigate than to innovate.

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

Anecdotal evidence suggests the sheer volume of pharmaceutical judicial review applications have led to long delays in getting trial dates for non-pharmaceutical cases. This unfortunate result is also clearly not in the broader public interest.

In short, brand-name drug companies should not be given automatic extensions of their market monopolies simply because they decide to sue a generic pharmaceutical manufacturer.

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

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.

Patentees would still be entitled to 20 years protection of their patents, and could still enforce their patents in the courts, and Canada would still be in compliance with its international obligations.

Footnotes

PART I

1. SOR/93-133
2. 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 portions 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.
3. 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.
4. *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.
5. *PM(NOC) Regulations*, s. 3, 4.
6. *PM(NOC) Regulations*, s. 5(1)(a).
7. *PM(NOC) Regulations*, s. 5(1)(b).
8. *PM(NOC) Regulations*, s. 5(3)(a).
9. *PM(NOC) Regulations*, s. 6(1).
10. *PM(NOC) Regulations*, s. 7. If litigation was commenced prior to March 12, 1998, the automatic stay is 30 months as in *Hatch-Waxman*.
11. *PM(NOC) Regulations*, s. 7.
12. *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.).
13. *PM(NOC) Regulations*, s. 6(1).
14. *Eli Lilly & Co. et al. v. Apotex Inc. et al.* (1997), 76 C.P.R. (3d) 1 (F.C.A.) at 5 - 6.
15. *Merck Frosst v. Minister of National Health & Welfare* (1994), 55 C.P.R. (3d) 302 at 319 (F.C.A.).
16. *Pharmacia Inc. v. Canada (Minister of National Health and Welfare)*(1994), 58 C.P.R. (3d) 209 (F.C.A.) at 217.
17. *Merck*, supra. at 320.
18. 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.
19. The damages section, section 8, was amended in 1998. There are now several cases ongoing seeking damages, but none have yet reached trial.
20. *PM(NOC) Regulations*, s. 5(2).
21. *SmithKline Beecham v. Apotex* (1999) 1 C.P.R. (4th) 99, affirmed (2001) 10 C.P.R. (4th) 338 (F.C.A.).
22. *SmithKline Beecham v. Apotex* (2001) 14 C.P.R. (4th) 76, affirmed (2002) 21 C.P.R. (4th) 129 (F.C.A.).
23. *GlaxoSmithKline v. Apotex* 2003 FCT 687.
24. A motion to have this case dismissed on the grounds the patents were not eligible for listing was dismissed; *GlaxoSmithKline v. Apotex* 2003 FC 1055.
25. *GlaxoSmithKline v. Genpharm* 2003 FC 1248.
26. 2003 FCT 687, paragraph 88.
27. Generic Drug Entry Prior to Patent Expiration, an FTC Study, Federal Trade Commission, July, 2002, p. viii.
28. *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.).
29. *Merck v. Minister of Health* (2001), 12 C.P.R. (4th) 383.
30. *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.

31. *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.
32. *Warner Lambert v. M. of H.* (2001) F.C.J. No. 801, *Eli Lilly v. M. of H.*, T-1212-00, January 10, 2002.
33. *Eli Lilly v. Minister of Health*, 2003 FCA 24
34. *Genpharm v. M.O.H.* 2003 FC 1148.
35. *Food and Drug Regulations*. C.08.003.
36. *Apotex v. Minister of Health* (1999), 87 C.P.R. (3d) 271, affirmed (2001) 11 C.P.R. (4th) 538.
37. *Bristol Myers Squibb v. Canada (A.G.)* 2002 FCA 32.
38. *Ferring v. Apotex* 2003 FCT 293.
39. 2003 FCA 274.
40. *Hoffmann-LaRoche v. Minister of Health* 2004 FC 1547.
41. *Abbott*, 2004 FCA 154.
42. The latest patent was listed in August, 2004.
43. *Patented Medicines (Notice of Compliance) Regulations (Reference)*, (2003), 22 C.P.R. (4th) 62.
44. Under section 28.1 of the *Patent Act*, a patent application filed in Canada can claim priority to the date of a patent application for the same subject matter filed in another country up to a year earlier, commonly known as the "priority date." The priority date is the key date when assessing whether the patent may be invalid because the invention was already known.
45. *Pfizer, Schering v. Canada* 2002 FCT 706, affirmed 2003 FCA 138, leave to appeal to SCC refused, [2003] S.C.C.A. No. 224.
46. Listed patents need not be addressed, however, if the first person's product was withdrawn from the market before the patents were listed. *AstraZeneca v. Minister of Health et al.* 2004 FC 1277.
47. On-line at http://patents1.ic.gc.ca/srch_sim_e.html.
48. Health Canada's Annual Drug Submission Performance Report, 2003, p. 36. Online at http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/tpd_annual03_e.pdf, last visited October 1, 2004.
49. Therapeutic Products Directorate Statistical Report 2003, page 7. On-line at http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/patent_statistical_report_2003_e.html, last visited October 1, 2004.
50. Romanow Commission: "Building on Values; the Future of Health Care in Canada," p. 208.
51. Romanow Report, p. 208 - 209.
52. Summary of evidence and submissions, *Patented Medicines (Notice of Compliance) Regulations*, Parliamentary Research Branch, 28 August 2003.
53. Letter from Sheridan Scott, Commissioner of Competition to Tim Gilbert, February 27, 2004.
54. *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.
55. 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.
56. *Food, Drug and Cosmetic Act*, Section 505 (j)(D).
57. *Generic Drug Entry Prior to Patent Expiration: An FTC Study*, Federal Trade Commission, July, 2002.
58. FTC Report p. ii.
59. 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>
60. *Federal Register*, June 18 2003 (68 FR 36676).
61. Statement of FDA counsel Daniel Troy to the Committee on the Judiciary, US Senate, August 1, 2003.
62. *Federal Register*, March 10, 2004 (69 FR 11309).
63. *Bayer AG et al. v. Apotex Inc.* (2002), 16 C.P.R. (4th) 417 (Ont. C.A.) at paragraph 11.
64. *Lubrizol Corp. v. Imperial Oil Ltd.* (1996) 67 C.P.R. (3d) 1 (FCA). *Apotex v. Merck* (2002), 19 C.P.R. (4th) 460.

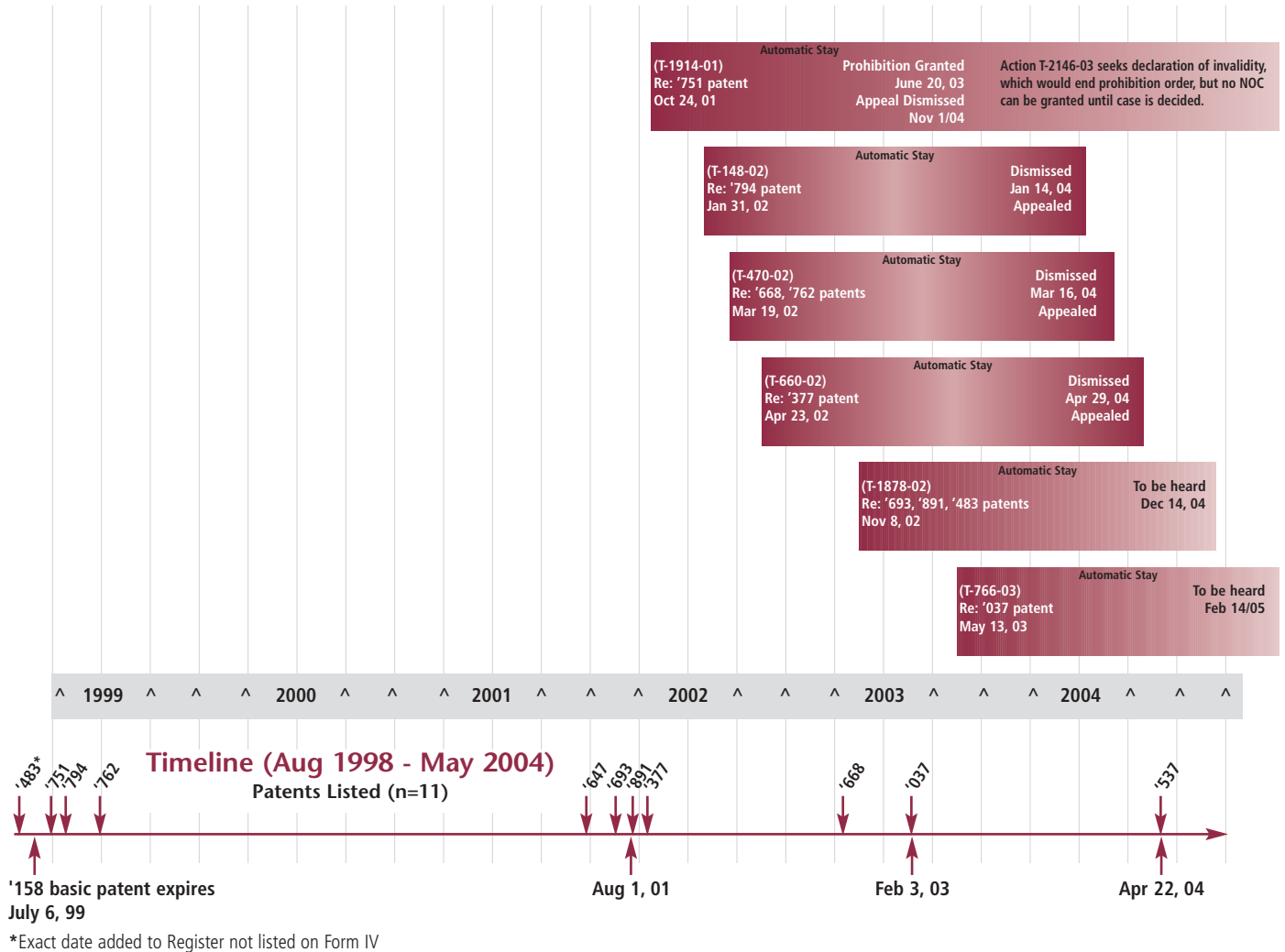
65. *RJR-Macdonald Inc. v. Canada*, [1994] 1 S.C.R. 311.
66. *Canada - Patent Protection of Pharmaceutical Products*, WT/DS/114 (March 17, 2000).
67. *Micro Chemicals Ltd. v. Smith Kline & French Inter-m. Corp.* [1972] S.C.R. 506, 520.

PART II

1. See for example, FTC Report, p. 48-49, which describes the multi-patent strategy used in the U.S. for paroxetine.
 2. *Eli Lilly v. Minister of Health* 2003 FCA 24.
 3. Such as *Warner-Lambert v. Minister of Health* 2001 FCT 514.
 4. *Genpharm v. Canada (Minister of Health)* 2003 FC 1148.
 5. *Abbott Labs v. Apotex* 2004 FCA 154; *Abbott Labs v. Pharmascience* 2004 FCA 154; *Abbott Labs v. ratiopharm* 2004 FCA 154.
 6. *Apotex Inc. v. Ferring and AG Canada* 2003 FCA 274. A similar strategy was attempted in *AstraZeneca v. M.O.H.*, 2004 FC 736.
 7. *Toba Pharma Inc. v. A.G. Canada*, 2002 FCT 927.
 8. *AstraZeneca v. AG Canada* 2004 FC 736.
 9. *Schering v. AG Canada* 2002 FCT 706; Appeal dismissed March 14, 2003; leave to SCC denied Nov. 27, 2003.
 10. The '071 patent, listed August 2003 was used by Pfizer to start automatic injunctions against four different generics in 2003 and 2004.
 11. *Apotex v. M.O.H., Astra Zeneca* 2004 FC 650.
 12. *AstraZeneca v. Apotex, Minister of Health* 2004 FC 1277.
 13. *Genpharm v. Canada (Minister of Health)* 2003 FC 1148; *Biovail v. Minister of Health and Rhoxalpharma* 2004 FC 257.
 14. *P&G v. Genpharm* (2002 FCA 290), *AB Hassle v. Rhoxalpharma* (2002 FCT 780) where generic drugs were prohibited because of method of use patents although generics did not seek approval for such use. In contrast, the court dismissed against a generic manufacturer that did not seek approval for patented use: *AB Hassle v. Apotex* 2002 FCA 421; leave to SCC denied March 23, 2003.
15. *Pfizer v. Apotex* 2002 FCT 1138.
 16. *AB Hassle v. Apotex Inc.* 2002 FCA 221.
 17. *AB Hassle v. Genpharm* 2003 FC 1443.
 18. *AB Hassle v. Apotex Inc.* 2002 FCA 221, paragraph 57.
 19. *Glaxo v. Apotex* T-415-98, aff'd 2001 FCA 96.
 20. *Glaxo v. Apotex* 2001 FCT 16.
 21. *Merck v. Apotex* T-418-98, May 3, 2000.
 22. *Merck v. Apotex* 2002 FCT 1195.
 23. *BMS v. Biolyse Pharma and A.G. Canada* 2003 FCA 180; leave to appeal to SCC granted Nov 20, 2003.
 24. *AstraZeneca v. Apotex, Minister of Health*, 2004 FC 1278 and 1277.
 25. *GlaxoSmithKline v. MOH, Apotex*, 2004 FC 1302.
 26. *AstraZeneca v. Apotex*, T-1409-04.
 27. *Merck v. Apotex*, T-2792-96.
 28. *Eli Lilly v. Apotex*, T-1100-97.
 29. *Merck v. Apotex*, T-1272-97. Timeline (Aug 1998 - May 2004).

APPENDIX A

Use of Automatic Stay Under NOC Regulations To Keep Apotex's Generic Product Off Market: Omeprazole Tablets (LOSEC)



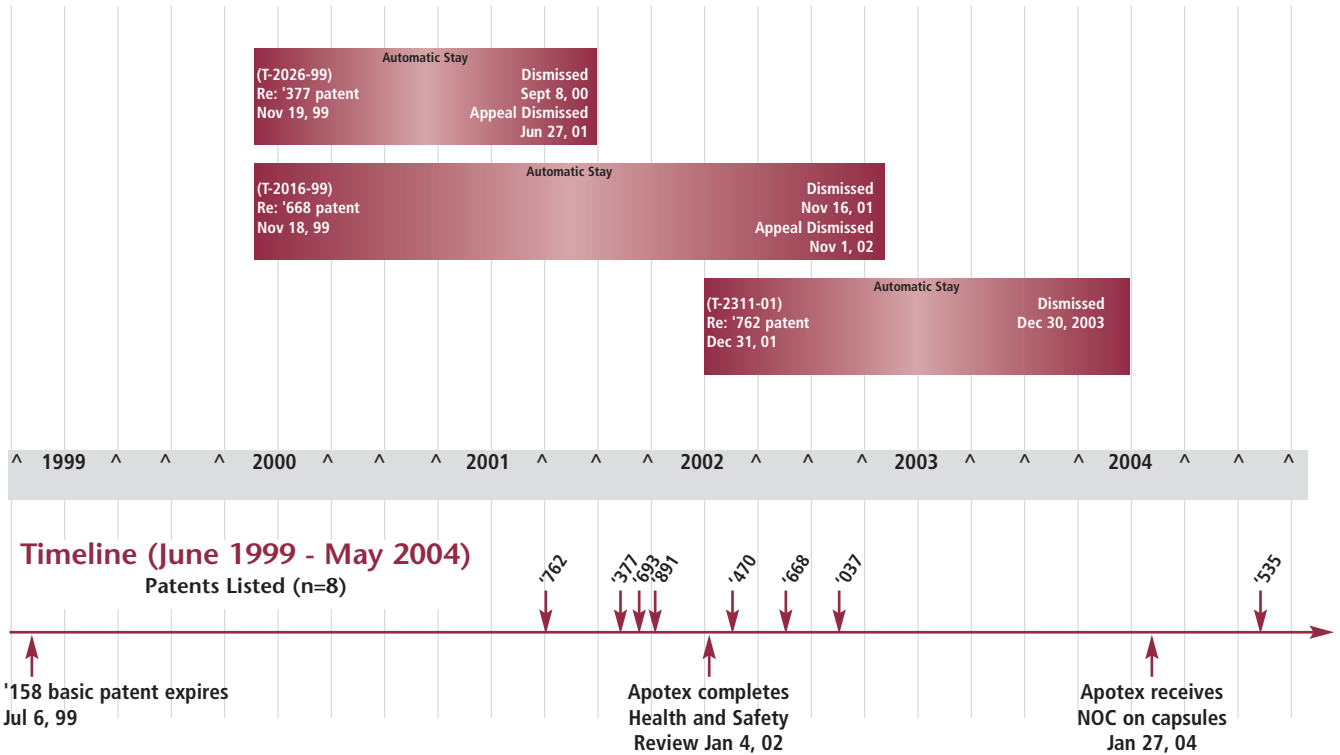
Notes

While the basic patent on omeprazole expired way back in 1999, machinations of the NOC Regulations allowed a continuing monopoly. For example:

1. There have been multiple automatic stays.
2. Multiple patents (11) listed.
3. Cases on tablets are still ongoing.
4. Delays have extended more than 4 years after expiry of basic patent.

APPENDIX B

Use of Automatic Stay Under NOC Regulations To Keep Apotex's Generic Product Off Market: Omeprazole Capsules (LOSEC)



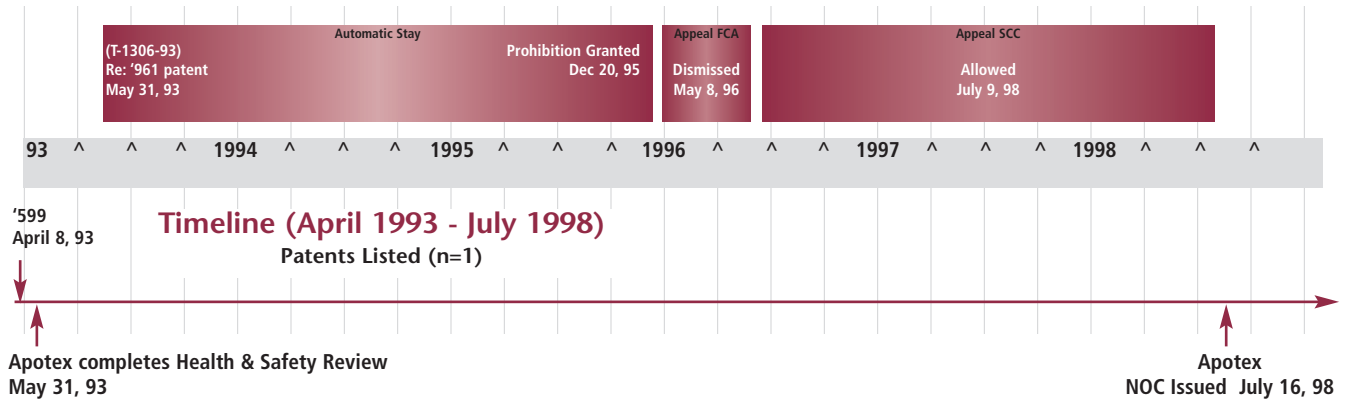
*Exact date added to Register not listed on Form IV

Notes

1. Multiple automatic stays.
2. Listed many patents around time of first dismissal.
3. Patentee applied to court to have Apotex NOC quashed in three court proceedings, all commenced in February 2004.

APPENDIX C

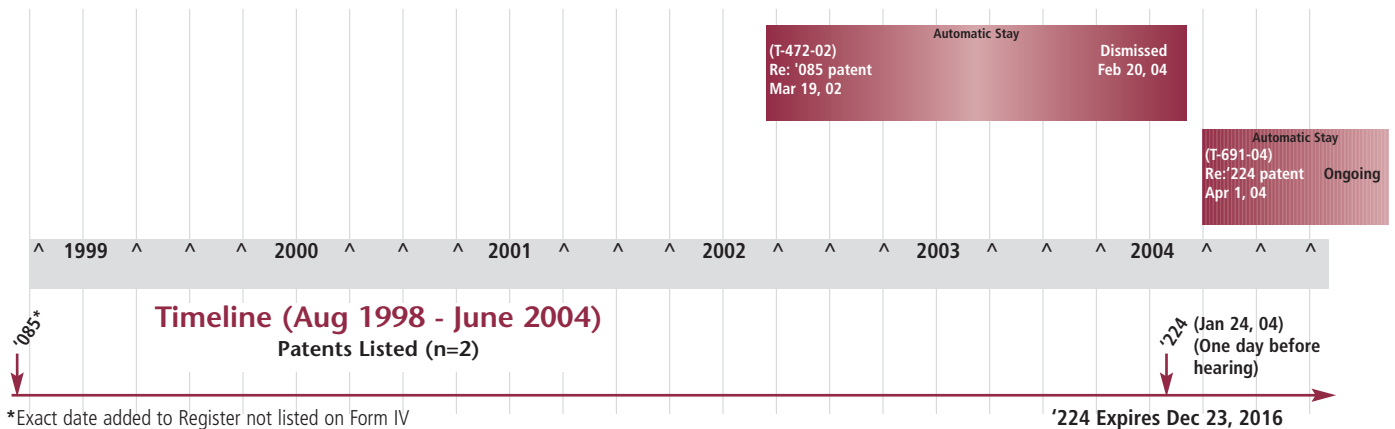
Use of Automatic Stay Under NOC Regulations To Keep Apotex's Generic Product Off Market: Norfloxacin Tablets (NOROXIN)



- Notes**
1. Delay is 5.1 years.
 2. Shows that only one patent on the list can cause long delays.

APPENDIX D

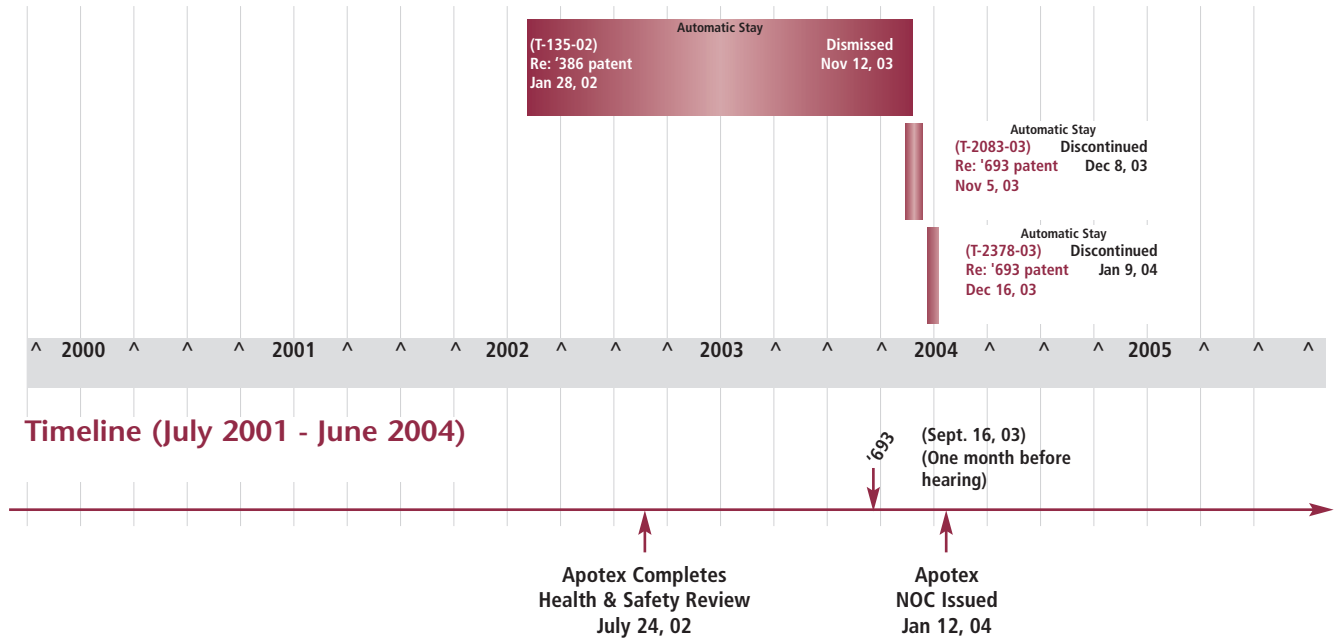
Use of Automatic Stay Under NOC Regulations To Keep Rhoxal Pharma's Generic Product Off Market: Diltiazem Capsules (TIAZAC)



- Notes**
1. Biovail guilty of misleading the US FDA in listing parallel patents in the Orange Book.
 2. Here, listed '224 one day before hearing of first prohibition proceeding.

APPENDIX E

Use of Automatic Stay Under NOC Regulations To Keep Apotex's Generic Product Off Market: Citalopram Tablets (CELEXA)

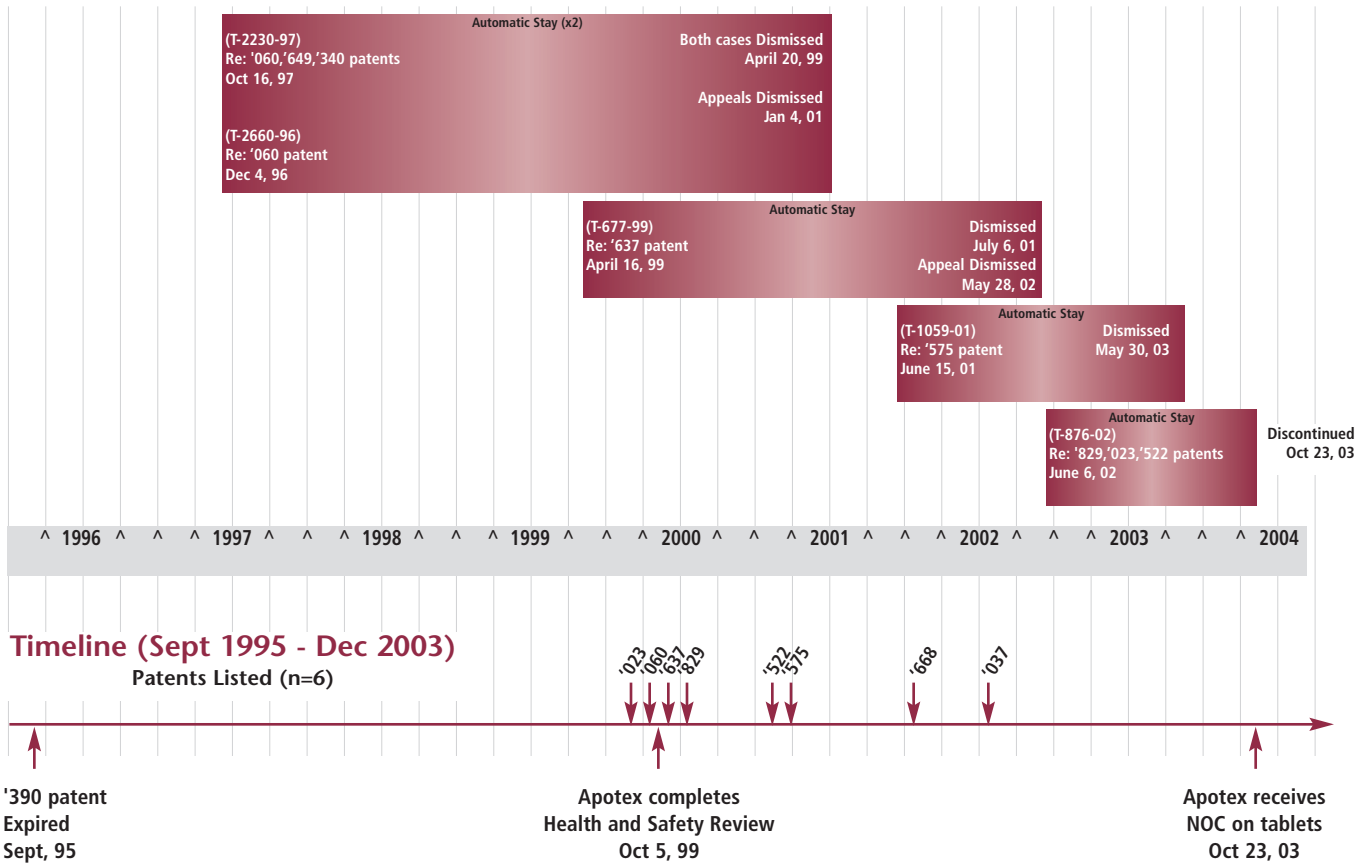


Notes

1. Example of listing a second patent immediately before a prohibition hearing.

APPENDIX F

Use of Automatic Stay Under NOC Regulations To Keep Apotex's Generic Product Off Market: Paroxetine (PAXIL)



Notes

1. Multiple automatic stays.
2. Multiple patents.
3. Issuance delay is 4 years.

Additional copies available from the Canadian Generic Pharmaceutical Association
www.canadiangenerics.ca