

Federal Court
of Appeal



Cour d'appel
fédérale

Date: 20110414

Docket: A-439-10

Citation: 2011 FCA 134

**CORAM: EVANS J.A.
DAWSON J.A.
STRATAS J.A.**

BETWEEN:

**APOTEX INC., and
APOTEX PHARMACHEM INC.**

**Appellants
(Defendants)**

and

**ALLERGAN, INC. and
ALLERGAN SALES, LLC. and
ALLERGAN USA, INC. and
KYORIN PHARMACEUTICAL CO., LTD**

**Respondents
(Plaintiffs)**

Heard at Toronto, Ontario, on April 12, 2011.

Judgment delivered at Ottawa, Ontario, on April 14, 2011.

REASONS FOR JUDGMENT BY:

DAWSON J.A.

CONCURRED IN BY:

**EVANS J.A.
STRATAS J.A.**

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REASONS FOR JUDGMENT

DAWSON J.A.

[1] The appellants (together Apotex) appeal from an interlocutory order of a judge of the Federal Court which dismissed a motion brought by Apotex for an order striking out the statement of claim filed by the respondents to this appeal. On this appeal, Apotex submits that the Judge of the Federal Court erred when he declined to strike out the pleading as disclosing no cause of action, because the statement of claim improperly consisted of bald or speculative pleas of patent

infringement and because the plea regarding its intended future actions falls short of the required standard when pleading a *quia timet* action.

[2] As the Judge recognized in his order, the test to be applied when considering whether a pleading should be struck is a stringent one. A defendant must establish that it is plain and obvious and beyond doubt that the claim cannot succeed (*Hunt v. Carey Canada Inc.*, [1990] 2 S.C.R. 959 at page 980). The pleading is to be read as generously as possible (*Operation Dismantle Inc. v. Canada*, [1985] 1 S.C.R. 441 at paragraph 14). On a motion to strike, the facts alleged in a pleading should generally be assumed to be true (*Hunt* at page 980). Where, as in this case, the motion to strike is based upon the ground that the pleading discloses no cause of action, no evidence should be received (Rule 221(2) of the *Federal Courts Rules*).

[3] On an appeal from an order disposing of a motion to strike a pleading, some deference is owed to the underlying decision. In *Apotex Inc. v. Canada (Governor in Council)*, 2007 FCA 374, 370 N.R. 336, at paragraph 15, this Court described the test to be applied in the following terms:

The respondents correctly point out that the decision to grant or refuse a motion to strike is a discretionary one. When the lower court judge has made a discretionary decision, it will usually be afforded deference by the appellate court. However, the latter will be entitled to substitute the lower court judge's discretion for its own if the appellate court clearly determines that the lower court judge has given insufficient weight to relevant factors or proceeded on a wrong principle of law: *Elders Grain Co. v. Ralph Misener (The)*, [2005] F.C.J. No. 612, 2005 FCA 139 at paragraph 13. This Court may also overturn a discretionary decision of a lower court where it is satisfied that the judge has seriously misapprehended the facts, or where an obvious injustice would otherwise result: *Mayne Pharma (Canada) Inc. v. Aventis Pharma Inc.*, [2005] F.C.J. No. 215, 2005 FCA 50, 38 C.P.R. (4th) 1 at paragraph 9. [emphasis added]

[4] Turning to the arguments advanced by Apotex, I agree that the mere fact that a defendant pharmaceutical company has sought regulatory approval to market a medicine does not by itself support an action for patent infringement. I also agree that an allegation of past infringement made without any evidentiary foundation is an abuse of process. See *AstraZeneca Canada Inc. v. Novopharm Ltd.*, 2010 FCA 112, 402 N.R. 95 at paragraph 5. In every case, what is required is careful attention to the precise pleading before the Court.

[5] In the present case the statement of claim, read with the additional particulars volunteered by the plaintiffs, alleges that Apotex has infringed, is infringing and will continue to infringe Canadian Patent 1,340,316 (a patent that covers the compound gatifloxacin). It is alleged that since 2007 one or other of the appellants has infringed the relevant patent by actions which include the following:

- Purchasing and importing bulk gatifloxacin for both commercial and regulatory purposes.
- Stockpiling bulk gatifloxacin for both commercial and regulatory purposes.
- Formulating bulk gatifloxacin into gatifloxacin ophthalmic solution, 0.3% for both commercial and regulatory purposes.

[6] It is further alleged that the appellants have infringed the relevant patent by:

- Formulating, processing, manufacturing and sterilizing 100 litre and 1000 litre batches of gatifloxacin ophthalmic solution, 0.3%.

- Manufacturing, using, storing and packaging gatifloxacin ophthalmic solution, 0.3% in 5 mL fill bottles containing caps and droppers for commercial sale.
- Stockpiling in Canada for commercial purposes gatifloxacin ophthalmic solution, 0.3% in 5 mL fill bottles for commercial sale to the United States.
- Preparing and affixing labels to gatifloxacin ophthalmic solution, 0.3% 5 mL fill bottles for commercial sale to the United States.
- Selling and intending to sell gatifloxacin ophthalmic solution, 0.3% to Apotex Corp. for commercial purposes.
- Offering, with Apotex Corp., to sell gatifloxacin ophthalmic solution, 0.3% to customers in the United States in October or November 2010.

[7] The statement of claim also alleges that an abbreviated new drug application filed by Apotex with the United States Food and Drug Administration indicates that Apotex has made and used gatifloxacin ophthalmic solution at its Richmond Hill manufacturing site and that it has, and intends to have, gatifloxacin manufactured in India by Apotex Pharmachem India Pvt. Ltd.

[8] The Judge concluded that the pleading alleged sufficient material facts by which Apotex is alleged to have infringed the relevant patent. In my view this conclusion was reasonably open to the Judge on this pleading. The statement of claim was, in my view, saved by the additional particulars which go beyond pleading generalities and conclusions of infringement. Apotex has not demonstrated that the Judge proceeded on a wrong principle of law or otherwise erred in a manner that would warrant this Court's intervention.

[9] Apotex also argues that, even if the allegations are true, its conduct is protected by the common law “experimentation use” exception to infringement and by subsections 55.2(1) and (6) of the *Patent Act*, R.S.C. 1985, c. P-4. However, the existence of even a strong defence to a claim does not justify an order striking the claim (*Hunt*, cited above, at page 980).

[10] In so concluding I have considered the argument of Apotex that the Judge failed to appreciate that the only paragraphs of the statement of claim pleading facts relating to infringement are the paragraphs that allege facts that “plainly fall within the well accepted ‘experimental use’ exception to infringement.” I have also considered its reliance upon *Eli Lilly Canada Inc. v. Nu-Pharm*, 2011 FC 255.

[11] With respect to the “experimental use” exception and section 55.2 of the *Patent Act*, when read with the particulars the statement of claim alleges facts that fall well beyond the scope of experimental or regulatory activity. Those allegations include allegations that Apotex has stockpiled bulk gatifloxacin for both commercial and regulatory purposes, stockpiled gatifloxacin ophthalmic solution, 0.3% for commercial purposes and both sold and, with Apotex Corp., offered to sell to customers gatifloxacin ophthalmic solution, 0.3% in October or November 2010.

[12] In the *Eli Lilly* decision relied upon by Apotex, the Federal Court struck the statement of claim. Apotex argues that the allegations considered by the Federal Court in *Eli Lilly* are indistinguishable from those in the claim in issue. On the facts before it, the Federal Court did not find it necessary to require Nu-Pharm to “put forward s. 55.2(1) as a defence in a properly-filed

Statement of Defence.” See paragraph 29 of the reasons. However, in *Eli Lilly* the Federal Court also found, at paragraph 28, that:

In the Statement of Claim before me, there is absolutely nothing pleaded that is not part of the regulatory requirements for the preparation and filing of an ANDS. Without something pleaded beyond the regulatory requirements, s. 52.2(1) [sic] of the Patent Act applies. Moreover, we have the clear, sworn statements of Mr. Benyak that Nu-Pharm has not done (or caused to be done) anything other than meet the requirements of the applicable regulatory scheme. The attempts of the Plaintiffs to characterize the actions of Nu-Pharm (or an unidentified third party) as something beyond meeting regulatory requirements are speculative, at best. [emphasis added]

[13] This case is distinguishable from the present case because the statement of claim now before the Court alleges facts, which must be presumed to be true for the purpose of this motion, that fall beyond the scope of regulatory activity. *Eli Lilly* is also distinguishable because there is no evidence before the Court similar to the Benyak evidence that was before the Federal Court in *Eli Lilly*.

[14] Finally, Apotex argues that the allegations with respect to its future intent fall short of meeting the required standard for pleading a *quia timet* action. Again, I agree that a *quia timet* action must be based on more than mere possibilities (*AstraZeneca* cited above at paragraphs 6 and 7). However, I respectfully reject the characterization of the pleading at issue as a *quia timet* action. As Justice Hughes observed at paragraph 19 of his reasons in *AstraZeneca Canada Inc. v. Novopharm Ltd.*, 2009 FC 1209, 359 F.T.R. 279, aff’d 2010 FCA 112, “[a]n action taken on the basis of anticipation has been called a *quia timet* (because one fears) action.” In the present case, the impugned pleading is not based merely upon the fear of future infringement. The claims of past and continuing infringement support the claim of future continuing infringement.

[15] For these reasons, I would dismiss the appeal with costs.

“Eleanor R. Dawson”

J.A.

“I agree

John M. Evans J.A.”

“I agree

David Stratas J.A.”

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKET: A-439-10

STYLE OF CAUSE: APOTEX INC., and APOTEX PHARMACHEM
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PLACE OF HEARING: Toronto, Ontario

DATE OF HEARING: April 12, 2011

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CONCURRED IN BY: EVANS J.A.
STRATAS J.A.

DATED: April 14, 2011

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