**Date: 20070710**

**Docket: T-2300-05**

**Citation: 2007 FC 696**

**Ottawa, Ontario, July 10, 2007**

**PRESENT: The Honourable Mr. Justice Shore**

**BETWEEN:**

**APOTEX INC.**

**Plaintiff**

**and**

**ASTRAZENECA CANADA INC.**

**Defendant**

## REASONS FOR ORDER AND ORDER

### OVERVIEW

[1] When does the clock start ticking? When do calendar days begin to be counted to determine profits? After an inventor's patent protection is no longer in effect, when can a generic entity begin to aspire to work towards and collect financial fruits of an orchard left for a newly-claimed harvest and its harvester? That is subject-matter for a trial to decide.

All that is examined and confirmed, in this proceeding, is, simply, who can make a claim as an interested party, initiating an action. The basis of the claim, and how much is to be acquired, if anything, is also for a trial to determine in respect of entitlement.

**INTRODUCTION**

[2] This is a motion brought by the Defendant, AstraZeneca Canada Inc. (AstraZeneca), to set aside the Order of Prothonotary Roza Aronovitch, dated June 6, 2007, that dismissed AstraZeneca's motion to strike Apotex Inc.'s (Apotex) Statement of Claim.

[3] The fundamental issue is whether AstraZeneca demonstrates that it is plain and obvious that Apotex's Statement of Claim discloses insufficient material facts to support a cause of action under section 8 of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 (Regulations).

[4] The interpretation of the law in regard to section 8 of the Regulations is in an "embryonic state". As such, the Court is hesitant to strike out section 8 claims at the pleadings stage. (*Apotex Inc. v. Eli Lilly an Co. et al.* (2004), 36 C.P.R. (4th) 111 (F.C.A.) at paras. 14, 16; *Apotex Inc. v. Laboratoires Fournier S.A.*, [2006] O.J. No. 4555 at paras. 10-11; *Apotex Inc. v. Syntex Pharmaceuticals International Ltd.* (2001), 16 C.P.R. (4th) 473 (F.C.T.D.) at para. 15, aff'd (2002, 20 C.P.R. (4th) 190 (F.C.A.); *Apotex Inc. v. Merck & Co.* (2004) 248 F.T.R. 82, [2004] F.C.J. No. 1495 (QL).)

[5] This Court has held that matters of the interpretation of section 8 should be deferred to trial:

> [15] …There is not yet a clear understanding of what s. 8 of the Patent Regulations really means…
>
> > [18] …the contentious issues are of a complex nature better suited for determination at trial…

(*Apotex Inc. v. Syntex Pharmaceuticals International Ltd.*, above.)

> [17] The Court has also had a number of other occasions to look at s. 8 without reaching a determination of its meaning. In total, on no less than 11 occasions, this Court and the Federal Court of Appeal have concluded that issues of interpretation of s. 8 should proceed to trial…

(*Apotex Inc. v. Merck & Co.*, above.)

## FACTS

### The Action

[6] This action was commenced by Statement of Claim issued December 29, 2005, which seeks various forms of relief in respect of Apotex's delayed entry into the market for its Omeprazole 20 mg capsules, Apo-Omeprazole. (Statement of Claim, Motion Record of AstraZeneca at Tab 3 (Statement of Claim), para. 1.)

[7] Apotex's essential complaint in this action is that, by virtue of the improper institution and prosecution by AstraZeneca of proceedings under the Regulations in Court File No. T-2311-01, as alleged by Apotex. Apotex was delayed in obtaining approval for its Apo-Omeprazole capsules and, thus, requests to be compensated for alleged harm suffered as a consequence. (Statement of Claim, paras. 15-20.)

### Regulatory Context

[8] As with all new drugs, before Apotex could market Apo-Omeprazole 20 mg capsules, it had to obtain marketing approval from the Minister of Health (Minister). Such marketing approval is received in the form of a Notice of Compliance (NOC). (Statement of Claim, paras. 6-7.)

[9] Prior to 1993, the Minister's process for the approval of new drug submissions was focussed solely on issues of the health and safety of the proposed product. (*Bristal-Myers Squibb Co. v. Canada (Attorney General)* (2005), 253 D.L.R. (4th) 1 at 13 (S.C.C.) (*Biolyse*).)

[10] In 1993, as part of a broad overhaul of the *Patent Act*, R.S.C. 1985, c. P-6, the Minister's health and safety approval process was linked with the enforcement of patent rights. This was accomplished, in part, via the enactment of the Regulations. (*Biolyse*, above.)

[11] The Regulations provide for, among other things, early notice, being given to a patentee (or its authorized Canadian representative) by a prospective competitor, that the competitor has filed or intends to file a new drug submission with the Minister seeking a NOC for a generic version of the drug already marketed by the patentee. (Regulations, section 5.)

[12] In response to such notice, the patentee has the opportunity to commence judicial review proceedings which, regardless of their substance or merit, have the effect of delaying the prospective competitor's NOC from the Minister. (*Biolyse*, above at pp. 16-17.)

[13] The operation of the Regulations has been described as follows:

> Enacted by the Governor in Council under provisions of the *Patent Act Amendment Act*, 1992, S.C. 1993, c. 2, which abolished the system of compulsory licensing for patented medicines, and grafted onto the regulatory controlling system established by the *Food and Drug Regulations*, C.R.C. 1978, c. 870, the new set of regulations were aimed at contributing to the protection of private commercial patent rights.

> The main features of the new protective scheme may be described in a nutshell as follows: The Ministerof National Health and Welfare ("the Minister") is responsible, under the Food and Drug Regulations, for the issuance of "notices of compliance" (hereinafter "NOC") attesting to the health, safety and efficacy of drugs. An NOC is a prerequisite for marketing drugs. The drug manufacturer who holds or is licensed under subsisting patents is invited to file a patent list with the Minister indicating each of the drugs for which it already holds an NOC. From that point on, any other manufacturer who applies for an NOC in respect of the same drug, must support its new drug submission (hereinafter "NDS") by an allegation asserting that the listed drug patent would not be infringed if its application was granted, and explaining the basis for the assertion. A notice of such allegation must be served on the holder of the patent. Within 45 days of service of the allegation, the holder of the patent who wishes to dispute the justification of the allegation must seek an order from the Federal Court prohibiting the Minister from issuing the NOC applied for, and the Court will issue the order unless it finds that the allegation is justified. An NDS for a listed medicine must be left in abeyance until the expiration of the time given to the patent-holder to respond and, if proceedings in prohibition are commenced, until they are dismissed or another 30 months expires. However, in the absence of proceedings, the Minister is directed to process the application and, unless there is any concern for public health and safety, will issue the NOC requested.

(*Apotex Inc. v. Canada (Minister of National Health and Welfare)* 1997, 76 C.P.R. (3d) 1 at 3

(F.C.A., leave to appeal to S.C.C. refused, [1997] S.C.C.A. No. 528.)

> [5] When a patent holder commences a prohibition application under the Regulations, the Minister's authority to issue the notice of compliance for the new drug is automatically stayed pending the determination of the prohibition proceedings. This automatic stay is in place for a maximum of 24 months, unless extended pursuant to s. 7(5). The automatic stay prescribed by the Regulations has been described as draconian because it permits a patent holder to delay the entry of competitors into the market without having to establish even a prima facie case of patent infringement: *Merck Frosst Canada Inc. v. Canada (Minister of National Health and Welfare)*, [1998] 2 S.C.R. 193, 80 C.P.R. (3d) 368.

(*Bristol-Myers Squibb Canada Inc. v. Canada (Attorney General)* (2001), 11 C.P.R. (4th) 539

(F.C.A.).)

[14] Given the draconian nature of the presumptive statutory stay and the lack of any corresponding undertaking as to damages, the Regulations provide for a right of action in favour of an aggrieved general company who has suffered delay in obtaining its NOC because of proceedings under the Regulations which ultimately turn out to be unsuccessful. (Regulations, section 8.)

[15] It is pursuant to its right of action that Apotex initiated its claim against AstraZeneca. AstraZeneca initiated and lost a proceeding against Apotex under the Regulations and, therefore, delayed Apotex's market entry.

**AstraZeneca's Motion to Strike**

[16] Rather than plead to Apotex's Statement of Claim by way of Statement of Defence, AstraZeneca has instead moved to strike Apotex's claim. The purported basis for AstraZeneca's motion was that Apotex had not pleaded the requisite elements of a section 8 claim. (Order of Prothonotary Aronovitch, dated June 6, 2007; Motion Record of AstraZeneca at Tab 4 (Strike Dismissal Order), p. 2.)

[17] By Order dated June 6, 20007, Prothonotary Aronovitch dismissed AstraZeneca's motion to strike Apotex's claim, granting two of AstraZeneca's alternate request for particulars.

[18] In her Reasons for Order, Prothonotary Aronovitch outlined the submissions of AstraZeneca, first raised at the return of its motion:

> At the hearing the defendant fleshed-out its argument, and urged on the Court that Apotex be required to plead the elements now recognized in the jurisprudence as

> identifying "a second person" for the purposes of triggering section 5(1) of the *Regulations*, (*Ferring Inc. v. Canada (Minister of Health)* [2007] F.C.J. No. 420, at para. 59). The point being that, having regard to those elements, Apotex may not be a "second person" with standing to bring this section 8 proceeding.
>
> One of the cumulative elements cited in *Ferring*, *supra*, as triggering section 5(1) of the *Regulations*, and thereby bringing a generic within the definition of a "second person", is that the "other drug has been marketed in Canada". Astrazeneca says that Losec was not marketed in Canada after 1996, and that Apotex may therefore not have standing to sue for damages.
>
> As further support for its argument, the defendant relies on *Sanofi-Aventis Canada Inc. v. Canada (Minister of Health)* (2006) 54 C.P.R. (4th) 387 (F.C.), where the Court was persuaded that Apotex was not a "second person", notwithstanding that a prohibition proceeding was pending.

(Strike Dismissal Order, p. 2.)

[19] The Prothonotary then rejected AstraZeneca's arguments for four distinct reasons.

[20] First, she held that AstraZeneca's arguments would be more properly raised by a defence. Apotex is not obliged to rebut the argument that it is not a "second person" before such an argument is raised by AstraZeneca.

[21] Second, she held, consistent with a long line of cases that an interpretation of section 8 is best left for trial; AstraZeneca is seeking an interpretation of section 8 which is thus left for trial.

[22] Third, the Prothonotary found that Apotex had pleaded sufficient facts to support a section 8 cause of action and that AstraZeneca had "not nearly" met its burden on a motion to strike. (Strike Dismissal Order, p. 3.)

[23] Fourth, and finally, the Prothonotary added that it was possible that, despite accepting AstraZeneca's arguments in respect of subsection 5(1), an interpretation of section 8 would nonetheless support Apotex's standing to bring a section 8 claim. This further issue of interpretation "presents an arguable issue of mixed fact and law that the jurisprudence holds must be reserved for trial." (Strike Dismissal Order, p. 3.)

[24] Further to the Order of Prothonotary Aronovitch, dated June 6, 2007, Apotex served and filed further particulars, as ordered. (Particulars of Statement of Claim, dated June 13 2007; Responding Motion Record of Apotex at Tab 1.)

**AstraZeneca Appeals the Dismissal of its Motion**

[25] AstraZeneca seeks to set aside the Order of Prothonotary Aronovitch and to have its underlying motion to strike granted.

**ISSUES**

[26] While AstraZeneca has urged this Court to engage in a *de novo* review, it has chosen to specify two alleged errors committed by the Prothonotary. In order to more fully respond to the two alleged errors of law, the Court addresses the following issues by which to answer AstraZeneca's request that the Statement of Claim be struck:

(a) The Test on a motion to Strike;

(b) The section 8 Claim;

(c) Did the Prothonotary reverse the burden?

(d) Did the Prothonotary misinterpret the Regulations?

**ANALYSIS**

**(a) <u>The Test on a Motion to Strike</u>**

[27] The threshold on a motion to strike paragraphs in a pleading is well-settled and difficult to meet: the Court must be convinced beyond doubt that it is "plain and obvious that the impugned paragraphs fail to disclose a reasonable cause of action or defence." (*Hunt v. Carey Canada Inc.*, [1990] 2 S.C.R. 959 at 980.)

[28] The Court must accept the facts as proven, and then ask whether the allegation contained in the impugned paragraphs is so clearly futile that the responding party would have no possible chance of success at trial. The pleading must be read generously with due allowance for drafting deficiencies. The Court should not resolve disputed questions of law. The Court should only strike paragraphs in the clearest of circumstances where there is no arguable basis for including the matters to which objection has been taken. (*Federal Courts Rules*, SOR/98-106; *Hunt*, above; *Operation Dismantle Inc. et al. v. The Queen* (1985), 18 D.L.R. (4th) 481 at 488 (S.C.C.).)

[29] Furthermore, the Court has stated repeatedly that the allegations in a Statement of Claim must stand unless the impugned portions fail to disclose a "scintilla of a cause of action". (*Charette v. Delta Controls*, 2003 FCA 425, [2003] F.C.J. No. 1696 (F.C.A.) (QL) at para. 3; *Apotex Inc. v. Wellcome Foundations Ltd.* (1996), 68 C.P.R. (3d) 23 (F.C.T.D.) at 41.)

[30] A motion to strike a Statement of Claim should not simply be granted even where "elements may be missing and others incomplete". The central question on the motion is whether the pleading contains enough information for the opposing party to know "with some certainty" the case to be met in respect of the Statement of Claim. (*Pharmaceutical Partners of Canada Inc. v. Faulding (Canada) Inc.* (2002), 21 C.P.R. (4th) (F.C.T.D.) 166 at para. 13; *Shubenacadie Indian Band v. Canada (Minister of Fisheries and Oceans)*, 2002 FCA 249, [2002] F.C.J. No. 880 (QL); *Sweet v. Canada* (1999), 249 N.R. 17 (F.C.A.) at para. 19; *Novartis AG v. Apotex Inc.*, 2006 FC 1277, [2006] F.C.J. No. 1595 (F.C.) (QL) at para. 15.)

**(b) Section 8 Claim**

[31] In order for AstraZeneca to sustain its appeal of the Prothonotary's decision, it must establish that it is plain and obvious that the Statement of Claim does not plead a reasonable cause of action.

[32] An issue raised in respect of the Statement of Claim is the purported failure of Apotex to plead that it is a "second person" under the Regulations.

[33] As a counterbalance for the "draconian" automatic statutory stay conferred upon a "first person" under the Regulations in the absence of an undertaking for damages, section 8 enables a generic manufacturer to bring an action in order to obtain compensation for having been improperly subjected to a proceeding under the Regulations.

| | |
|---|---|
| **8.** (1) If an application made under subsection 6(1) is | **8.** (1) Si la demande présentée aux termes du |

| | |
|---|---|
| withdrawn or discontinued by the first person or is dismissed by the court hearing the application or if an order preventing the Minister from issuing a notice of compliance, made pursuant to that subsection, is reversed on appeal, the first person is liable to the second person for any loss suffered during the period | paragraphe 6(1) est retirée ou fait l'objet d'un désistement par la première personne ou est rejetée par le tribunal qui en est saisi, ou si l'ordonnance interdisant au ministre de délivrer un avis de conformité, rendue aux termes de ce paragraphe, est annulée lors d'un appel, la première personne est responsable envers la seconde personne de toute perte subie au cours de la période : |
| (*a*) beginning on the date, as certified by the Minister, on which a notice of compliance would have been issued in the absence of these Regulations, unless the court concludes that | *a*) débutant à la date, attestée par le ministre, à laquelle un avis de conformité aurait été délivré en l'absence du présent règlement, sauf si le tribunal conclut : |
| … | [...] |
| (*b*) ending on the date of the withdrawal, the discontinuance, the dismissal or the reversal. | *b*) se terminant à la date du retrait, du désistement ou du rejet de la demande ou de l'annulation de l'ordonnance. |

(*Apotex Inc. v. Laboratoires Fournier S.A.*, above, at paras. 10-11.)

[34] From both the language of the subsection and from the purpose of the right of action, it appears that a significant element of a section 8 claim is that an application made under subsection 6(1) of the Regulations is withdrawn or discontinued by the first person or dismissed by the Court.

[35] The latter part of subsection 8(1) is of relevance for the purpose of treating the determination of the loss of the second person, as set out, in section 8. (Regulations, subsection 8(2).)

[36] As found by the Prothonotary, "Apotex has pleaded sufficient facts to support a cause of action pursuant to section 8." For the purpose of this proceeding, AstraZeneca has not established an error, legal or otherwise, that undermines this decision. (Strike Dismissal Order, p. 3.) (The future cannot be foresee at this juncture; it must be witnessed when encountered; reference is made to paragraphs [53] and [54] below.)

[37] First, paragraph 16 of the Statement of Claim pleads that there was a prohibition proceeding that was commenced by AstraZeneca which was dismissed by the Court.

> … By Order dated December 30, 2003, Mr. Justice O'Keefe dismissed a prohibition proceeding bearing Court File no. T-2311-01 that had been commenced by the Defendant in respect of the '762 Patent.

[38] Second, the Statement of Claim pleads, at paragraphs 15, 16 and 17, the time at which Apotex would have received a NOC, if it was not for the prohibition proceedings which had a bearing as to the date of dismissal and the date upon which Apotex received its NOC.

[39] Third, Apotex pleads the losses suffered at paragraph 18 of the Statement of Claim:

> By reason of the *Patent Regulations*, the issuance of Apotex's NOC for Apo-Omeprazole 20 mg capsules was delayed from January 3, 2002 to January 27, 2004.

[40] Fourth, Apotex claims for losses suffered and makes an alternative claim for an accounting of profits and an additional claim for disgorgement of AstraZeneca's revenues. In addition, Apotex

has further pleaded particulars in respect of its claims for damages and disgorgement. (Statement of Claim, paras. 19-20; Particulars of Statement of Claim dated June 13, 2007, Responding Motion Record of Apotex at Tab 1.)

[41] Furthermore, AstraZeneca was a party to the prohibition proceedings and, therefore, the facts to those proceedings are relevant. (*AstraZeneca Canada Inc. v. Apotex Inc.*, 2005 FC 43, [2005] F.C.J. No. 74; 2005 (F.C.) (QL) at paras. 17-18.)

[42] AstraZeneca has not established a deficiency in Apotex's pleading that would prevent AstraZeneca from pleading its case in regard to the Statement of Claim.

[43] The definition of a "second person" under the Regulations is a "person referred to in subsection 5(1) or (2) who files a submission or supplement referred to in those subsections." (Regulations, section 2.)

[44] By pleading, first, that Canadian Letters Patent No. 2,133,762 ('762 Patent) was listed on the Patent Register and prevented Apotex from receiving a NOC and, second, that AstraZeneca commenced a prohibition proceeding against Apotex in respect of the '762 Patent, Apotex has pleaded material facts in support of its conclusion that it was a "second person". As pleaded, it was obliged to address the '762 Patent pursuant to subsection 5(1) of the Regulations and did so by way of notice of allegation that led to a prohibition proceeding. In addition, it was AstraZeneca that initiated the prohibition proceedings.

[45] In her reasons, Prothonotary Aronovitch identifies the “second person” argument of AstraZeneca:

> At the hearing the defendant fleshed-out its argument, and urged on the Court that Apotex be required to plead the elements now recognized in the jurisprudence as identifying “a second person” for the purposes of triggering section 5(1) of the *Regulations*, (*Ferring Inc. v. Canada (Minister of Health)* [2007] F.C.J. No. 420, at para. 59).

[46] In *Ferring Inc. v. Canada (Minister of Health)*, 2007 FC 300, [2007] F.C.J. No. 420 (QL):

> [59] It is important to note that the Supreme Court was quite specific in paragraph 40 as to the reason for the reference, it was for demonstrating bioequivalence. Section 5(1) of the *NOC Regulations* are specific in stating that a person is only required to take steps to issue a notice of allegation to the innovator who has listed patents (thus become a "second person") if:
>
> - that person has filed for an NOC;
> - that person has compared reference or made reference to another drug;
> - for the purposes of demonstrating bioequivalence;
> - and that other drug has been marketed in Canada pursuant to an NOC; and
> - there is a patent list pertinent to that NOC.

[47] Significantly, given the putative state of section 8 jurisprudence to which reference is made, regardless of whether AstraZeneca is or is not ultimately correct, such a determination should be made on the basis of a full record at the close of trial.

[48] The interpretation of the law in regard to section 8 is in an “embryonic state”. As such, the Court is hesitant to strike out section 8 claims at the pleadings stage. (*Apotex Inc. v. Eli Lilly and*

*Co. et al.*, above; *Apotex Inc. v. Laboratoires Fournier S.A.*, above; *Apotex Inc. v. Syntex Pharmaceuticals International Ltd.*, above; *Apotex Inc. v. Merck & Co.*, above.)

[49] This Court has held that matters of the interpretation of section 8 should be deferred to trial:

> [15] …There is not yet a clear understanding of what s. 8 of the Patent Regulations really means…
>
> > [18] …the contentious issues are of a complex nature better suited for determination at trial…

(*Apotex Inc. v. Syntex Pharmaceuticals International Ltd.*, above.)

> [17] The Court has also had a number of other occasions to look at s. 8 without reaching a determination of its meaning. In total, on no less than 11 occasions, this Court and the Federal Court of Appeal have concluded that issues of interpretation of s. 8 should proceed to trial…

(*Apotex Inc. v. Merck & Co.*, above.)

[50] Applied to the present case, the arguments of AstraZeneca relate to the interpretation of section 8. The Prothonotary rejected AstraZeneca's assertion that it was not seeking or advocating an interpretation of section 8 by the Court. (Strike Dismissal Order, p. 3.)

[51] The inclusion of the words "second person" in section 8 by which to import the case law in respect of subsection 5(1) would have to be analyzed in respect of the *Ferring* factors to determine relevance in regard to section 8; such a requirement can only arise from an actual interpretation of section 8.

[52] Moreover, it is, as yet, to be determined whether the interpretation proposed to the Court by AstraZeneca is appropriate under the specific circumstances of the case at bar.

[53] It is possible that a purposive interpretation of section 8 of the Regulations would result in a different nuance to the understanding of "second person" within the context of section 8.

[54] Regulations in respect of second persons are, yet, to be determined as to what second persons have a right to avail themselves, subsequent to a determination as to which party is, in fact, a second party.

[55] For resolution in regard to the above, an in-depth analysis is required, thus, a need exists to proceed to trial.

**(c) Did the Prothonotary reverse the burden?**

[56] The first error that AstraZeneca alleges is that the Prothonotary improperly reversed the burden of the parties by not obliging Apotex to plead the elements of a section 8 cause of action.

[57] AstraZeneca has characterized the Prothonotary's decision as requiring AstraZeneca to plead as an improper reversal of the onus upon the motion:

> The Prothonotary's holding also fails to recognize that the burden is on Apotex to plead that it has standing as a "second person" to seek relief under s. 8 of the *Regulations*. By requiring Astra to allege that Apotex has not pleaded that it is a "second person" within s. 8, the finding improperly shifts the burden to Astra.

(AstraZeneca Written Representations at para. 37.)

[58] The Prothonotary did not decide that AstraZeneca could plead by way of defence that "Apotex has not pleaded that it is a 'second person'". Rather, the Prothonotary's Order, simply determined that the Statement of Claim was sufficient and that AstraZeneca could plead its own set of material facts in that regard.

[59] As set out above, Apotex has pleaded the material facts for consideration as to its section 8 claim, including material facts to establish the legal conclusion for consideration that Apotex is a second person under the Regulations. AstraZeneca, therefore, has notice of Apotex's position and is able to plead in respect of this version of the facts in its response. The Prothonotary, therefore characterized the arguments of AstraZeneca as requiring Apotex to anticipatorily plead an answer to a possible defence.

> In my view, these are not arguments to impugn the sufficiency of the pleadings. Rather, they raise defences to the action that must be pleaded. It is not for Apotex to answer to the defence before it is made, nor to rebut the argument that it may not be a "second person" in its statement of claim.

(Srike Dismissal Order, p. 2.)

**(d) Did the Prothonotary misinterpret the Regulations?**

[60] The Prothonotary's Reasons for Order determined that the question of whether AstraZeneca's construction of section 8 is correct, and, therefore, also the question of whether any competing interpretations are correct, "calls for the interpretation of s. 8 and presents an arguable issue of mixed fact and law that the jurisprudence holds must be reserved for trial." (Strike Dismissal Order, p. 3.)

[61] As is set out above, the Prothonotary's decision that it was inappropriate to come to a final conclusion as to the interpretation of section 8 of the Regulations at the pleadings stage is well supported by the jurisprudence.

[62] Once the Prothonotary determined that the interpretation advocated by AstraZeneca could not be accepted as conclusive at this stage, she was well supported in her determination that Apotex has pleaded sufficient material facts to support a section 8 claim. In addition, as set out above, Apotex had further pleaded material facts to support consideration of the legal conclusion that it was a second person.

[63] For all of the above reasons, at this stage of the proceedings, the Prothonotary did make an appropriate determination, recognizing that all else is left to the trial.

**CONCLUSION**

[64] For all of these reasons, AstraZeneca's motion is dismissed with costs in the cause and AstraZeneca is ordered to deliver its Statement of Defence within forty five days (rather than 15 days), based on a consideration of particulars recently delivered by Apotex to AstraZeneca, for the purpose of greater clarity in respect of preparation of the matter for trial.

## ORDER

**THIS COURT ORDERS:**

1. AstraZeneca Canada Inc.'s motion to set aside the Order of Prothonotary Aronovitch, dated June 6, 2007, be dismissed with costs in the cause; and

2. AstraZeneca Canada Inc. is to deliver its Statement of Defence within forty five days (rather than 15 days), based on a consideration of particulars recently delivered by Apotex to AstraZeneca, for the purpose of greater clarity in respect of preparation of the matter for trial.

"Michel M.J. Shore"
Judge

**FEDERAL COURT**

**SOLICITORS OF RECORD**

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| **DOCKET:** | T-2300-05 |
| **STYLE OF CAUSE:** | APOTEX INC. v. ASTRAZENECAZENECA CANADA INC. |
| **PLACE OF HEARING:** | Ottawa, Ontario |
| **DATE OF HEARING:** | June 28, 2007 |
| **REASONS FOR ORDER AND ORDER:** | SHORE J. |
| **DATED:** | July 10, 2007 |

**APPEARANCES:**

| | |
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| Mr. Gunars A. Gaikis<br>Mr. Mark G. Biernacki | FOR THE PLAINTIFF |
| Mr. Benjamin Hackett | FOR THE DEFENDANT |

**SOLICITORS OF RECORD:**

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| GOODMANS, LLP<br>Toronto, Ontario | FOR THE DEFENDANT |