

Date: 20081024

Docket: T-2078-00

Citation: 2008 FC 1196

Ottawa, Ontario, October 24, 2008

PRESENT: The Honourable Mr. Justice Martineau

BETWEEN:

**BRISTOL-MYERS SQUIBB COMPANY and
BRISTOL-MYERS SQUIBB CANADA INC.**

Plaintiffs

and

APOTEX INC.

Defendant

REASONS FOR ORDER AND ORDER

[1] The Defendant, Apotex Inc. (“Apotex”), seeks to set aside that part of the Order of the Prothonotary made on June 23, 2008, denying leave to make certain amendments by way of a Fourth Amended Statement of Defence and Counterclaim, here paragraphs 14A, 14C and 17 (b.1) of same as per schedule “A” of the Notice of Motion (the proposed amendments).

[2] Apotex asserts for the first time in this patent infringement proceeding that if Apotex’s alleged activities are ultimately found to have infringed Canadian Patent No. 1, 198, 436 (the “

patent in issue”) and to have caused the Plaintiffs to suffer lost sales of Serzone (Plaintiff’s nefazodone product) (which is denied by Apotex):

- a. It is inequitable for the Plaintiffs to obtain a benefit, based on the common law doctrine of *ex turpi causa*;
- b. The Plaintiffs owed a duty to Apotex (whether same would flow from the regulatory scheme or the common law is not specified by Apotex), at all material times, to ensure that Serzone was safe for human consumption; and,
- c. Apotex would not have sought approval to market, would not have developed a generic formulation of Serzone and would not have marketed and sold Apo-Nefazodone (Apotex’s nefazodone product) were it not for the Plaintiffs’ activities of bringing their Serzone product to market in Canada.

As a result, the Plaintiffs are not entitled to recover damages for such lost sales (paragraph 14A) and/or Apotex is entitled to set-off against any such damages the millions of dollars it invested in developing a generic formulation of Serzone and stock piling inventory (paragraphs 14C and 17 (b.1)).

[3] The granting or refusal of an amendment is always a matter of discretion: Rule 75 of the *Federal Court Rules*, SOR/98-106 (the Rules). If no questions vital to the final issue of the case are

involved, as the reviewing Judge, I ought to not interfere with the exercise of this discretion unless the Prothonotary's decision was based upon a wrong principle or upon a misapprehension of the facts: *Canada c. Aqua-Gem Investments Ltd. (C.A.)*, [1993] F.C.J. No. 103 at para. 95, [1993] 2 F.C. 425; *Merck & Co. v. Apotex Inc.*, [2003] F.C.J. No. 1725 (QL) at para. 9 (F.C.A.), (2003), 28 C.P.R. (4th) 491. Moreover, with respect to factual findings coming within the arena of its jurisdiction, the Prothonotary, who has been acting in this proceeding as the case manager for quite a number of years, should be entitled to an "additional level of deference" (while same does not isolate him or her from review where an error of principle has been made): *Sawridge Band v. Canada (C.A.)*, [2002] 2 F.C. 346 at para. 11 (F.C.A.), [2001] F.C.J. No. 1684; *Merck & Co. v. Apotex Inc.*, (2003), 28 C.P.R. (4th) 491, [2003] F.C.J. No. 1725 (QL); *Novopharm Limited v. Eli Lilly Canada Inc. et al.*, 2008 FCA 287, at paras. 54 and 55.

[4] General principles applicable to Apotex's motion to amend are not in controversy in the herein appeal. An amendment to a pleading may be allowed at any stage of an action for the purpose of determining the real questions in controversy between the parties, provided that an allowance will not result in an injustice to the other party (not capable of being compensated by an award of costs) and that it will serve the interests of justice: *Visx Inc. v. Nidek Co.*, (1998), 234 N.R. 94, [1998] F.C.J. No. 1766 (QL) (*Visx*); *Canderel Ltd. v. Canada*, [1993] F.C.J. No. 777 (QL) at para. 10 (F.C.A.), [1994] 1 F.C. 3; *Merck & Co. v. Apotex Inc.*, [2003] F.C.J. No. 1925 (QL)(F.C.A.) at para. 30, [2004] 2 F.C.R. 45. Counsel also agree that the test which governs a motion to strike a pleading should also be applied on a motion for leave to amend a pleading. Therefore, if an amendment could be struck out for showing no reasonable cause of action or

defence (or if it is scandalous, frivolous or vexatious), it should not be allowed in whatever circumstances: *Visx Inc. Nidex Co.*, [1996] F.C. J. No. 1721 at para.16, (1996), 72 C.P.R. (3d) 19; *Merck & Co. v. Apotex Inc.*, *above*, at paras. 29 and 35 to 37 (F.C.A.).

[5] There was certainly no error of principle made in this case by the Prothonotary who considered and applied the general principles above, and ultimately denied the proposed amendments on the ground that they were “scandalous and vexatious”. This leaves the question whether such finding was based on a misapprehension of the facts amounting to a “misuse of judicial discretion” (since the Prothonotary was acting as the case manager), or whether the impugned order was based on some error of law. However, the appeal does not turn on these points since I must first ask myself whether the proposed amendments were “vital amendments” as opposed to “routine amendments”. If the proposed amendments were vital in themselves, a *de novo* review of the decision of the Prothonotary will be warranted in any case: *Merck & Co. v. Apotex Inc.*, *above* at paras. 18, 24 and 28 (F.C.A.); *Canada v. Aqua-Gem Investment Ltd.* (C..A.), *above*.

[6] There is a long list of decisions which support the conclusion that amendments that advance additional causes of action or defence are likely to be “vital”: *Merck & Co. v. Apotex Inc.*, *above* at paras. 25 and 28; *Trevor Nicholas Construction Co. v. Canada (Minister for Public Works)*, [2003] F.C.J. No. 357 at para. 7, 2003 FCT 255; *Louis Bull Band v. Canada*, [2003] F.C.J. No. 961 at para. 20, 2003 FCT 732. This case is no exception and as such, I find that the proposed amendments are vital to the final issue of the case, as I accept Apotex’s proposition and reasoning in this regard.

[7] Again, let me summarize what is the object of the proposed amendments which raise new and additional grounds of defence and/or counterclaim in relation to the Plaintiffs' entitlement to damages. First, Apotex seeks to plead that the Plaintiffs should not be entitled to damages from Apotex for lost sales of Serzone because, had the Plaintiffs made those sales, instead of Apotex, they would have exposed consumers taking their product to serious health-related side effects (that they knew about or ought to have known about through pre-marketing studies of their product). Second, Apotex seeks to set-off the damages the Plaintiffs seek against the losses incurred by Apotex for investments made in developing a generic formulation of Plaintiffs' nefazodone product.

[8] Having reviewed the matter *de novo*, the present appeal must fail. I am not satisfied that the proposed amendments are in the interests of justice and that they can be made without injustice to the other side. Moreover, the proposed amendments would not withstand a motion to strike. It is plain and obvious that the proposed amendments fail to disclose a reasonable cause of defence or counterclaim in the context of the present patent infringement proceeding. I would also add that their characterization by the Prothonotary as being "scandalous and vexatious" reflects my own assessment of the situation.

[9] The real issues in controversy in this proceeding are those of patent infringement and validity. They exclusively concern the patent in issue and any related conduct by the parties. A person who infringes a patent is liable to the patentee and to all persons claiming under the patentee for all damage sustained by the patentee or by any such person, after the grant of the patent, by reason of the infringement: subsection 55(1) of the *Patent Act*, R.S.C. 1985, c. P-4 (the Act). In turn,

the defendant may plead any fact or default which by the Act or by law renders the patent void, and the court shall take cognizance of that pleading and of the relevant facts and decide accordingly: section 59 of the Act. Moreover, a patent or any claim in a patent may be declared invalid or void by the Federal Court at the instance of the Attorney General of Canada or at the instance of any interested person: subsection 60 (1) of the Act.

[10] As such, I find that the proposed amendments are too remote and do not have a sufficient relationship with the real questions in controversy in this action. In coming to this conclusion, I have considered the parties respective pleadings in the action, including the existing allegations of inutility and the existing allegations regarding the availability of relief or the computation of damages. There is a clear difference between allowing amendments to clarify the issues in dispute and those that permit a distinct defence or counterclaim to be raised for the first time. The proposed amendments clearly fall in the latter category.

[11] In Apotex's own admission, the common law doctrine of *ex turpi causa* operates as a distinct defence to frustrate what would otherwise be a complete cause of action. The Court will use the doctrine on rare occasions where allowing recovery would undermine the integrity of the legal system. The doctrine can be invoked where a defendant is first found responsible but responsibility is suspended because concern for the integrity of the legal system overrides a concern that the defendant be responsible. Apotex has not convinced me that it has any reasonable chance of convincing the judge on merit that this doctrine can apply in the present patent infringement action. Assuming for the purpose of the present motion that there was

immoral conduct on the part of the Plaintiffs as alleged by Apotex, it is plain and obvious that the proposed amendments cannot sustain a motion to strike.

[12] Based on common law principles, Apotex's proposed amendments purport to claim that, as a result of an illegal or immoral conduct and/or the existence of some unclear duty owed to Apotex (all allegations which are of the outmost vagueness at this time), the Plaintiffs should be denied any equitable relief and/or there should be a set-off of damages (corresponding to the amount of investment made by Apotex in developing a generic formulation of Serzone). Assuming that the new pleas Apotex wishes to put forward at this late date have their root in "equity", the alleged improper conduct by the Plaintiffs and/or duty allegedly owed to Apotex should relate directly to the subject matter of the party's claim and/or the equitable relief sought. Clearly, this is not the case in this instance.

[13] The issue is whether, and in what circumstances, improper conduct on the part of a claimant of equitable relief will be a sufficient basis upon which a court can deny the request. Subsection 57 (1) of the Act empowers the court or any judge thereof, on the application of the plaintiff or defendant, to make certain orders "as the court or judge sees fit". Assuredly, this would cover equitable relief in the form of an injunction restraining the alleged infringement by Apotex and an accounting of profits in respect of the alleged infringing activities. However, this would not cover damages claimed from Apotex for loss of sales incurred by the plaintiffs as a result of the alleged infringing activities of Apotex (subsection 55 (1) of the Act). That said, in the context of a patent infringement action, it is required that the alleged improper conduct "cast a shadow" on the

patent rights themselves or on the question of whether infringement has occurred: *Sanofi-Aventis Canada Inc. v. Apotex Inc.*, [2008] F.C.J. No. 743 at paras. 16 to 18 (F.C.A.), 2008 FCA 175. In the present case, there is simply no such relationship that would justify the allowance of the proposed amendments.

[14] For the proposed amendments to have any practical effect, this Court would have to undertake a full examination of whether, in fact, liability was first engaged. The alleged immoral or illegal conduct would have to be proven by Apotex before any adverse conclusion against the Plaintiffs may be reached. This goes far beyond determining whether the patent in issue lacks utility for any of the grounds recited in paragraphs 20 to 22 of Apotex's existing Statement of Defence and Counterclaim. Furthermore, the alleged existence of some additional duty of care owed to Apotex and the extent to which same would permit Apotex to recover its own investment in developing and marketing a generic version of nefazodone are extrinsic and distinct matters which can only be decided upon finding that the Plaintiffs were somewhat negligent or careless in not ensuring that their nefazodone product was safe for human consumption. As submitted by the Plaintiffs, Apotex has framed its Defence and Counterclaim for set-off as what amounts to be a disguised tort claim. I agree. Since the Federal Court has no inherent jurisdiction and no explicit conferral of jurisdiction has been granted to the Federal Court between subjects in respect of tort or product liability type of claims, it follows that the proposed amendments could likely be struck out summarily as constituting improper pleadings.

[15] Moreover, by its motion to amend, it appears that Apotex is indirectly seeking to have this Court find the Plaintiffs responsible of some illegal or immoral conduct without pleading the material facts during the damages calculation phase of the trial. This is clearly improper and prejudicial to the other side. While Apotex would not seek further discovery in respect of proposed amendments in the liability phase of the action, it seeks to nevertheless open a second front should the Court find that there has been infringement activity and the patent in issue is valid. That said, the new edifice elevated by Apotex rests on shaky and untenable foundations, as the allegations and arguments advanced by Apotex do not even resist a minimum level of examination by the Court.

[16] In addition, it appears that Apotex could have presented its motion to amend long ago. Apotex has been aware of the voluntary discontinuance of Serzone since at least November 10, 2003 when the Health Canada Advisory was issued. Sometime later, Apotex removed its own product from the market. Furthermore, Apotex has been aware of class action litigation relating to the drug nefazodone since at least November 21, 2003 as Apotex is a named Defendant to those proceedings. Despite the long discovery process and related appeals with respect to same, the reasons invoked by Apotex in its motion material for not bringing its motion to amend earlier are not convincing. For instance, I note that there has been no admission of liability by the Plaintiffs in the settlement of the class action and the Defendant is not part of the settlement reached on November 15, 2007. Apotex's suggestion that such settlement would now establish some legal foundation for it to claim set-off, is absurd. I entirely agree with the Plaintiffs that Apotex is simply attempting to conjure "new" facts to support its delay in bringing the proposed amendments

forward. In this regard, I find that the proposed amendments are scandalous, frivolous and vexatious.

[17] In conclusion, granting of the proposed amendments would not be in the interests of justice. Moreover, they cannot be made without injustice to the other side. Indeed, their allowance at this late date would only serve to complicate the trial of this action by an unwarranted addition of extraneous matters which can have no practical effect on the litigation at hand or that are simply not justiciable by this Court. In the exercise of my discretion *de novo*, I therefore dismiss the present appeal. Costs should be awarded to the Plaintiffs in any event of the cause as was granted by the Court below.

ORDER

THIS COURT ORDERS that the present motion in appeal be dismissed with costs payable to the Plaintiffs in any event of the cause.

“Luc Martineau”

Judge

FEDERAL COURT
SOLICITORS OF RECORD

DOCKET: T-2078-00

STYLE OF CAUSE: BRISTOL MYERS SQUIBB CO. ET AL v. APOTEX
INC.

PLACE OF HEARING: OTTAWA, ONTARIO

DATE OF HEARING: October 16, 2008

**REASONS FOR ORDER
AND ORDER:** MARTINEAU J.

DATED: October 24, 2008

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