Date: 20090204

Docket: T-2300-05

Citation: 2009 FC 120

Ottawa, Ontario, February 4, 2009

PRESENT: The Honourable Mr. Justice Kelen

BETWEEN:

APOTEX INC.

Plaintiff

and

ASTRAZENECA CANADA INC.

Defendant

and

ASTRAZENECA CANADA INC.
AKTIEBOLAGET HASSLE and ASTRAZENECA AB

Plaintiffs by Counterclaim

and

APOTEX INC.,
HER MAJESTY THE QUEEN
and THE ATTORNEY GENERAL OF CANADA

Defendants to Counterclaim

REASONS FOR ORDER AND ORDER

[1] This is an appeal by Her Majesty the Queen (the Crown) pursuant to Rule 51(1) of the *Federal Courts Rules* of an Order by Madam Prothonotary Aronovitch dated August 19, 2008, dismissing in large part the Crown's motion to strike out one of two separate counterclaims against the Crown.

Overview

[2] In this action, AstraZeneca counterclaims against Her Majesty the Queen for damages caused by the alleged negligence of the Crown in requiring a generic drug manufacturer, Apotex, to file a notice of allegation under the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133, amended by SOR/98-166; SOR/99-379; SOR/2006-242 (*NOC Regulations*) with respect to a New Drug Submission (NDS). AstraZeneca brought an application for prohibition under the *NOC Regulations*, which was dismissed. Apotex is now suing AstraZeneca for damages under section 8 of the *NOC Regulations*, and AstraZeneca is counterclaiming against Her Majesty the Queen for alleged negligence in requiring Apotex to file the notice of allegation which precipitated AstraZeneca commencing the application for prohibition. The learned Prothonotary found that while this cause of action by counterclaim was novel, she would not strike it out because it was not plain and obvious and without doubt that such a cause of action in negligence did not exist. The Court is asked to set aside the Prothonotary's Order, which the Court will do if the Order is clearly wrong. For the reasons below, the Court finds that the decision of the learned Prothonotary was well reasoned and not clearly wrong so that the motion to strike was properly dismissed.

FACTS

[3] In 1994, Apotex filed a NDS for its Apo-Omeprazole 20 capsules. In 1997, Apotex re-filed its NDS as an abbreviated new drug submission (ANDS). Pursuant to subsection C.08.002.1 of the *Food and Drug Regulations*, C.R.C., c-870, an ANDS may be filed instead of an NDS where the new drug is the pharmaceutical equivalent of a Canadian reference product.

[4] In September 2001, the Minister of Health decided that Apotex's submission could proceed as an NDS rather than an ANDS. In November 2001, Apotex served a notice of allegation in respect of AstraZeneca's Patent No. 2,133,762 ('762 Patent). In December 2001, AstraZeneca commenced a prohibition action pursuant to s. 6 of the *NOC Regulations.*

[5] In 2003, the prohibition application was dismissed. In 2004, the minister issued a notice of compliance (NOC) to Apotex for Apo-Omeprazole capsules based on its NDS. The Minister specifically advised Apotex that the NOC was not based on a bioequivalence comparison/reference to AstraZeneca's LOSEC capsules as a Canadian reference product.

[6] In 2007, Apotex sued the Minister seeking, *inter alia*, a declaration that Apotex was not required to address the '762 patent under subsection 5(1) of the *NOC Regulations*. Justice O'Keefe found that subsection 5(1) properly applied to Apotex's NDS: *Apotex Inc. v. the Minister of Health, AstraZeneca AB and AstraZeneca Canada Inc.*, 2004 FC 650, 252 F.T.R. 8.

The Main Action

[7] Apotex commenced this action against AstraZeneca under subsection 8 of the *NOC Regulations.* Apotex alleges that AstraZeneca's prohibition action delayed it from receiving market approval for Apo-Omeprazole from January 3, 2002 to January 27, 2004. Apotex seeks, *inter alia*, to recover damages from AstraZeneca for the alleged delay.

Counterclaims against the Crown

[8] AstraZeneca has raised numerous counterclaims, including distinct counterclaims against Her Majesty the Queen (the Crown). AstraZeneca seeks a declaration that s. 8 of the *Regulations* is of no force and effect, which the Crown is not contesting in this motion.

[9] In addition, AstraZeneca alleges that the Minister's conduct in issuing an NOC to Apotex was negligent towards both AstraZeneca and Apotex, because the *NOC Regulations* did not apply to the NDS for Apotex's Apo-Omeprazole capsule. AstraZeneca seeks full contribution and indemnity if it is found liable to Apotex, and compensation for costs and damages as a consequence of the negligence of the Minister.

[10] The Crown brought a preliminary motion to strike out the negligence-based counterclaim entirely or in part or, in the alternative, require AstraZeneca to provide further and better particulars of the allegations. This motion was denied by the learned Prothonotary on August 19, 2008, except for allowing minor changes to the style of cause and the pleadings. The Crown appeals this decision.

Decision under review

[11] The Crown submitted that the counterclaim should be struck on any one, or all, of the following four grounds:

1. that any action or decision of the Minister may be found unlawful only by way of judicial review;

2. that there is no right of action against the Crown as the Minister is specifically exempted from liability for damages under section 8(6) of the *NOC Regulations*;

3. that the Minister did not have a duty of care to AstraZeneca or Apotex; and

4. that even if there were a duty of care by which the Minister might be liable, no breach is made out because the Court found in *Apotex Inc. v. the Minister of Health*, supra, that Apotex was required to address the '762 patent.

[12] With respect to the first ground, the Prothonotary found that the counterclaim was not an attack on the lawfulness of a decision of the Minister because AstraZeneca is not seeking to overturn or invalidate the decision of the Minister to issue an NOC to Apotex. The Prothonotary found that the counterclaim was expressly based on the alleged negligence and thus the Court of Appeal's ruling in *Grenier v. Canada*, 2005 FCA 348, 262 D.L.R. (4th) 337, that a Minister's unlawful conduct can only be impugned by way of judicial review, is not applicable.

[13] Second, the Crown submitted that that there is no right of action as the claim is based entirely on subsection 8 of the *NOC Regulations*, which expressly exempts the Minister from liability. The Prothonotary stated at page 6 of the Order:

> AstraZeneca alleges that the minister is liable in negligence and for that purpose relies upon section 3 of the *Crown Liability and Proceedings Act* which provides for the vicarious liability of the Crown for torts committed by its servants. Arguably, *Apotex Inc. v. Syntex Pharmaceuticals International Ltd.*, 2005 FCA 424, [2006] 3 F.C.R. 318 (*Syntex*) leaves open the possibility that such a claim, if properly pleaded, might succeed.

[14] Third, the Crown submitted there was no duty of care owing to AstraZeneca, the breach of which would give rise to any claim for economic loss. The Prothonotary found that AstraZeneca was entitled to maintain its action at the pleadings stage, stating at page 8 of the Order:

> …AstraZeneca is entitled to maintain its action unless the Crown, who has the burden in that regard, can demonstrate that it is plain and obvious that the governing statue, as a whole cannot be said, expressly or by implication to give rise to sufficient proximity or "neighbourhood" between AstraZeneca and the Minister such that it [is] just and fair to impose a duty of care on the Minister…
>
> In light of the particular circumstances of this case, the alleged negligence of the Minister in the processing of Apotex's regulatory submissions, the failure to warn the parties, and judicial consideration of the *Regulations*, the Crown, in my view, fails to meet that burden.
>
> Indeed, when looking at the purpose of the *Patent Act* and the *Regulations* through the lens of recent jurisprudence, the Court has indicated that the primary concern of legislators has been the protection of the rights of both generics and innovators.

[15] The Prothonotary stated at page 9 of the Order:

> AstraZeneca pleads that the administration of the FDA *Regulations* and the *NOC Regulations* includes deciding whether the manufacturer is required to make an allegation pursuant to s. 5(1) of the *Regulations.* That pleading and the additional allegations regarding the Minister's dealings with Apotex on its regulatory submissions, the fact that drug submissions are dealt with in confidence and with no knowledge to the innovater, in this case, AstraZeneca, are all grounded in the regulatory process, and arguably sufficient to establish the proximity necessary [t]o give rise to a duty of care…

[16] Fourth, the Prothonotary found that neither *res judicata* nor issue estoppel applied as a result this Court's decision in *Apotex Inc. v. the Minister of Health*, supra, as neither of the grounds argued

before Justice O'Keefe dealt with the issue critical to the claim for negligence, which the learned Prothonotary characterized as the allegation that section 5 of the *NOC Regulations* did not apply because the submission was an NDS rather than an ANDS, and the alleged failure of the Minister to advise the parties accordingly.

[17] With respect to the remaining issues, the Prothonotary held at page 11 of the Order:

> In respect of paragraphs 201 and 203, I accept and agree with AstraZeneca's submissions.
>
> In addition, Her Majesty has not either by way of affidavit evidence, or on the basis of the adequacy of the pleading, on its face, satisfied the Court that it requires particulars to plead.

[18] The Prothonotary therefore allowed the motion with respect to minor amendments to the style of cause and the statement of defence, and otherwise denied the motion.

ISSUES

[19] The Crown raises three issues in this appeal:

1. Should the second counterclaim be struck out and the action dismissed under Rule 221 of the *Federal Courts Rules*, because it discloses no cause of action, is frivolous or vexatious, or is otherwise an abuse of the process of the Court? The Crown submits that there are four grounds for dismissal of the second counterclaim in its entirety:

    a. AstraZeneca has no right of action against Her Majesty, because its complaint amounts to a collateral attack on decisions of a federal board, commission or tribunal (the Minister of Health) that may be found unlawful only by way of a judicial review proceeding;

    b. AstraZeneca has no right of action because subsection 8(6) of the *NOC Regulations* expressly exempts the Minister from liability;

    c. No duty of care was owed to AstraZeneca; and

d. There was no breach of any duty of care owed to AstraZeneca which would give rise to any claim for economic loss.

2. In the alternative, should the Court overturn the Prothonotary's refusal to strike out parts of paragraphs 201 and 203 of the Statement of Defence and Counterclaim under Rule 221?

3. Also in the alternative, should the Court overturn the Prothonotary's refusal to require AstraZeneca to provide further particulars of its allegations?

STANDARD OF REVIEW

[20] Discretionary decisions of Prothonotaries may be set aside on appeal only if:

(a) they are clearly wrong, in the sense that the exercise of discretion by the Prothonotary was based upon a wrong principle or a misapprehension of the facts; or

(b) they raise questions vital to the final issue of the case.

Canada v. Aqua-Gem Investments Ltd. [1993] 2 F.C. 425 (C.A.), per Justice MacGuigan at paragraph 95; *Z.I. Pompey Industrie v. ECU-Line N.V.*, 2003 SCC 27, 224 D.L.R. (4th) 577, per Justice Bastarache at paragraph 18.

[21] Where either of these factors exists, the reviewing Court ought to exercise its discretion *de novo: Aqua-Gem*, supra; *Merck & Co. v. Apotex Inc.*, 2003 FCA 488, 315 N.R. 175 at paragraph 17.

[22] The Crown submits that a decision pertaining to a motion to strike is vital to the final resolution of the case, and that the Court must therefore review the Prothonotary's decision *de novo*, as it relates to the Crown's submission that the counterclaim be struck in its entirety. The Crown

submits that in the alternative, the Prothonotary's findings with respect to the partial strike and the request for particulars are clearly wrong and should be set aside for that reason.

[23] AstraZeneca submits that it is not what is sought but what was ordered that must be "vital to the final issue of the case" in order to warrant *de novo* review. In *Peter G. White Management Ltd. v. Canada*, 2007 FC 686, 314 F.T.R. 284, Justice Hugessen stated at paragraph 2:

> ...the mere fact that what was sought before the prothonotary might have been determinative of the final issues in the case does not result in the judge hearing the matter entirely de novo. A reading of the decisions, and particularly the key decision of the Court of Appeal in the case of Canada v. Aqua-Gem Investments Ltd., [1993] 2 F.C. 425 (C.A.), makes it quite clear that it is not what was sought but what was ordered by the prothonotary which must be determinative of the final issues in order for the judge to be required to undertake de novo review... Put briefly, barring extraordinary circumstances, a decision of a prothonotary not to strike out a statement of claim is not determinative of any final issue in the case. In determining the standard of review the focus is on the Order as it was pronounced, not on what it might have been.

[24] Similarly, in the recent decision of *Chrysler Canada Inc. v. Canada*, 2008 FC 1049, Justice Hughes stated at paragraph 4:

> Where a prothonotary has struck out a proceeding such a decision is, of course, one vital to the final issue of the case. Where, however in circumstances such as the present case, the Prothonotary has not struck out the proceeding, that decision is not finally determinative of any issue vital to the case, thus the decision presently under consideration is to be reviewed on appeal on the second ground set out in Merck, supra, namely, is the decision clearly wrong as being based on a wrong principle or misapprehension of the facts.

[25] I agree with my colleagues that where the decision of the Prothonotary was not to strike out a statement of claim, the decision is not to be reviewed *de novo.* Therefore, the decision will be set aside only if the learned Prothonotary's decision is found to be clearly wrong.

ANALYSIS

Test for a Motion to Strike

[26] There is a high threshold for striking a statement of claim. A claim will be struck where it is plain and obvious that it discloses no reasonable cause of action, where the Court is satisfied beyond doubt that the case cannot be supported. The Prothonotary stated at p. 3 of the Order:

> The party moving to strike has the onus of showing that it is plain, obvious and beyond doubt that the case cannot succeed at trial. In applying the test the Court must take the allegations as proven, and give a broad and generous interpretation to the claim, declining to strike if a cause of action, however tenuous, can be gleaned from the statement of claim so construed, (*Hunt v. Carey Canada Inc.,* [1990] 2 S.C.R. 959 at paras. 30 to 33; *Shubenacadie Indian Band v. Canada (Minister of Fisheries and Oceans),* 2002 FCA 255.

[27] I agree with the Prothonotary that this is the standard for striking a claim. Moreover, the Crown has not alleged that the Prothonotary erred in stating the test.

Issue No. 1: Should the second counterclaim be struck out entirely?

a) Is there a right of action available to AstraZeneca outside of judicial review?

[28] The Crown reiterates its submission before the Prothonotary that the claim is based on the Minister's decision to issue an NOC to Apotex and any such decision can only be challenged on judicial review. The Crown relies on *Grenier,* supra, for the proposition that a party must challenge

a decision of a federal board by way of judicial review and cites several decisions where the courts have dismissed proceedings where a party sought to challenge the lawfulness of such a decision by way of an action. In particular, the Crown points to *Nu-Pharm Inc. v. Canada*, 2008 FCA 227, a recent decision in which the Federal Court of Appeal upheld the dismissal of drug manufacturer's action for damages related to the Minister's declaration that the drug could not be sold without an NOC.

[29] In her decision, the learned Prothonotary found that the counterclaim was not an attack on the lawfulness of the decision of the Minister but a claim in negligence against the Minister for the manner in which he carried out his duties. She cited *Peter G. White Management Ltd.*, supra, wherein Justice Hugessen found that *Grenier* did not preclude an action being brought against a Crown official for failing to "respect his employer's contractual obligations," and also my decision in *Agustawestland International Ltd. V. Canada (Minister of Public Works and Government Services)*, 2006 FC 767, wherein I found at paragraph 7 that *Grenier* does not apply to acts by the Crown which are normally subject to legal actions for breach of contract or tort. The Prothonotary also distinguished the *Nu-Pharm* case on numerous grounds. The Prothonotary stated at page 5 of the Order:

> ...*Nu-Pharm* was not an instance of a counterclaim running parallel with a subsisting main action. Assuming that there was a reviewable decision, it is unclear that AstraZeneca would have had standing to challenge any decision made by the Minister in the course of processing Apotex's drug submissions. Moreover, there would be no utility in forcing AstraZeneca to seek declaratory relief in respect of conduct that occurred prior to the issuance of the NOC in 2004, in order to then claim contribution and indemnity or damages in a section 8 proceeding, where the assertion that Apotex was not required to address the '762 patent has been raised as a defence to the

> claim by Apotex, and must be determined in this action irrespective of the claim against the Crown. This would run contrary to the principle of judicial economy and to the "utilitarian and pragmatic approach" referenced by the Court of Appeal in *Grenier*.

[30] I agree with the Prothonotary. In this case, the NOC has issued and AstraZeneca is not challenging or seeking to set aside any decision of the Minister. Moreover, the Crown has not responded to the findings of the Prothonotary. The Crown's submissions evidently assume that the decision of the Prothonotary would be reviewed *de novo*, as there are no submissions before the Court as to why the Prothonotary's reasons on any of the issues, save the partial strike and the request for particulars, are clearly wrong. The decision is not being reviewed *de novo* and the Court must therefore consider the reasons of the Prothonotary and whether they are clearly wrong. Her findings with respect to the first issue are clear and reasonable, and will not be set aside.

b) Is there no right of action due to section 8 of the *Regulations*?

[31] The Crown submits that the counterclaim cannot be sustained in law because section 8(6) of the *NOC Regulations* expressly specifies that the Minister is not liable for any damages under section 8. The Prothonotary found that AstraZeneca's claim is not being brought under section 8, but in based in negligence. This is consistent with the pleadings, wherein AstraZeneca relies on the section 3 of the *Crown Liability and Proceedings Act*, R.S.C. 1985, c. C-50.
AstraZeneca does not plead or argue that the Minister is liable under section 8 of the *NOC Regulations.*

c) Is it plain and obvious that no duty of care was owed to AstraZeneca?

[32] The Crown submits that no duty of care to AstraZeneca is made out on the pleadings. First, the Crown acknowledges that AstraZeneca has pleaded negligence but submits that the pleading amounts to a claim of breach of statutory duty, and that no such tort exists. AstraZeneca submits that the pleading is not so limited and moreover, that a breach of statutory duty may be evidence of negligence where it has an effect on civil liability. Second, the Crown submits that AstraZeneca cannot meet the two-step test set out in *Anns v. Merton London Borough Council,* [1978] A.C. 728 (H.L.), adopted in *Kamloops (City) v, Neilsen* [1984] 2 S.C.R. 2 and refined in *Cooper v. Hobart,* [2001] 3 S.C.R. 537 and confirmed in subsequent cases. The Prothonotary cited *Edwards v. Law Society of Upper Canada,* [2001] 3 S.C.R. 562, which summarized the *Anns* test at paragraphs 9-10:

> 9 At the first stage of the Anns test, the question is whether the circumstances disclose reasonably foreseeable harm and proximity sufficient to establish a prima facie duty of care. The focus at this stage is on factors arising from the relationship between the plaintiff and the defendant, including broad considerations of policy. The starting point for this analysis is to determine whether there are analogous categories of cases in which proximity has previously been recognized. If no such cases exist, the question then becomes whether a new duty of care should be recognized in the circumstances. Mere foreseeability is not enough to establish a prima facie duty of care. The plaintiff must also show proximity -- that the defendant was in a close and direct relationship to him or her such that it is just to impose a duty of care in the circumstances. Factors giving rise to proximity must be grounded in the governing statute when there is one, as in the present case.
>
> 10 If the plaintiff is successful at the first stage of Anns such that a prima facie duty of care has been established (despite the fact that the proposed duty does not fall within an already recognized category of recovery), the second stage of the Anns test must be addressed. That question is whether there exist residual policy considerations which justify denying liability. Residual

> policy considerations include, among other things, the effect of recognizing that duty of care on other legal obligations, its impact on the legal system and, in a less precise but important consideration, the effect of imposing liability on society in general.

[33] The Crown submits that it is impossible for AstraZeneca to establish a relationship of proximity between the Minister and itself, because there is no duty of care to AstraZeneca. The Crown submits that nothing in the *Regulations* indicates a relationship between drug manufacturers and the Minister through which that Minister might be responsible for their losses. The Crown further submits that if a duty of care is established, there are residual policy reasons to negate the duty of care.

[34] The Prothonotary found the Crown had not met its burden of demonstrating that it was plain and obvious that the action could not be maintained. The Prothonotary engaged in an analysis of the case-law supporting her finding that the purpose of the *NOC Regulations* is to protect patent holders and generics, which I will not repeat here. On page 8 of the Order, the learned Prothonotary held:

> In my view, the present case does not fall within, nor is it analogous to, any category of cases in which a duty of care has previously been recognized by Canadian courts...At the pleadings stage, then, AstraZeneca is entitled to maintain its action unless the Crown, who has the burden in that regard, can demonstrate that it is plain and obvious that the governing statute, as a whole cannot be said, expressly or by implication to give rise to sufficient proximity or "neighbourhood" between AstraZeneca and the Minister...in light of the particular circumstances, the alleged negligence of the Minister inthe processing of Apotex's regulatory submissions, the failure to warn the parties and judicial consideration of the *Regulations*, the Crown, in my view, fails to meet that burden.

> Indeed, when looking at the purpose of the *Patent Act* and the *Regulations* through the lens of recent jurisprudence, the Court has indicated that the primary concern of legislators has been the protection of the rights of both generics and innovators...

[35] The Prothonotary continued on page 9:

> The regulatory scheme of the *NOC Regulations* provides the Minister with a role in maintaining a register of patents, processing drug submissions and issuing NOCs. The Minister, moreover, is said to be acting in a purely administrative capacity in processing drug submissions...AstraZeneca pleads that the administration of the FDA *Regulations* and the NOC *Regulations* includes deciding whether the manufacturer is required to make an allegation pursuant to s. 5(1) of the *Regulations.* That pleading and the additional allegations regarding the Minister's dealings with Apotex on its regulation submissions, the fact that drug submissions are dealt with in confidence with no means of knowledge to the innovator, in this case, AstraZeneca, are all grounded in the regulatory process, and arguably sufficient to establish the proximity necessary to give rise to a duty of care. In other words, it is arguable from the scheme of the *Regulations*, once engaged, that the relationship between the Minister and AstraZeneca as a "first person" under the NOC *Regulations* is such that the Minister ought to be mindful of AstraZeneca's "legitimate interests" in conducting his affairs. (*Cooper*, para. 33)

[36] The Crown has not made submissions directly addressing the Prothonotary's findings, which I find were reasonably open to her.

[37] The Crown further submits that under the second stage of the *Anns* test, policy considerations must limit any duty of care, because section 8(6) of the *Regulations* explicitly limits the Minister's liability and therefore negates any duty of care. The Crown also submits that section 8 already provides AstraZeneca with a remedy, because it is open to AstraZeneca to attempt to

show that it bears no responsibility for the delay and have the amount of compensation owed to Apotex reduced accordingly. The Prothonotary found at page 10:

> …The potential for conflicting duties is not evident on the face of the *Patent Act* nor the NOC *Regulations.* Nor does the jurisprudence addressing the purpose of the NOC *Regulations* and the *Patent Act* indicate that recognizing a duty of care in this case would create a conflict that would prevent the Minister from discharging some other over-riding statutory duty, whether it be to the public, or Parliament. There is no basis, at this juncture, to determine whether a private law duty to AstraZeneca ought to be precluded as giving rise to an untenable conflict, or on other policy grounds.
>
> As to the argument that the amendment at subsection 8(6) of the *Regulations* is to be viewed as an expression of the legislator's intention to shield the Minister from liability, the provision appears limited to claims made pursuant to section 8, and is not *prima facie* determinative of the policy considerations or of the legislators intent to immunize the Minister from private law claims in respect of the Minister's conduct in the performance of his duties in administering the *Regulations.*

[38] I agree with the Prothonotary that the burden is on the Crown to show the policy reasons for limiting the duty of care and that at this stage, there is no basis for striking out the claim based on policy considerations under the *Anns* test. In *Holland v. Saskatchewan*, 2008 SCC 42, 294 D.L.R. (4th) 193, per Chief Justice McLachlin, the Court recognized that while a mere breach of a statutory duty does not constitute negligence, and there is no action for negligent breach of statutory duty, there can coexist a potential liability in negligence in accordance with the *Anns* test. The learned Prothonotary engaged in an excellent analysis of the proximity and duty of care under the *NOC Regulations* toward the innovator and found that there could be an action for negligence. The Prothonotary found that this case is novel and this duty of care has not previously been recognized by the Courts, but that Astrazenca is nontheless entitled to maintain its action unless the Crown

could demonstrate that it was plain and obvious and beyond doubt that the Regulations did not give rise to sufficient proximity or duty of care between Astrazeneca and the Minister. The Prothonotary reasonably found the Crown could not meet this burden.

d) Is it plain and obvious that there was no breach of any duty of care?

[39] Finally, the Crown submits that no breach is made out because the matter is *res judicata* as a result of Justice O'Keefe's decision in *Apotex Inc. v. the Minister of Health,*supra. I agree with the Prothonotary that this decision did not deal with the issue of negligence and therefore, *res judicata* and issue estoppel are not applicable. The issue of the alleged negligence is a new issue raised in the counterclaim based on alleged facts not known to the parties at that time.

Issue No. 2: Should certain specified allegations be struck out?

[40] The Crown submits that paragraphs 201 and 203 of the counterclaim should be struck out.

[41] At the hearing, the parties agreed to a mutually acceptable amendment to paragraph 201, which the Court will allow when the parties file the appropriate documents.

[42] Paragraph 203 of the counterclaim states:

> AstraZeneca had neither knowledge of nor means of knowledge of the Minister's negligent conduct until well after Apotex received a NOC for Apo-Omeprazole in January 2004. Apotex sued the Minister in the Ontario Superior Court of Justice, Court File No. 07-CV-325077 on 3 January 2007, alleging the Minister was, inter alia, negligent with respect to the Minister's handling of Apotex's submission for its Apo-Omeprazole capsules.

[43] The Crown submits the second sentence is immaterial to any claim made in this case by AstraZeneca.

[44] The Crown states that the Prothonotary's decision not to strike the paragraph was clearly wrong because she gave no explicit reason for refusing to do so. The Prothonotary stated at page 11 of the Order:

> In respect of paragraphs 201 and 203, I accept and agree with AstraZeneca's submissions.

[45] I cannot agree with the Crown that the Prothonotary did not give explicit reasons for refusing to strike these paragraphs such as to render her decision clearly wrong, as she accepted and agreed with AstraZeneca's submissions. AstraZeneca submitted that the allegation regarding the Ontario litigation was not immaterial because the claim alleged detailed facts relating to the regulatory submissions for Apo-Omeprazole, and further, that the Crown has not established that the impugned allegation is prejudicial and that it should therefore not be struck even if it is surplus. It was open to the Prothonotary to accept these submissions, and given the brevity of the Crown's submissions as to these paragraphs, it was not necessary for the Prothonotary to give lengthy reasons for doing so.

Issue No. 3: Should particulars be ordered?

[46] The Prothonotary stated at page 11 of the Order:

> Her Majesty has not either by way of affidavit evidence, or on the basis of the adequacy of the pleading, on its face, satisfied the Court that it requires particulars to plead.

[47] The Crown submits the Prothonotary's refusal was based on a wrong principle, and that Her Majesty cannot properly know the matters at issue or the case to be met without particulars of the material facts. The Crown submits that particulars are required for material facts relied on in paragraphs 170(c), 196, 200, 203 and 204.

[48] AstraZeneca submits that particulars will not be ordered at the pleadings stage unless the requesting party: (i) establishes by affidavit evidence that the requested particulars are necessary for pleading and not within the knowledge of the requesting party; or (ii) shows that the pleading is plainly inadequate on its face: *Huzar et al v. Canada et al* (1997), 139 F.T.R. 81 at paragraphs 32-33; *Flexi-coil Ltd. v. F.P. Bourgault Industries Air Seeder Division Ltd.* (1988), 19 C.P.R. (3d) 125 at 127 (F.C.T.D.).

[49] The Crown has not filed affidavit evidence to show that the requested particulars are necessary and not within its knowledge. AstraZeneca submits that the Minister's specific acts and omissions in relation to Apotex's drug submissions for Apo-Omeprazole capsules must be fully within the knowledge of the Crown, and that impugned paragraphs are not inadequate on their face when read in context and altogether. For example, AstraZeneca points out that particulars of paragraph 196 are found in paragraph 197, which alleges that the Minister breached the duty of care to AstraZeneca by failing to advise Apotex that the *NOC Regulations* did not apply to its NDS.

[50] The Prothonotary's finding that the Crown has not adduced sufficient affidavit evidence or otherwise made out that particulars are required at this stage is not based on any wrong principle and will not be set aside. It is not appropriate for the Court to substitute its opinion on this issue for that of the learned Prothonotary.

Conclusion

[51] For these reasons, I find that the Crown has not established that the Prothontary's decision was clearly wrong in that it was based on a wrong principle or misapprehension of the facts. The Crown's appeal is dismissed.

ORDER

THIS COURT ORDERS THAT:

1. The appeal by the Crown of the Prothontary's Order dated August 19, 2008 is dismissed; and
2. Costs of this motion shall be to Astrazeneca, in the cause.

"Michael A. Kelen"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-2300-05
STYLE OF CAUSE:	APOTEX INC. Plaintiff and ASTRAZENECA CANADA INC. Defendant ASTRAZENECA CANADA INC. AKTIEBOLAGET HASSLE AND ASTRAZENECA AB Plaintiffs by Counterclaim and APOTEX INC., HER MAJESTY THE QUEEN and THE ATTORNEY GENERAL OF CANADA Defendants to Counterclaim
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REASONS FOR ORDER AND ORDER:	KELEN J.
DATED:	February 4, 2009

APPEARANCES:

Ms. Nancy Pei	FOR THE DEFENDANT/ PLAINTIFFS BY COUNTERCLAIM
Mr. F.B. (Rick) Woyiwada	FOR THE PLAINTIFF/ DEFENDANTS TO COUNTERCLAIM

SOLICITORS OF RECORD:

Mr. John R. Morrissey, Mr. Gunars A. Gaikis and Ms. Nancy Pei Smart & Biggar Toronto, Ontario	FOR THE DEFENDANT/PLAINTIFFS BY COUNTERCLAIM
Mr. F.B. (Rick) Woyiwada Mr. David Cowie Department of Justice Canada Ottawa, Ontario	FOR THE PLAINTIFF/DEFENDANTS TO COUNTERCLAIM