

## **2006 Amendments to the *Patented Medicines (Notice of Compliance) Regulations* and the *Food and Drug Regulations***

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## **Introduction**

The government of Canada passed new amendments to the *Patented Medicines (Notice of Compliance) Regulations* (“*PMNOC Regulations*”) and the *Food and Drug Regulations* (“*F&D Regulations*”) on October 5, 2006. The amendments are substantially the same as those pre-published on June 17, 2006, in the *Canada Gazette*,<sup>2</sup> although there are some differences.

The amendments went through a number of drafts; the government published earlier proposed amendments on December 11, 2004, in the *Canada Gazette*,<sup>3</sup> and yet another draft in outline form in the summer of 2005 on a confidential basis.

The most significant amendments to the *PMNOC Regulations* are:

- **Removed the words “or profits” from section 8:** Section 8 cases commenced prior to October 5, 2006 are unaffected.
- **Patent register is “frozen”** as of the “date of filing” of the generic submission, that is, a generic need send an NOA only in respect of patents listed on the register on that day (s. 5(4)). If the generic submission has already been filed, the deemed “date of filing” is October 5, 2006, not when the submission was actually filed.
- **Tightened listing requirements:** Patents can be listed with an NDS for the medicinal ingredient, the formulation, the dosage form, or the use, but the medicinal ingredient, the formulation, the dosage form, or the use must be approved. Patents on a change in formulation, a change in dosage form or a change in use can be listed with an SNDS but must claim the changed formulation, dosage form or use. Patents submitted prior to June 17, 2006 are unaffected, meaning some recently listed patents will presumably be removed. The PMNOC Regulations are broadened to allow patents claiming a “dosage form” to be listed.
- **Wording re the obligation to send an NOA in s. 5(1) and (2) may now be broader:** A patent must be addressed if the generic submission “directly or

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<sup>2</sup> “Regulations Amending the Food and Drug Regulations (Data Protection)” and “Regulations Amending the Patented Medicines (Notice of Compliance) Regulations”, *Canada Gazette*, Part I, June 17, 2006.

<sup>3</sup> “Regulations Amending the Food and Drug Regulations (1390 -- Data Protection)” and “Regulations Amending the Patented Medicines (Notice of Compliance) Regulations”, *Canada Gazette*, Part I, December 11, 2004.

indirectly” compares with, or makes a reference to, a brand drug; the comparison need no longer be “for the purposes of demonstrating bioequivalence”.

Some minor changes appeared since the proposed regulations were published on June 17, 2006:

- **Early dismissal motion under s. 6(5) can dismiss a case *in part*:** A motion can now be brought to dismiss the application *in whole or in part*, or *in respect of one or more patents*. Under the old wording, an early dismissal motion could not succeed if there are several patents at issue but only some of them are ineligible for listing or frivolous.
- **Second person must retract NOA 90 days after notice of non-compliance:** The time frame proposed on June 17 was 30 days (s. 5(6)). The rationale is that the longer period will “afford the sponsor of a submission found to be non-compliant a reasonable opportunity to have that finding overturned.”
- **Name change re Minister document certifying when ANDS filed:** As the date the ANDS is filed is now key to which patents must be addressed, the June 17 draft proposed that the generic would serve the brand “a statement, certified by the minister, of the date of filing of the submission or supplement” with the NOA. That document is now called “a certification by the Minister of the date of filing of the submission or supplement” (s. 5(3)(c)).
- **Government will “examine” authorized generics:** Although there is no change in the Regulations relating to authorized generics, the RIAS notes authorized generics in the US are under investigation by the Federal Trade Commission, and states: “While the Government is of the view that there is insufficient information on the impact of this practice on market dynamics in the industry to support regulatory action at this time, it will be examining this practice more closely in response to these concerns.”

These changes became law at the same time as amendments to the F&D Regulations, which can be summarized as follows:

- **A generic cannot get an NOC for 8 years from brand NOC**, and the generic cannot file for 6 years. The transition changed since the June 17, 2006 Canada Gazette proposal, as discussed below.
- **Six month pediatric exclusivity:** Six months additional exclusivity if the brand files clinical trials “designed and conducted for the purpose of increasing knowledge of the use” of the drug in pediatric populations “and this knowledge would thereby provide a health benefit in those populations.”

## **Part 1: Amendments to PMNOC Regulations**

### **Section 8(4): removal of words “or profits”**

Most generic companies view the most significant change in the new amendments to be the removal of the words "or profits" from s. 8(4).

The subsection will now read:

(4) If a court orders a first person to compensate a second person under subsection (1), the court may, in respect of any loss referred to in that subsection, make any order for relief by way of *damages* that the circumstances may require.

It formerly read:

(4) The court may make such order for relief by way of *damages or profits* as the circumstances require in respect of any loss referred to in subsection (1).

Section 8 cases commenced prior to October 5, 2006 are under the former wording. There are approximately ten such cases, but none has reached trial as yet. Cases commenced after that day will be under the new wording.

In generic manufacturers' view, the inclusion of the words "or profits" in the former wording allows the courts in the on-going cases to order disgorgement of the first person's profits resulting from an extended but improper monopoly caused by litigation under the *PMNOC Regulations*.

Innovator companies, on the other hand, have argued that the words "or profits" means merely the second persons' lost profits, i.e. that "damages or profits" has no different meaning from the word "damages" on its own. On this view, the removal of "profits" from s. 8(4) is a mere housekeeping measure with no particular impact.

As generic manufacturers see it, the removal of “or profits” from s. 8(4) took away an all-important disincentive to abuse of the *PMNOC Regulations*, because the first person’s profits from its monopoly will always be far greater than any damages the second person will suffer.

Innovator companies have in fact argued in the section 8 cases now in progress that the generics suffer no damages, even if their products are delayed by ultimately unsuccessful litigation under the *PMNOC Regulations*. They argue that if the generic had not been delayed by *PMNOC litigation*, not only would there have been an ultra-generic product (i.e. the brand's licensed generic), but that several other generic parties would have entered the market at the same time (as has now become common). Because so many generic manufacturers would have been competing to sell the same product, the argument goes, prices to pharmacists would have dropped to the point where no generic manufacturer was able to recover its sunk costs in product development and in some cases it costs from years of litigation.

If that argument is successful, then limiting s. 8 recovery to "damages" could mean that the first person can enjoy a wrongful monopoly, possibly for years, at the expense of the Canadian public yet face no downside risk. The first person would have an incentive to litigate frivolous cases as long as possible. The change is seemingly to the detriment of the public.

The word "or profits" in s. 8(4) was a vital disincentive to abuse because it meant that a first person who litigated non-infringed or invalid patents to delay competition faced a serious downside: possible disgorgement of profits wrongfully obtained as a result of the delay. This discouraged meritless litigation under the PMNOC Regulations intended only to perpetuate that stay.

## **Evergreening-related changes**

I outlined the evergreening problems created by the *PMNOC Regulations* in an earlier paper presented at this conference in 2004, entitled “Evergreening under the Patented Medicine Notice of Compliance Regulations.” That paper is attached as Appendix “A”, updated in a few places to reflect cases or events that have occurred in the interim. Appendix “B” is a brief description of how the *PMNOC Regulations* work.

The Regulatory Analysis Impact Statement (“RIAS”) that accompanies the new amendments to the *PMNOC Regulations* states that one purpose of the amendments is to “preempt” certain behaviours by brand companies.

The RIAS observes: “an innovator company may delay generic market entry by listing new and sometimes irrelevant patents on the basis of minor product revisions … such that generic companies may be prevented from entering the market with a competing version of the original innovator product even when the original patents have long since expired or been addressed.” The brand company can thus obtain “repeat 24-month stays against the same generic competitor”.

The RIAS also mentions “a number of recent court decisions” which “have given rise to the need to clarify the patent listing requirements. These decisions, which relate to timing and relevance issues, are not a function of judicial error but rather of deficiency in the language of the PM(NOC) Regulations themselves.”

The “recent decisions” which were a function of the “deficiency in language” in the *Regulations* are *Apotex v. Minister of Health*<sup>4</sup>, which held that a “submission” for the purposes of the time limit on patent listing in s. 4(4) includes a supplement to a new drug submission (“SNDS”), and *Eli Lilly v. Minister of Health*<sup>5</sup>, in which the court held that patents on non-approved formulations can be listed on the patent register.

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<sup>4</sup> *Apotex v. Minister of Health* (1999), 87 C.P.R. (3d) 271, affirmed (2001) 11 C.P.R. (4<sup>th</sup>) 538.

<sup>5</sup> *Eli Lilly v. Minister of Health*, 2003 FCA 24.

The RIAS goes on to explain that “The Government is concerned that the combined effect of the above-described jurisprudence is a weakening of the listing requirements, potentially to the point of redundancy.”

The amendments purport to strengthen the rules on patent eligibility in s. 4, limit when a generic must serve an NOA under s. 5.

#### **Section 4: tightened listing requirements**

##### **Patent listed with new drug submission (“NDS”) must cover an approved product:**

A patent can be listed with an NDS if it contains a claim for the medicinal ingredient itself, a formulation or dosage form containing the medicinal ingredient, or the use of the medicinal ingredient, and only if filed with a submission which led to approval for that medicinal ingredient, formulation, dosage form, or use.<sup>6</sup> This appears to be intended to reverse the effect of the *Eli Lilly* case, described above. As before, a patent can be listed within 30 days of issuance if its filing date is prior to the NDS.<sup>7</sup>

**Brand can list a patent with an SNDS – but only for a change in formulation, dosage form, or use:** Previously, a patent could be filed with almost any SNDS except one for an administrative change such as a name change (see Appendix A). The patent did not need to be relevant to the subject matter of the SNDS. Now, a patent can be listed with an SNDS only if the SNDS is for the change in formulation, dosage form, or use.<sup>8</sup> As before, the filing date of the patent must be prior to the filing date of the SNDS with which it is submitted.<sup>9</sup> A patent claiming only a polymorphic form cannot be filed with an SNDS.<sup>10</sup>

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<sup>6</sup> New ss. 4(1), 4(2).

<sup>7</sup> New s. 4(6).

<sup>8</sup> New s. 4(3).

<sup>9</sup> New s. 4(6).

<sup>10</sup> Under new s. 2 the definition of “claim for the medicinal ingredient” includes polymorphs. Thus a patent which claims only polymorphs of the medicinal ingredient can only be filed with an NDS.

Again, there could be many patent applications on a single “change in formulation or dosage form” or “change in use”, which could issue at intervals, in order to restart the stay. The new amendments do not seem to address the ease with which a brand could make a minor change in formulation such as removing an excipient. Furthermore, allowing dosage form variations will invite litigation over whether such things as patches and inhalers are included.

## **Section 5: “freezing” the patent register**

**A generic no longer needs to address a patent added after its ANDS is filed:** Until now, if a first person added a patent to the register after litigation commenced, the *PMNOC Regulations* required the second person to amend its ANDS and serve a new NOA to address that patent.<sup>11</sup> Such a requirement effectively grants brand companies the ability to invoke multiple stays in order to extend the term of its monopoly. The new amendments address that loophole by “freezing the register” at the time a generic files its ANDS.<sup>12</sup> That is, a generic only needs to address patents that are already on the register at the time of its ANDS.

**Biology section repealed:** A manufacturer who “directly or indirectly compares” its drug with a drug for which patents are listed, must address the patents.<sup>13</sup> The requirement that the comparison be made “for the purpose of demonstrating bioequivalence” is repealed.<sup>14</sup> This replaces, among other things, the previous s. 5(1.1) which, if interpreted literally, provided that even a manufacturer who relies on clinical trials must serve an NOA, if its drug has the same route of administration and a comparable strength and dosage form as a drug for which patents are listed. The ambiguous wording in section 5(1.1) has been a source of great confusion ever since it appeared in 1999, particularly when it was interpreted by the Federal Court of Appeal to apply to non-abbreviated submissions.

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<sup>11</sup> Old s. 5(2).

<sup>12</sup> New s. 5(4).

<sup>13</sup> New ss. 5(1), 5(2).

<sup>14</sup> Old s. 5(1).

However, this broad interpretation was recently in effect ruled *ultra vires* by the Supreme Court of Canada.<sup>15</sup>

**Generic obligation to retract NOA:** A generic must retract its NOA within 90 days if it cancels its submission or it receives notice of non-compliance by the Minister.<sup>16</sup> Once the NOA is retracted the first person must apply for a discontinuance of the proceedings “without delay”.<sup>17</sup>

**Section 6(5): early dismissal motion:** New wording was added allowing a second person to bring a motion to dismiss an application “in whole, or in part...in respect of one or more patents”,<sup>18</sup> removing an old problem with the *PMNOC Regulations* where a motion for early dismissal could not succeed if there were several patents in issue and only some of them were ineligible for listing or frivolous.

## Transition provisions

The amendments to the *PMNOC Regulations* related to submitting a patent list do not apply to patents submitted before June 17, 2006.<sup>19</sup> Therefore, well-known existing evergreening patents such as those now listed for clarithromycin or omeprazole are not affected by the amendments.

Presumably, patents submitted after June 17, 2006, which do not meet the tightened listing requirements, will be removed from the register.

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<sup>15</sup> *Biolyse v Bristol-Myers Squibb* 2005 SCC 26.

<sup>16</sup> New s. 5(6).

<sup>17</sup> New s. 5(7).

<sup>18</sup> New s. 6(5).

<sup>19</sup> “Transitional Provisions”, s. 6.

Generic ANDSs that are already filed are deemed to have a filing date of October 5, 2006, meaning any patents on the register as of October 5, 2006, must be addressed in the NOA.<sup>20</sup>

As discussed above, the amendments removing disgorgement of profits do not apply to any ongoing proceedings under the *PMNOC Regulations* commenced before October 5, 2006.<sup>21</sup>

## **Part 2: Proposed amendments re Data Protection**

### **Eight years' data protection for medicinal ingredient, if not previously approved:**

The *Regulations Amending the Food and Drug Regulations* introduce 8 years data protection if a medicinal ingredient was not previously approved.<sup>22</sup> The new amendments also introduce a six-year “no-filing” period within the eight-year term of data protection.<sup>23</sup> According to the RIAS this will “allow innovators to enjoy market exclusivity without the threat of any challenges that may be brought against them during that six year period.”

The obvious consequence is that innovators have six years in which to list patents, before the earliest possible ANDS is filed, thus “freezeing” the patent list.

**Six month pediatric exclusivity:** If pediatric studies are in the brand submission and the Minister finds they “were designed and conducted for the purpose of increasing knowledge”, the 8 years of exclusivity becomes eight and a half years.<sup>24</sup>

The RIAS to this amendment states that this provision has been brought in to “clarify and effectively implement Canada’s North American Free Trade Agreement (“NAFTA”) and

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<sup>20</sup> “Transitional Provisions”, s. 7.

<sup>21</sup> “Transitional Provisions”, s. 8.

<sup>22</sup> New C.08.004.1(3)(b).

<sup>23</sup> New C.08.004.1(3)(a).

<sup>24</sup> New C.08.004.1(4).

the Trade Related Aspects of Intellectual Property Rights (“TRIPS”) obligations with respect to data protection.”

The relevant wording of NAFTA is in Article 1711: Trade Secrets, subparagraphs 5 and

6. Again, key phrases are in bold:

5. If a Party requires, as a condition for approving the marketing of pharmaceutical or agricultural chemical products that utilize new chemical entities, the submission of undisclosed test or other data necessary to determine whether the use of such products is safe and effective, the **Party shall protect against disclosure of the data** of persons making such submissions, where the origination of such data involves considerable effort, except where the disclosure is necessary to protect the public or unless steps are taken to ensure that the data is protected against unfair commercial use.

6. Each Party shall provide that for data subject to paragraph 5 that are submitted to the Party after the date of entry into force of this Agreement, no person other than the person that submitted them may, without the latter's permission, **rely on such data in support of an application for product approval during a reasonable period of time after their submission**. For this purpose, a reasonable period shall normally mean not less than **five years** from the date on which the Party granted approval to the person that produced the data for approval to market its product, taking account of the nature of the data and the person's efforts and expenditures in producing them. Subject to this provision, there shall be no limitation on any Party to implement abbreviated approval procedures for such products on the basis of bioequivalence and bioavailability studies.

The relevant wording of the TRIPS Agreement is in Article 39, paragraph 3, and is considerably less specific:

3. Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, **shall protect such data against unfair commercial use**. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.

Canada’s courts have held that Canada’s data exclusivity provision, in C.08.004.1, as it was just prior to October 5, 2006, is in compliance with NAFTA. The Federal Court of Appeal stated in the *Bayer* case<sup>25</sup> that approval of a generic product through bioequivalence testing does not affect the brand’s right to confidentiality in its data

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<sup>25</sup> *Bayer v. A.G. Canada* (1999), 87 C.P.R. (3d) 293, leave to appeal to Supreme Court of Canada denied (1999) SCCA No. 386. At the hearing, Bayer also relied on the less stringent requirement in TRIPS Article 39, paragraph 3 but the Court did not refer to TRIPS in its reasons. No complaint about Canada’s long-standing interpretation has ever been made under the dispute settlement process in TRIPS or NAFTA.

because that data remains confidential. The government does not “rely” on the data unless it actually examines the innovator file while reviewing the generic submission.

The Court stated:

Specifically, if a generic manufacturer is able to establish the safety and effectiveness of its product on the basis of bioequivalence or bioavailability studies without the Minister having to examine and rely upon confidential data filed by the innovator, there is no reason or justification for the minimum five year protection from competition. *This interpretation of subsection C.08.004.01(1) is consonant with section 5 and 6 of Article 1711 of the NAFTA.*<sup>26</sup>

In changing the wording of C.08.004.1 to “codify more clearly Canada’s data protection commitments”, the government appears to have decided that the Federal Court of Appeal was wrong in *Bayer* when it held that the existing section, and the Minister’s interpretation of it, is in compliance with NAFTA.

NAFTA Article 1711, subparagraph 6, mentions five years of data exclusivity. Neither NAFTA nor TRIPS mention pediatric testing. Thus the government, in increasing it to eight years plus a six month pediatric testing extension, seems to be doing something more than “implementing” treaty commitments.

The section defines "innovative drug" as a drug that contains a medicinal ingredient not previously approved in a drug by the Minister, and excludes variations of an approved medicinal ingredient “such as a salt, ester, enantiomer, solvate or polymorph.”<sup>27</sup>

## **Transition provisions**

The old data protection regime applies to any drug for which a NOC was issued prior to June 17, 2006.<sup>28</sup> This is more favourable from the innovator point-of-view than the June 17, 2006 draft regulations, which made the relevant date the coming into force of the new

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<sup>26</sup> *Bayer*, supra, at para. 12.

<sup>27</sup> New C.08.004.1(1).

<sup>28</sup> “Regulations amending the Food and Drug Regulations (Data Protection)”, Transitional Provision s.2.

regulations, which would have been October 5, 2006. Any new product approved over the three and a half months prior to October 5 is therefore the recipient of an extraordinary and perhaps unexpected bonus.

## **Appendix A: “Evergreening” under the *Patented Medicines (Notice of Compliance) Regulations***

[This is an updated version of the paper “Drug Patents: The Latest Legal, Policy and Strategic Developments,” Insight Information Co., Marriott Downtown Hotel, 475 Yonge Street, Toronto March 29, 2004]

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

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

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

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

- Even if a generic company is subject to the 24 month stay as a result of such a prohibition proceeding, it must still address any other patents that the patentee may list on the patent register.<sup>29</sup>
- 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 by repeatedly triggering the automatic stay.

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

- Apotex filed an abbreviated submission for Apo-paroxetine on August 29, 1997, and served NOAs 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<sup>30</sup> 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<sup>31</sup>; the Court found Apotex's allegation of invalidity was justified.

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<sup>29</sup> *PM(NOC) Regulations*, s. 5(2), as it read prior to October 5, 2006.

<sup>30</sup> *SmithKline Beecham v. Apotex* (1999) 1 C.P.R. (4<sup>th</sup>) 99, affirmed (2001) 10 C.P.R. (4<sup>th</sup>) 338 (F.C.A.).

<sup>31</sup> *SmithKline Beecham v. Apotex* (2001) 14 C.P.R. (4<sup>th</sup>) 76, affirmed (2002) 21 C.P.R. (4<sup>th</sup>) 129 (F.C.A.).

- 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.<sup>32</sup>
- However, another prohibition proceeding had meanwhile been commenced against Apotex concerning 3 further patents on "Form A" (T-876-02).<sup>33</sup>
- Several generic parties finally received NOCs in October 2003, when Genpharm, another generic company, also won prohibition proceedings on some of the same patents already litigated by Apotex,<sup>34</sup> and SmithKline (now owned by GSK) seems to have decided that the risk of damages outweighed the benefit of continuing to litigate.

Note that the delay in market entry of 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.<sup>35</sup>

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

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<sup>32</sup> *GlaxoSmithKline v. Apotex* 2003 FCT 687.

<sup>33</sup> A motion to get this case dismissed on the grounds the patents were not eligible for listing was dismissed *GlaxoSmithKline v. Apotex* 2003 FC 1055.

<sup>34</sup> *GlaxoSmithKline v. Genpharm* 2003 FC 1248.

<sup>35</sup> 2003 FCT 687, paragraph 88.

The 75% figure is about the same as in the US. The Federal Trade Commission studied equivalent litigation in the US in 2002, and found “The data in the [FTC] study suggest that the generic applicants have brought appropriate patent challenges: generic applicants prevailed in nearly 75% of the patent litigation ultimately resolved by a court decision.”<sup>36</sup>

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

### **Eligibility: what patents can be listed?**

Given the extraordinary benefit to the first person of listing as many patents as possible over time, the rules governing the eligibility of patents for listing are of critical importance. A summary of the rules as they stand follows:

Section 4 of the *PM (NOC) Regulations*, as it read prior to October 5, 2006, governed 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.

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<sup>36</sup> Generic Drug Entry Prior to Patent Expiration, an FTC Study, Federal Trade Commission, July, 2002, p. viii.

(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, 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 former 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,<sup>37</sup> claims to metabolites,<sup>38</sup> claims to medical devices such inhalers, patches, or kits.<sup>39</sup> Claims to compositions or formulations are claims to the medicine itself.<sup>40</sup>

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<sup>37</sup> *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.)

<sup>38</sup> *Merck v. Minister of Health* (2001), 12 C.P.R. (4<sup>th</sup>) 383.

<sup>39</sup> *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.

<sup>40</sup> *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. See, however,

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.<sup>41</sup> However, the Federal Court of Appeal, in *Eli Lilly*, a 2 to 1 decision, held that patents on non-approved formulations could be listed.<sup>42</sup>

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.<sup>43</sup> In reaching that decision, Justice Blais commented that the Regulations are ambiguous with respect to patent eligibility, and that although he was bound to apply the *Eli Lilly* majority decision, he found it "opposite" to "logic". He stated: "No doubt clearer language in the *PM (NOC) Regulations* would go a long way to dispel the fog we find ourselves in, and prevent the abundant litigation which is sure to continue as long as the ambiguity remains."

## **Timing restrictions**

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

Under former 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

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*Glaxosmithkline v. M.O.H.*, 2005 FCA 197, where the court said patents on delivery systems cannot be listed.

<sup>41</sup> *Warner Lambert v. M. of H.* [2001] F.C.J. No. 801, *Eli Lilly v. M. of H.*, T-1212-00, January 10, 2002.

<sup>42</sup> *Eli Lilly v. Minister of Health*, 2003 FCA 24

<sup>43</sup> *Genpharm v. M.O.H.*, 2003 FC 1148.

within 30 days after the patent issues. A “supplement to a new drug submission” (SNDS)<sup>44</sup> has been held to be a "submission" for the purposes of this section.<sup>45</sup>

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

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

In *Bristol Myers*, a case involving a SNDS for a name change, the Federal Court of Appeal held that if the SNDS does not “change the drug,” then the SNDS cannot be used to list a patent.<sup>46</sup>

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

The Federal Court of Appeal has held in motions brought by various generic manufacturers that an SNDS for a brief product monograph revision can be used to list patents on various crystalline forms of clarithromycin,<sup>47</sup> with the result that at least nine crystalline form patents have now been listed by the patentee for clarithromycin since 2003. A generic manufacturer recently succeeded on seven of the crystalline form patents,<sup>48</sup> but continues to be kept off the market by two others listed in March, 2005.

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<sup>44</sup> *Food and Drug Regulations*, C.08.003.

<sup>45</sup> *Apotex v. Minister of Health* (1999), 87 C.P.R. (3d) 271, affirmed (2001) 11 C.P.R. (4<sup>th</sup>) 538.

<sup>46</sup> *Bristol Myers Squibb v. Canada* (A.G.), 2002 FCA 32.

<sup>47</sup> *Abbott et al v. Canada*, 2004 FCA 154.

<sup>48</sup> *Abbott Labs. v. Ratiopharm*, 2005 FC 1095, 2005 FC 1093

In short, prior to October 5, 2006, the situation seemed to be that patents can be listed with *any* SNDS except one for a product name change<sup>49</sup> or company name change.<sup>50</sup> Even an SNDS for a product monograph revision will suffice.

The subject matter of the patent need not correspond with that of the SNDS with which it is listed, as long as they both somehow refer to the same active ingredient. For example, a patent on a crystalline form may be listed with a SNDS for an unrelated product monograph revision.

In late February 2002, the Minister of Health commenced a "Reference by Federal Tribunal" under Rule 18.3(1), as to whether patents must be "relevant" to the SNDS with which it is submitted. However, the Reference was struck out on the grounds the facts put to the court by the Minister were in dispute.<sup>51</sup>

As noted above, the "filing date" of the patent must be prior to the "submission." Patentees argued that the words "filing date" in section 4(4) include a priority date, and initially convinced TPD to adopt that position. But TPD then changed its mind, and refused to list various patents where the priority date, not the filing date, was prior to the submission, including a patent for azithromycin submitted by Pfizer. In the *Pfizer* and *Schering* case, the courts held that "filing date" does not include a priority date.<sup>52</sup>

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

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<sup>49</sup> *Bristol Myers v. Canada*, (2001) 10 C.P.R. (4<sup>th</sup>) 318, affirmed (2002) 16 C.P.R. (4<sup>th</sup>) 425.

<sup>50</sup> *Toba Pharma Inc. v. A.G. Canada*, see above

<sup>51</sup> *Patented Medicines (Notice of Compliance) Regulations (Reference)*, (2003), 22 C.P.R. (4<sup>th</sup>) 62.

<sup>52</sup> *Pfizer, Schering v. Canada* 2002 FCT 706, affirmed 2003 FCA 138, leave to appeal to SCC refused, [2003] S.C.C.A. No. 224.

Prior to October 5, 2006, the register included 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 eleven patents on the register for some products.<sup>53</sup> A generic manufacturer never knows when more patents will be added to the register for a given drug.

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

The question arises: is this chaotic and unpredictable system what the regulator intended when it passed the *PM (NOC) Regulations*. If so an aggressive patentee, by ensuring patents issue every year or two which mention the active ingredient, can essentially forestall generic competition indefinitely.<sup>54</sup>

### **The *Biolyse* case**

In the recent *Biolyse* case of the Supreme Court of Canada, the Court held that the Regulations may be *ultra vires*, if interpreted to apply to any patent other than a patent on the “medicine” - by which the Court appears to have meant the active ingredient. Justice Binnie, writing for the majority, appears to state that interpreting the Regulations more broadly would amount to evergreening.

66. The broad interpretation urged by BMS would lead to an absurd result. The “medicine” in the drug to which the patent list relates need not itself be patented, or indeed owe anything to the ingenuity of the “first” person. It could be a “medicine” whose usefulness was discovered by somebody else (as in the case of *paclitaxel*) or something in the public domain as common as penicillin. So long as such “medicine” shows up as a component, however minor, in the chemical composition of the drug to which the patent list relates, the “second person” (including an innovator who is seeking to manufacture a new and useful drug) is barred from proceeding to market by the automatic statutory

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<sup>53</sup> There are 20 patents listed on the register for atorvastatin.

<sup>54</sup> Such a patentee is likely eventually to be liable for damages under s. 8, and there are now numerous cases seeking damages under that section but none have come to trial as yet. In the absence of case law as to how the quantum of damages under s. 8 will be calculated, it remains unclear whether the economic benefit to the first person of maintaining its monopoly through triggering the automatic stay will exceed its liability in damages.

freeze, and this “bar” will continue for so long as the patent list holder can evergreen its product by resort to patentable improvements to other components or additions, be they ever so minor. This would stifle competition and innovation in the pharmaceutical industry and produce a result at odds with what the regulator was trying to achieve. (Italics added, underlining in original)

67. The “plain meaning” adopted by the Federal Court of Appeal in this case would suggest that s. 5(1.1) is *ultra vires* the regulation-making power which, as noted earlier, only authorizes regulations “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 ‘early working’ exception] or (2) [the ‘stockpiling’ exception – now repealed]”. While there are other similarities between the Biolyse product and the BMS product, the decision of the Federal Court under s. 5(1.1) rests entirely on the presence of *paclitaxel* in both the BMS and the Biolyse products.

68. The interpretation put forward by BMS should be rejected, based not only on the limiting language of s. 55.2 of the *Patent Act* but on the more fundamental objection that on such a view a “first person” could extend its monopoly far beyond the scope of any possible *quid pro quo* its own skill and ingenuity have contributed to the public.<sup>55</sup>

The NOC *Regulations* are once again before the Supreme Court in the omeprazole case, which is currently under reserve.<sup>56</sup>

### **Policy-makers’ concerns**

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. (Italics in original)<sup>57</sup>**

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

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<sup>55</sup> *Biolyse v. Bristol-Myers Squibb*, 2005 SCC 26.

<sup>56</sup> SCC Case No. 30985.

<sup>57</sup> Romanow Commission: “Building on Values; the Future of Health Care in Canada,” p. 208.

manufacturers to develop cheaper products for the marketplace and is a questionable outcome of Canada's patent law.

The Report comments specifically on the Regulations as follows:

Furthermore, regulations under the patent law require generic drug manufacturers to demonstrate that their product is not infringing on a patent held by another drug manufacturer rather than putting the onus of the patent drug manufacturer to show that their patent has been infringed - what is referred to as the notice of compliance regulations. Suggestions have been made that this leads to "pre-emptory" lawsuits from patented drug manufacturers was a way of delaying the approval of generic drugs. Clearly, if this is the case, the practice is not in the public interest. The federal government should review this issue, determine what constitutes a legitimate extension of patent protection, and also consider ways of streamlining approval of generic drugs...<sup>58</sup>

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

At the hearings, the brand and generic industries expressed opposing views about the Regulations. Industry Canada was, as usual, supportive of the Regulations in general, but also suggested recent court decisions dealing with the timing of the listing of patents and the relevance of the patents "require the balance to be looked at carefully."<sup>59</sup>

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

The Senate expressed dissatisfaction with the Regulations in its Observations on Bill S-17 (the most recent amendment to the *Patent Act*). On April 5, 2001, the Senate Banking Committee commented the Regulations "may not be working in the manner that Parliament originally anticipated."

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<sup>58</sup> Romanow Report, p. 208 - 209.

<sup>59</sup> Summary of evidence and submissions, *Patented Medicines (Notice of Compliance) Regulations*, Parliamentary Research Branch, 28 August 2003.

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."

Recent times have seen provincial policymakers express concerns over the Regulations as well. On July 5, 2006, provincial and territorial health ministers finalized a report for Premiers stating that the federal government's expected amendments to the *PM(NOC) Regulations* and *Food and Drug Regulations* must meet the goal of accelerating access to non-patented drugs.

### **Comparable legislation in the US**

Canada's *PM (NOC) Regulations* are loosely modeled on the Hatch-Waxman amendments of 1984,<sup>60</sup> the equivalent US legislative scheme.<sup>61</sup>

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

In the summer of 2002, as mentioned above, the US antitrust authority, the Federal Trade Commission, released a report<sup>62</sup> dealing with, among others things, the anti-competitive effect of listing multiple patents for a single drug in the Orange Book (equivalent to the patent register in Canada). The Report found multiple stays had extended the patentees' monopolies in certain drugs improperly, an example being paroxetine (the US situation was not dissimilar to the Canadian chronology set out above).

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<sup>60</sup> *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.

<sup>61</sup> 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.

<sup>62</sup> *Generic Drug Entry Prior to Patent Expiration: An FTC Study*, Federal Trade Commission, July, 2002.

The FTC's primary recommendation was:

Recommendation 1: Permit only one automatic 30-month stay [equivalent to Canada's 24 month stay] per drug product per ANDA [generic submission] to resolve infringement disputes over patents listed in the Orange Book prior to the filing date of the generic applicant's ANDA.<sup>63</sup>

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

When a drug patent is about to expire, one method some companies use is to file a brand new patent based on a minor feature, such as the color of the pill bottle or a specific combination of ingredients unrelated to the drug's effectiveness. In this way, the brand name company buys time through repeated delays, called automatic stays, that freeze the status quo as the legal complexities are sorted out. In the meantime, the lower-cost generic drug is shut out of the market. These delays have gone on, in some cases, for 37 months or 53 months or 65 months. This is not how Congress intended the law to work. Today, I'm taking action to close the loopholes, to promote fair competition and to reduce the cost of prescription drugs in America.<sup>64</sup>

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.<sup>65</sup> It was estimated the change would save consumers \$35 billion over ten years.<sup>66</sup>

The FDA Final Rule was somewhat awkwardly drafted, so as not to step outside the existing statutory wording of the 1984 Hatch-Waxman 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.

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<sup>63</sup> FTC Report p. ii.

<sup>64</sup> 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>

<sup>65</sup> *Federal Register*, June 18, 2003 (68 FR 36676).

<sup>66</sup> Statement of FDA counsel Daniel Troy to the Committee on the Judiciary, US Senate, August 1, 2003.

On December 8, 2003, the President signed the *Medicare Prescription Drug, Improvement, and Modernization Act* into law. This omnibus bill made changes to the Medicare system in the US, but also included in Title XI amendments to the Waxman-Hatch Act to limit the brand to one automatic stay per ANDA, retroactive to August 18, 2003, the effective date of the FDA Final Rule. The FDA has just revoked its Final Rule as unnecessary in light of this new statutory language.<sup>67</sup>

### **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, (b) interlocutory injunctions are difficult to get in patent litigation, (c) 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 (d) 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."<sup>68</sup> 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.<sup>69</sup>

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.

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<sup>67</sup> *Federal Register*, March 10, 2004 (69 FR 11309).

<sup>68</sup> *Bayer AG et al. v. Apotex Inc.* (2002), 16 C.P.R. (4<sup>th</sup>) 417 (Ont. C.A.) at paragraph 11.

<sup>69</sup> *Lubrizol Corp. v. Imperial Oil Ltd.* (1996) 67 C.P.R. (3d) 1 (FCA). *Apotex v. Merck* (2002), 19 C.P.R. (4<sup>th</sup>) 460.

*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 a possible 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.<sup>70</sup>

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

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<sup>70</sup> *RJR-Macdonald Inc. v. Canada*, [1994] 1 S.C.R. 311.

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.<sup>71</sup> The "early working" exception in any event existed at common law before the passing of ss. 55.2(1) or (4).<sup>72</sup>

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

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<sup>71</sup> *Canada - Patent Protection of Pharmaceutical Products*, WT/DS/114 (March 17, 2000)

<sup>72</sup> *Micro Chemicals Ltd. v. Smith Kline & French Inter-m. Corp.*, [1972] S.C.R. 506, 520.

market. This raises drug costs. It also creates an economic disincentive to the challenging of potentially invalid patents, although such challenges have the potential to benefit the public at large, and are indeed essential if the patent system is to function as intended.

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

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

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

## **Conclusion**

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

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

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

## **Appendix B: How the PM(NOC) Regulations work**

[Author's note: This section was written before amendments to the *PM(NOC) Regulations* came into force on October 5, 2006. Any reference to the *PM(NOC) Regulations* refers to the regulations as they read just prior to that date.]

The *PM (NOC Regulations* were enacted under s. 55.2 of the *Patent Act* in 1993.<sup>73</sup> They were amended in 1998,<sup>74</sup> and again in 1999.<sup>75</sup>

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

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

The Regulations have been described as "draconian" in their effect on generic manufacturers by the Supreme Court of Canada.<sup>76</sup>

### **The procedure under the Regulations**

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

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<sup>73</sup> SOR/93-133

<sup>74</sup> 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.

<sup>75</sup> 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 18, but this was overturned by the Supreme Court of Canada, *Biolyse v. Britsol-Myers Squibb*, 2005 SCC 26.

<sup>76</sup> *Merck Frosst v. Canada (Minister of National Health and Welfare)*, (1998), 80 C.P.R. (3d) 368 (S.C.C.) at 384, paras. 32, 33.

*The register:* Patentees, referred to as "first persons," may list patents on a patent register in connection with drug products for which they hold regulatory approval.<sup>77</sup> 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,<sup>78</sup> or serve an "allegation" on the first person that the listed patent or patents are invalid or are not infringed by its submission,<sup>79</sup> together with a detailed statement of the legal and factual basis of the allegation.<sup>80</sup>

*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.<sup>81</sup>

*Automatic stay:* If the application is commenced, the NOC may not be issued for 24 months,<sup>82</sup> or until the court hearing or patent expiry.<sup>83</sup> As the Federal Court of Appeal stated, "By merely commencing the proceeding, the applicant obtains what is tantamount to an interlocutory injunction for up to 30 months [as the time frame then was] without

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<sup>77</sup> *PM(NOC) Regulations*, ss. 3, 4.

<sup>78</sup> *PM(NOC) Regulations*, s. 5(1)(a).

<sup>79</sup> *PM(NOC) Regulations*, s. 5(1)(b).

<sup>80</sup> *PM(NOC) Regulations*, s. 5(3)(a).

<sup>81</sup> *PM(NOC) Regulations*, s. 6(1).

<sup>82</sup> *PM(NOC) Regulations*, s. 7. If litigation was commenced prior to March 12, 1998, the automatic stay is 30 months as in Hatch-Waxman.

<sup>83</sup> *PM(NOC) Regulations*, s. 7.

having satisfied any of the criteria a court would require before enjoining issuance of an NOC.<sup>84</sup>

*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.<sup>85</sup> If the court finds the applicant has failed to establish the allegation is not 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.<sup>86</sup> Procedurally, the litigation consists of an exchange of affidavit evidence and cross-examination, followed usually by a one to five 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."<sup>87</sup> 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.<sup>88</sup> As the Federal Court of Appeal observed, "patent invalidity, like patent infringement, cannot be litigated in this type of proceeding [i.e. an application under the *Regulations*]. I can only think that the draftsperson had in mind the possibility of there being parallel proceeding instituted by

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<sup>84</sup> *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.)

<sup>85</sup> *PM(NOC) Regulations*, s. 6(1).

<sup>86</sup> *Eli Lilly & Co. et al. v. Apotex Inc. et al.* (1997), 76 C.P.R. (3d) 1 (F.C.A.) at 5 - 6.

<sup>87</sup> *Merck Frosst v. Minister of National Health & Welfare* (1994), 55 C.P.R. (3d) 302 at 319 (F.C.A.)

<sup>88</sup> *Pharmacia Inc. v. Canada (Minister of National Health and Welfare)* (1994), 58 C.P.R. (3d) 209 (F.C.A.) at 217.

the second person which might give rise to such a declaration [of invalidity or non-infringement] and be binding on the parties."<sup>89</sup>

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.<sup>90</sup>

*Damages:* If a generic product is delayed by the Regulations, the generic may be able to claim damages from the first person.<sup>91</sup> 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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<sup>89</sup> *Merck*, supra. at 320.

<sup>90</sup> 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.

<sup>91</sup> The damages section, section 8, was amended in 1998. There are now several cases on-going seeking damages, but none have yet reached trial.