Some Comments on the Regulatory Amendments to the *Patented Medicines (Notice of Compliance) Regulations* and the *AstraZeneca* decision, One Year Later

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Introduction

This past year has seen a number of changes in the law as to pharmaceutical patent litigation, in particular under the *Patented Medicines (Notice of Compliance) Regulations* (the "NOC Regulations" or "Regulations").[2] Some of the changes are regulatory, and others are the result of court decisions, in particular the decision of the Supreme Court of Canada in *Apotex v. AstraZeneca*, 2006 SCC 49 ("*AstraZeneca*"). This paper will provide some comments.

The question to keep in mind in reviewing these changes I think is: what will their ultimate effect be on the market penetration of generic drugs, overall? Brand and generic companies will of course differ on what the proper balance should be.

There is no doubt pharmaceutical patents can be enforced under the normal procedures in the *Patent Act*, just like patents in any industry. The court in an infringement or impeachment action under the *Patent Act* can also determine whether a potential defendant is entitled to the protection of the early working exception in s. 55.2(1) of the *Patent Act*.

[1] Many thanks to David Katz of Hazzard & Hore for his assistance in preparing this paper.
[2] Appendix A summarizes briefly how the NOC Regulations work.

The purpose of the NOC Regulations, including the recent amendments, as well as the new so-called "data protection" regulations, is therefore to place *additional* pitfalls and obstacles in the path of a potential generic market entrant, beyond the remedies granted to patentees under the *Patent Act*. The laws discussed in this paper, for all their arcane complexity, are in the end legal barriers to market entry for generic products. They are a political *quid pro quo* for the right to "early work" a patent in s. 55.2(1) of the *Patent Act*.

This means, I think, that the rules in this area of the law cannot be assessed by the criteria that one would usually use to evaluate new laws or amendments, such as: are they just, or administratively efficient? They are clearly neither, and the amendments have done little to remedy that fact.

Patent disputes, as is well known, cannot be resolved under the NOC Regulations. The Regulations create litigation which resolves nothing, except the self-created, circular question: how long will a generic drug be kept out of the market through the operation of the litigation and rules created by the Regulations themselves?

The fundamental policy question therefore really is: how high should the market barriers to entry for generic drugs be? What procedural obstacles should be placed in the path of a potential generic market entrant aside from facing the risk of the normal remedies that any patentee has to enforce its patents? The generic industry says there should be none; the brand name industry says there should be many. Where the line is drawn is largely dictated by the effectiveness of each sides' political lobbying.

It should be kept in mind that Canada is diverging from the U.S. in terms of the percentage of all prescriptions filled by generics in the market place. In both countries, generic substitution has increased due to some major patent expiries, but the rate of increase has been much slower in Canada. Ten years ago, the percentage was about the same: about 41% of prescriptions were filled with generic drugs in Canada versus about 40% in the US.[3] By 2006, there had been an increase in the prescriptions filled by generics in Canada to 46%,[4] but a much more rapid increase to about 63% of prescriptions filled by generics in the U.S.[5]

This difference, I think, shows it is now much more difficult to get a generic drug on the market in Canada than in the US, because of evergreening strategies and the delays created by NOC Regulations. Omeprazole, for example, to cite one well known drug, was genericized in the US years before it was in Canada. Enalapril is another example.

What will be the effect be of the amendments on the actual availability of generic products in the market?

This is not an easy question to answer. For each of the recent regulatory changes that might conceivably speed up the market entry of generic drugs, the transitional provisions or some other factor reduce the impact in the real world. Other regulatory changes, in particular the 8 years of "data protection" will clearly slow down the market entry of generic drugs.

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[3] "Policy Relating to Generic Medicines in the OECD", National Economic Research Associates, Economic Consultants, a table prepared for the European Commission, Table 4.2., p. 24, cited in Hore, E. "A Comparison of United States and Canadian Laws as they Affect Generic Pharmaceutical Market Entry," Food and Drug Law Journal, Vol 55, Number 3, 2000, p. 373, note 4.

[4] IMS data.

[5] Generic Pharmaceutical Association.

The federal government in fact seems to have intended that the regulatory changes not have much impact. The Regulatory Impact Analysis Statement ("RIAS"), the explanatory text that accompanies the recent regulatory changes, speaks of the need for "balance", which may be another way of saying "our goal is to make the rules more complicated, without actually changing their effect at the end of the day."

On balance I would say that the net effect of the regulatory changes is probably to slow down the introduction of generic drugs. The *Astra-Zeneca* case may have some effect in the opposite direction, but it is still too early to tell.

The recent changes fall roughly into three groups:

1. **Amendments to the *Patented Medicines (Notice of Compliance) Regulations* ("NOC Regulations"):** These were passed on October 5, 2006. The immediate impact of the amendments so far seems to have been that they have increased the number of 6(5) motions seeking early dismissal, particularly when combined with the effect of the ruling of the Supreme Court of Canada in *Astra-Zeneca* that (1) only patents that the generic "early works" are within the scheme of the NOC Regulations, and (2) patents listed with an Supplementary New Drug Submission (SNDS) must be relevant to the SNDS.

2. **"Data Protection" amendments to the Food and Drug Regulations**: Also on October 5, 2006, the government amended the *Food and Drug Regulations* to impose an eight year ban preventing the grant of regulatory approval to generic manufacturers, regardless of the presence or absence of patents.

3. **Changes to the case law**: There have been some recent changes in the case law, some arising from the *Astra-Zeneca* case, as set out above.

I. Amendments to the PM(NOC) Regulations

The major changes passed October 5, 2006 are as follows, roughly in their order of importance, in my view.

Section 8 damages

First person no longer potentially liable for disgorgement of profits: Perhaps the most significant change in the new amendments is the removal of the words "or profits" from s. 8(4). The subsection now reads:

> (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 about a dozen or more such cases, none of which has yet reach trial. Only one section 8 case has

so far been commenced under the new wording, I believe.[6] Therefore, even if the delay was on-going as of October 5, 2006, as it was for some valuable products, the first person got the benefit of the new wording.

Oddly, this change was made before the courts have ruled on what the old language meant. In the cases already commenced under section 8 before October 5, 2006, none of which have yet reached trial as I said, generic manufacturers argue that the phrase "damages or profits" means that they can be awarded not only lost profits resulting from delays in approval of their drugs, but also disgorgement of the first person's profits during its period of unjustified monopoly. "Profits" were included, generics argue, to create a disincentive to abuse the NOC Regulations, and a reward for the first generic to win a case and get on the market. The first person companies, on the other hand, argue the words "or profits" meant the *generic manufacturer's* lost profits i.e. that "damages" and "profits" were synonymous. This reasoning, if correct, would imply the recent amendment was pointless.

In the long term, the amendment of section 8 may be of profound importance, because it is essential to have a disincentive against abuse of the Regulations, and also an incentive for generic manufacturers to challenge drug patents, which benefits the public. The out-of-pocket "damages" suffered by a generic as a result in the delay in its approval are very small, argue the first persons in section 8 cases. They say such profits would be limited by competition from other generic manufacturers and the authorized generic introduced by the brand. They argue in fact that generics really make no profits as a result of competition on price and thus suffered no damage.

[6] T- 1396-07 in which Apotex seeks damages from Abbott Labs for delay in obtaining an NOC for clarithromycin.

If that interpretation is right, then an award of "damages" is no disincentive to abuse of the NOC Regulations and, even more important, also no incentive to spend the millions of dollars that are involved in making a full scale challenge to the patents on major products. Yet it is essential that generic manufacturers be rewarded for undertaking the years of expenditure and risk involved in trying to get a generic product on the market, or in the end there will be no generic versions of new products.

That is why the change to section 8 may ultimately be fatal from a policy point of view: it removed the incentive to challenge patents, which must exist if the system is to function as it should, and so that generic products get on the market, to the great benefit of the public and the provincial drug plans.

Section 4: patent eligibility

Patent listed with new drug submission (NDS) must cover 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.[7] This appears to be intended to reverse the effect of the *Eli Lilly* case, which allowed the listing of patents claiming non-approved formulations.[8] As before, a patent

[7] ss. 4(1), 4(2).
[8] *Eli Lilly Canada Inc. v. Canada (Minister of Health)*, 2003 FCA 24.

can be listed within 30 days of issuance if its filing date is prior to the brand new drug submission.[9]

Brand can list a patent with a supplement to a new drug submission (SNDS) – but only for a change in formulation, dosage form, or use: Previously, under some case law, a patent could be filed with almost any SNDS except one for an administrative change such as a name change. The patent did not need to be relevant to the subject matter of the SNDS, at least prior to the A*straZeneca* decision.[10] Under the amendments, a patent can be listed with an SNDS only if the SNDS is for a change in formulation, dosage form, or use, and the patent "contains a claim for" the change in formulation, dosage form, or use.[11] As before, the filing date of the patent must be prior to the filing date of the SNDS with which it is submitted.[12] A patent claiming only a polymorphic form cannot be filed with an SNDS.[13]

There has been only one case interpreting the amended listing requirements, so far as I know, and it interpreted the amendments to be largely meaningless. In *Abbott v. Canada*[14], the court interpreted "contains a claim for" very broadly in a case concerning lansoprazole. The patent was for solvent-free lansoprazole crystals (i.e. was a polymorph patent). The claims mention the drug is used in treating ulcers, but the invention was clearly not that use, which was old. The patent was submitted listed in conjunction with an SNDS for a new use in treating NSAID ulcers. Since the patent was listed after June 17, 2006, it was subject to the new listing

[9] s. 4(6).
[10] See the discussion of *AstraZeneca* in *Ratiopharm v Wyeth*, 2007 FCA 264, interpreting that case to mean a patent can only be listed with an SNDS to which it is relevant.
[11] s. 4(3).
[12] s. 4(6).
[13] Under s. 2 the definition of "claim for the medicinal ingredient" now includes polymorphs. Thus a patent which claims only polymorphs of the medicinal ingredient can only be filed with an NDS.
[14] 2007 FC 797

requirements. The Minister refused to list the patent, claiming that the patent was ineligible to be listed with an SNDS for a changed use, the treatment of NSAID-related ulcers, because the patent did not "contain a claim for" NSAID-related ulcers. On judicial review, Justice Simpson ruled that the general claims mentioning the use to treat ulcers (the old use) included the treatment of NSAID ulcers. Therefore she said it should be listed. The Minister has appealed.[15] There was no generic party before the court.

Patents claiming a "dosage form" can be listed

Patents claiming a "dosage form" can be listed with an NDS,[16] or, if claiming a change in the dosage form, with an SNDS.[17] This will clearly lead to more patents on the register and more litigation, and thus is likely to lead to further delays in generic market entry. The law with respect to patents filed prior to the October 5, 2006 amendments is that a patent claiming a formulation cannot be listed because it claims a "delivery system" and not the "payload", and thus does not claim the medicine itself.[18]

The amendments to the listing requirements in the Regulations do not apply to patents submitted before June 17, 2006.[19] Therefore, well-known existing evergreening patents such as those now listed for clarithromycin or omeprazole magnesium were not affected by the amendments.

[15] A-383-07.
[16] s. 4(2)(c)
[17] s. 4(3)(b)
[18] See most recently *Abbott v. Novopharm*, T-773-06, 2007 FC 865, *Janssen Ortho v. AG Canada*, 2007 FC 729 and *Procter & Gamble v. AG Canada*, 2007 FCA 31.
[19] "Transitional Provisions", s. 6.

Patents submitted after June 17, 2006, which did not meet the tightened listing requirements, should have been removed from the register, but it appears that some ineligible patents were not removed for a long time, presumably at the request of first persons.[20]

Section 5: obligation to send NOA

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 Regulations required the second person to serve a new NOA to address that patent.[21] Such a requirement effectively allowed brand companies the ability to invoke multiple stays in order to extend the term of its monopoly, the evergreening problem which the federal government admitted was caused by "deficiencies in the language of the PM(NOC) Regulations".[22] The new amendments address that loophole by "freezing the register" at the time a generic files its ANDS.[23] That is, a generic only needs to address patents that are already on the register at the time of its ANDS.

Section 6(5): early dismissal

Court may dismiss an application in part: New wording was added to the subsection allowing a second person to bring a motion to dismiss an application "in whole, or in part…in respect of one or more patents"[24]

[20] Particularly controversial in this regard has been the 201 patent for celecoxib, now delisted by the Minister, but allowed to remain listed until the release of an appeal decision favourable to the first person on another patent, thus preventing the issuance of an NOC to the second person, Novopharm.
[21] Previous s. 5(2).
[22] Regulatory Impact Analysis Statement, *Canada Gazette, Part II*, Vol 140, no 21, p. 1512.
[23] s. 5(4).
[24] s. 6(5).

Section 6(5) was introduced in the 1998 amendments, but was worded in such a way that 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. Because there are usually many patents at issue, this meant that few 6(5) motions were brought.

The new wording provides a means for generic companies to dispose of some of the patents before the hearing.

The result has been many more 6(5) motions, where for example, the issue raised by the first person had been determined in other litigation, and the first person's argument is merely speculative,[25] or the patent is ineligible for listing.[26]

A section 6(5) motion succeeded where a similar allegation of invalidity made by another generic had been held justified. The Federal Court of Appeal considered it an abuse of process for the first person to attempt to re-litigate against another generic manufacturer. *Sanofi-Aventis v. Novopharm*[27] concerned ramipril. The Federal Court of Appeal upheld the lower court's early dismissal of the application under s. 6(5)(b). That section allows an application to be dismissed, in whole or in part, if the application is "redundant, scandalous, frivolous or vexatious or is otherwise an abuse of process." Below, Madam Justice Tremblay-Lamer held the application was an abuse of process because Novopharm's allegation that the patent was invalid for lack of sound prediction was in all material respects similar to Apotex's earlier allegation, found justified

[25] *Novopharm v. Sanofi-Aventis*, 2007 FCA 167.
[26] *Ratiopharm v. Wyeth*, 2007 FCA 264.
[27] 2007 FCA 163.

by Justice Mactavish in *Aventis v. Apotex*[28]. In a 2-1 decision, the Federal Court of Appeal upheld Madame Justice Tremblay-Lamer's early dismissal. The majority reasons written by Justice Sexton held that even though a subsequent judge would not be bound by Justice Mactavish's finding and the first person said it had better evidence than in the earlier case, the application was abusive. The possibility of inconsistent judicial decisions on the same issue would jeopardize the integrity of the adjudicative process. The applicant is required to put its best foot forward the first time an issue is litigated. No prejudice would result from the early dismissal because Sanofi can still pursue an infringement action.

II. Amendments to the Food and Drug Regulations

The so-called "data protection" amendments in section C.08.004.1 of the *Food and Drug Regulations* can be summarized as follows:

Eight years' data protection for medicinal ingredient, if not previously approved: The new amendments introduce an eight year ban (previously it was five years) on generic competition from the date the innovator drug is first approved, if the medicinal ingredient was not previously approved.[29] The new amendments also introduce a six-year "no-filing" period within the eight-year term,[30] that is, the generic manufacturer may not file its regulatory submission during the six-year period.

[28] 2005 FC 1283.
[29] C.08.004.1(3)(b), as amended
[30] C.08.004.1(3)(a), as amended.

Six month pediatric exclusivity: If pediatric studies are included 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.[31] These changes obviously greatly favour the "innovator" industry, and confer no benefit on the generic industry.

Under the transition provisions, the old data protection regime applies to any drug for which a NOC was issued prior to June 17, 2006.[32] This transition regime is more favourable from the innovator point-of-view than that in the June 17, 2006 draft regulations, which made the relevant date the coming into force of the new 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.

There are now, by my count, 33 products on the "register of innovative drugs".[33]

Soon after the amendments were passed, two judicial review applications were launched challenging the amendments: *Apotex v. Canada (Attorney General),*[34] and *Canadian Generic Pharmaceutical Association (CGPA) v. Canada (Attorney General),*[35] the latter brought by CGPA, an industry association representing generic drug manufacturers, in which I represent the CGPA.

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[31] C.08.004.1(4), as amended.
[32] "*Regulations amending the Food and Drug Regulations (Data Protection)*", Transitional Provision s.2.
[33] On-line at http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/regist/reg_innov_dr_e.html. Last visited October 12, 2007.
[34] Federal Court File No. T-2047-06.
[35] Federal Court File No. T-1976-06.

The Attorney General of Canada brought preliminary motions this spring to strike both of these proceedings, arguing that both CGPA and Apotex lack standing to challenge the regulations. One judge of the Federal Court struck out Apotex's application for judicial review[36] but another dismissed the Attorney General's motion, and declined to strike CGPA's application.[37] Both decisions are currently under appeal, and the appeals will be heard together.

In these cases, generic manufacturers argue the so-called "data protection" amendments are outside the federal government's power to pass regulations because they are not authorized by the *Food and Drugs Act*. The *Act* only authorizes regulations "deemed necessary" for the implementation of NAFTA and TRIPS. The data protection however create what is in effect a new form of intellectual property, imposing a monopoly far more sweeping than a patent in that no novelty is required.

The relevant wording of NAFTA is in Article 1711: Trade Secrets, subparagraphs 5 and 6. 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.

[36] 2007 FC 232.
[37] 2007 FC 154.

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[38] that approval of a generic product through bioequivalence testing does not affect the brand's right to confidentiality in its data 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 new regulations cannot be deemed necessary to implement NAFTA or TRIPS because they go well beyond both, both in scope and duration. NAFTA only requires that confidential data not be disclosed or relied on. The Minister does not rely on innovator data when the generic submission is processed by Health Canada, as confirmed by the *Bayer* case. No trade secrets are revealed to anyone in the course of reviewing a generic submission. Rather, the generic manufacturer does a bioequivalence study against the innovator's physical drug which is openly sold in the market. The innovator, of course, does not keep confidential that its drug has been found to be safe and effective.

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[38] *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.

In addition, generic manufacturers argue the new regulations are not within the constitutional power of the federal government. While purportedly enacted under the *Food and Drugs Act*, they have nothing to do with health and safety. Rather, the purpose of the regulations is the protection of confidential information, a matter of provincial jurisdiction.

III. Supreme Court ruling in *AstraZeneca*

The Supreme Court of Canada's decision in *AstraZeneca* was released November 3, 2006, after the amendments of October 5, 2006, but made no reference to those amendments. It did however make a number of fundamental observation about the Regulations, reasoning from the scope of regulatory authority conferred by s. 55.2 of the *Patent Act*. It would appear that the Court's observations about the fundamental limit on that regulation-making authority must also apply therefore to the Regulations after the amendments of October 5, 2006, as the scope of regulatory authority conferred has obviously not changed.

In *AstraZeneca*, patents were listed for AstraZeneca's omeprazole capsules years after Apotex submitted its ANDS for a generic equivalent. Applying *Biolyse*, the Court ruled that only patents that the generic manufacturer "early worked" in preparing its submission need to be addressed under the NOC Regulations. The Supreme Court held Apotex could not have "early worked" these patents, and therefore did not need to address them by sending an NOA.[39] Therefore, the Minister was right to issue an NOC to Apotex for its generic version of omeprazole.

[39] They were not capable of being early worked by Apotex because Apotex acquired the omeprazole capsules before the patents in question issued.

The court also observed that a patent for must be relevant to the submission with which it is listed.

The *AstraZeneca* decision had almost immediately effects on some other generic drugs held up by the NOC Regulations. For example, the Minister applied the *AstraZeneca* case to issue generic NOCS to ramipril, in December 2006, and to desmopressin in January, 2007. The Minister's interpretation of *AstraZeneca* was that a second person need not address a patent on the register if it acquired the "comparator" drug used in its bioequivalence studies before the brand submission was filed which led to the NOC with which the patents were listed. (Patents are often out of time to be listed against the original brand NDS and are therefore submitted with later SNDSs.) As well, the generic submission must not have "made use of" any changes in NOCs with which the patents were listed.

There was of course litigation over whether this interpretation was correct, and whether the Minister of Health was correct to have issued the ramipril and desmopressin NOCs.[40] Justice Hughes for the most part upheld the Minister's interpretation, with minor changes, in the *Ferring* decision. [41]

[40]*Ferring et al. v. Minister of Health*, 2007 FC 300.

[41] He proposed that the relevant date should be not when the generic acquires the product but when it files its submission, and that the changes made by the generic must be those as specified in section 5(1) of the NOC Regulations, namely, for the purpose of bioequivalence. His decision was upheld with very brief reasons, 2007 FCA 276.

About a month later, Justice Hughes also applied *AstraZeneca* in another case, in another way. *Wyeth Canada v. Ratiopharm*,[42] which was overturned in part on appeal, was a motion for dismissal concerning venlafaxine. The issue was whether the patent was properly listed with the various SNDSs with which it had been listed. Ratiopharm brought a s.6(5)(a) motion for early dismissal on the grounds that the patent was not properly listed. At the lower court, Justice Hughes reviewed a part of the *AstraZeneca* decision dealing with listing patents against an SNDS and interpreted it to mean that, in order for a patent to be properly listed with an SNDS, it must be "relevant" to the NOC which resulted from the SNDS. He found that the patent in question was relevant to some of the NOCs with which it was listed, but not others. On appeal, the Federal Court of Appeal unanimously agreed with his interpretation of *AstraZeneca* but unlike Hughes, the court found that *none* of the NOCs were relevant to the patent and so the application was dismissed.[43]

Parallel litigation: does it make sense?

The only issue to be decided in PMNOC proceedings is whether the Minister should be prohibited from issuing an NOC to the generic. Issues of patent validity or infringement cannot be resolved. Neither party is precluded from commencing a separate action for patent infringement or a declaration of invalidity.

As a result, there can be a decision under the NOC Regulations going one way, and a decision in subsequent litigation under the *Patent Act* on the same patent, going the other.

[42] 2007 FC 340.
[43] 2007 FCA 264.

This occurred recently in *Janssen-Ortho v. Novopharm*[44], in which the Federal Court of Appeal upheld the lower court in finding a patent on an enantiomer, levofloxacin, valid over the known racemate, and infringed. In the prior PMNOC proceeding, however, Justice Mosley held the generic's allegation of invalidity to be justified.[45]

The reverse situation has also occurred. Apotex was prohibited in prohibition proceedings under the NOC Regulations on naproxen SR,[46] but then won at trial; the same patent was found invalid and not infringed.[47]

It is now becoming more common for the losing party in litigation under the PMNOC Regulations, whether a first or second person, to commence an action under the *Patent Act* for infringement or impeachment.[48]

From the point of view of generic manufacturers, this peculiarity means being subject to a form of double jeopardy. After years of litigation under the NOC Regulations without revenue, a generic manufacturer may get its product on the market, but nothing is resolved. At that point, it may face years of more litigation on the same patent. It is not a system notable for its judicial efficiency.

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[44] 2007 FCA 217.
[45] 2004 FC 1631, appeal dismissed 2005 FCA 2.
[46] *Hoffman LaRoche v. Canada*, (1996) 67 C.P.R. (3d) 484, aff'd (1996) 70 C.P.R. (3d) 1.
[47] *Apotex v. Syntex*, (1999) 1 C.P.R. (4th) 22.
[48] Recent examples: Ratiopharm commenced T-1712-07, an action for a declaration the 393 patent on amlodipine besylate is invalid, after being prohibited, *Pfizer v. Ratiopharm* 2006 FCA 214, overturning lower court dismissing application, 2006 FC 220. Eli Lilly commenced infringement action,T-1048-07, on the 113 patent for olanzapine, after its prohibition application was dismissed, *Eli Lilly v. Novopharm*, 2007 FC 596.

Not only does the so-called "summary litigation" under the NOC Regulations not resolve anything, but it is also very hard on the judges. Two judges recently complained in their reasons (despite the amendments) about the procedure under the NOC Regulations.

Justice Gauthier Gauthier noted that "since the adoption of the Regulations, it appears that NOC proceedings have become more and more complex. Today, they can hardly be described as summary… Hopefully, we will find a more efficient way of dealing with these so-called 'summary proceedings' given that, in this case the need to limit the hearing to seven days meant that the Court had to review more than 100 cases as well as a substantial amount of evidence after the hearing."[49]

In his decision in a prohibition application involving the same patent, and a different generic manufacturer, but reaching the opposite result, Justice Hughes quoted Justice Gauthier, and concurred. In making those comments, he said, Justice Gauthier spoke for every judge hearing a prohibition proceeding. He added "The procedure is wholly unsatisfactory from almost any point of view" and "the whole process is strongly in need of revision."[50]

I can assure you generic manufacturers enjoy litigation under the NOC Regulations even less than the judges.

[49] *Eli Lilly v.* Apotex, 2007 FC 455, paragraph 5 and 6.
[50] *Eli Lilly v. Novopharm*, 2007 FC 596, paragraphs 50, 68.

Appendix A: How the NOC Regulations work

The NOC Regulations were enacted under s. 55.2 of the *Patent Act* in 1993.[51] They were amended in 1998,[52] in 1999,[53] and again in 2006[54], as discussed above.

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.[55]

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[51] SOR/93-133

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

[53] 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) was 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. This section was repealed in the 2006 amendments, although the "directly or indirectly compares" wording was incorporated into the remaining trigger provision, s. 5(1).

[54] SOR/2006-242. The amendments are outlined above.

[55] *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, *Bristol-Myers v. Biolyse*, 2005 SCC 26, para. 24.

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.[56] The health and safety regulator at Health Canada maintains the register, through a body known as the Office of Patented Medicines Liaison (“OPML”).

Allegation: If a generic manufacturer, referred to as a "second person," files a submission that makes a direst or indirect reference to the first person's drug (i.e. is an Abbreviated New Drug Submission (ANDS)), or a supplement, and if it can be said to have “early worked” patents listed for that drug,[57] the Minister of Health 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 such patent listed at the date it files it ANDS.[58]

The second person must either accept that it will not get regulatory approval until expiry of those patents,[59] or serve an "allegation" on the first person that the listed patent or patents are invalid or are not infringed by its submission,[60] together with a detailed statement of the legal and factual basis of the allegation.[61]

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[56] s. 3, 4.
[57] *AstraZeneca v. Apotex*, 2006 SCC 49, para. 37.
[58] s. 5(1),(2) and (4).
[59] s. 5(1)(a).
[60] s. 5(1)(b).
[61] s. 5(3)(b)(ii).

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.[62]

Automatic stay: If the application is commenced, the NOC may not be issued for 24 months, or until the court hearing or patent expiry.[63] 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."[64]

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.[65] 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 health and safety regulatory review is complete.

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.[66] Procedurally, the litigation consists of an exchange of affidavit evidence and cross-examination, followed usually by a one to seven day hearing. There are many procedural

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[62] s. 6(1).
[63] s. 7.
[64] *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.)
[65] *PM(NOC) Regulations*, s. 6(1).
[66] *Eli Lilly & Co. et al. v. Apotex Inc. et al*. (1997), 76 C.P.R. (3d) 1 (F.C.A.) at 5 - 6.

pitfalls; a body of complex procedural jurisprudence has grown up unique to this kind of proceedings. For example, the first person can never amend its NOA. Its NOA must be "sufficient", thus every possible argument and counter-argument, and all facts must be contained in it. A second NOA may be considered an "abuse" in certain circumstances, even if it raises an argument not included in the first NOA.

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."[67] 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.[68] As the Federal Court of Appeal observed, "patent invalidity, like patent infringement, cannot be litigated in this type of proceeding [i.e. an application under the *Regulations*]. I can only think that the draftsperson had in mind the possibility of there being parallel proceeding instituted by the second person which might give rise to such a declaration [of invalidity or non-infringement] and be binding on the parties."[69]

[67] *Merck Frosst v. Minister of National Health & Welfare* (1994), 55 C.P.R. (3d) 302 at 319 (F.C.A.)
[68] *Pharmacia Inc. v. Canada (Minister of National Health and Welfare)*(1994), 58 C.P.R. (3d) 209 (F.C.A.) at 217.
[69] *Merck*, supra. at 320.