

Date: 20070627

Docket: T-2146-03

Citation: 2007 FC 683

Ottawa, Ontario, June 27, 2007

PRESENT: The Honourable Mr. Justice Harrington

BETWEEN:

APOTEX INC.

Plaintiff

and

AKTIEBOLAGET HÄSSLE

Defendant

REASONS FOR ORDER AND ORDER

[1] In the impeachment action underlying this motion, Apotex seeks a declaration that AB Hässle's Canadian Patent No. 1,264,751 "...is invalid, void and of no force and effect." The reason for its interest is that had it not been for this patent, and another, it would have been able to market one of its medicines earlier. It eventually hopes to recover damages under the *Patented Medicines (Notice of Compliance) Regulations*.

[2] Following the patent's expiry this past January, AB Hässle moved to have the action dismissed because "now that the '751 patent has expired the Impeachment Action is moot and Apotex lacks standing." Madam Prothonotary Tabib dismissed the motion. She said it was not

“plain and obvious” that a judgment in the action would have no legal effect or consequences on the parties. It followed that the action had not become moot and that Apotex had not lost standing.

[3] This is the appeal of Madam Prothonotary Tabib’s order.

THE STANDARD IN APPEAL

[4] AB Hässle’s motion relates to, but is not limited to, Rule 221 of the *Federal Courts Rules* under which the Court may (emphasis added) strike out a pleading and dismiss an action if, among other things, it:

(a) discloses no reasonable cause of action or defence, as the case may be,

(b) is immaterial or redundant,

(c) is scandalous, frivolous or vexatious,

[...]

(f) is otherwise an abuse of the process of the Court,

[5] Quite apart from Rule 221, the Court has inherent power to control its own process and so in any event may dismiss pointless litigation.

[6] Rule 51 provides that an order of a Prothonotary may be appealed by motion to a judge of the Federal Court. Prothonotaries’ orders may be based on points of law, findings of fact, or may be discretionary. To the extent points of law are involved, the standard in appeal is correctness. To the extent an order is discretionary, it must be reviewed *de novo* if the questions raised in the motion are

vital to the final outcome, or if the decision is based upon a wrong principle of law or upon a misapprehension of the facts (*Merck & Co., Inc. v. Apotex Inc. (F.C.A.)*, [2004] 2 F.C.R. 459).

[7] The question is not whether the actual decision was vital to the outcome of the case but, rather whether it could have been. Had Madam Prothonotary Tabib granted the motion, the action would have been dismissed. That decision would clearly be vital. As it turns out, she dismissed the motion, and the action continues. However, since the motion called upon her to dismiss the action, it was vital, and so, if there is discretion to exercise it must be exercised *de novo*.

[8] This point was driven home by Mr. Justice Décarý in *Winnipeg Enterprises Corporation v. Fieldturf (IP) Inc.*, 2007 FCA 95, [2007] F.C.J. No. 334 (QL) where he said at paragraph 6:

Contrary to the Judge's findings, a decision made on a status review is vital to the final issue of the case because the prothonotary may have ended up dismissing the action for delay (see Rule 382(2)(c)). As stated in *Canada v. Aqua-Gem Investments Ltd. (C.A.)*, [1993] 2 F.C. 425 (C.A.) at paragraph 98 (QL), a decision which can be either interlocutory or final depending on how it is decided, even if interlocutory because of the result, must nevertheless be considered vital to the final resolution of the case.

BACKGROUND

[9] Canadian patent '751, which was issued to the defendant in January 1990, claims novel salts of the compound omeprazole. Omeprazole is useful as a gastric acid secretion inhibiting agent.

[10] It was listed by AstraZeneca Canada Inc., with AB Hässle's consent, on the list maintained by the Minister of Health pursuant to the Regulations. Apotex wants to market its generic version of

omeprazole. Presumably, the Minister has determined that its product is bioequivalent to AstraZeneca's. However, since the '751 patent and others were listed against omeprazole, the Regulations prohibit him from issuing a notice of compliance until the patents expire, unless in the meantime Apotex successfully takes the measures contemplated therein.

[11] In September 2001, Apotex delivered a notice of allegation that the '751 patent was invalid. AstraZeneca and AB Hässle responded by applying to this Court under docket number T-1914-01 for an order prohibiting the Minister from issuing an NOC until the patent expired. By order, with accompanying reasons, Mr. Justice Campbell granted the application and issued a prohibition order in June 2003 (2003 FCT 771).

[12] His order was maintained in appeal in November 2004 (2004 FCA 369). Chief Justice Richard held that Mr. Justice Campbell made no reviewable error when he concluded on the balance of probabilities that the patent was not invalid. An application for leave to appeal to the Supreme Court was dismissed ([2005] S.C.C.A. No. 15 (QL)).

[13] This particular action was instituted in November 2003 and has been set down for a ten-day trial commencing in February 2009.

[14] AB Hässle owns another listed Canadian patent: 1,292,693 (the '693 patent), which also relates to omeprazole. It expires in December 2008. That patent was the subject of two other notices of allegation from Apotex. AB Hässle and AstraZeneca responded by applying to this Court

for prohibition orders against the Minister. They succeeded on all counts. In September 2002, Mr. Justice Kelen issued a prohibition order (2002 FCT 931), as did Madam Justice Layden-Stevenson (2005 FC 234). Both decisions were upheld by the Federal Court of Appeal. In one, Apotex unsuccessfully sought leave to appeal to the Supreme Court; in the other it did not.

ANALYSIS

[15] Notwithstanding that the Court's right to dismiss an action on the grounds that it is moot is not limited to the circumstances set out in Rule 221, that rule serves as a useful guide. As Prothonotary Hargrave put it in *British Columbia Native Women's Society v. Canada*, [2000] F.C.J. No. 588 (QL) at paragraph 6:

A proceeding may be struck out for mootness: see for example *Taylor v. A.G.C.*, [1990] F.C.J. No. 459, a 25 May 1990 decision of Mr. Justice Dubé in action T-818-90, in which the defendants successfully struck out a moot action, alleging it was, among other things, redundant, vexatious and an abuse, under what was then Rule 419 and is now Rule 221. Such a moot claim will plainly and obviously not succeed, in the sense that it will not produce a practical result, for there is no controversy to support the claim and thus it ought, subject to certain exceptions, to be struck out.

[16] Simply so as to put the point aside, I mention that notwithstanding the decision of Mr. Justice Campbell which was upheld by the Federal Court of Appeal, it could not be said (and AB Hässle does not say) that when the statement of claim was first filed there were grounds upon which the action could be peremptorily dismissed.

[17] It is well settled that the purpose of an application under the Regulations is to prohibit the Minister from issuing a notice of compliance until the patent, or patents, in question have expired.

In reaching its decision, the Court may have to determine, on the record before it, whether the generic drug manufacturer's allegations that the patent is not valid, or will not be infringed, are justified. However, the application is not an action seeking a declaration that the patent is valid and will be infringed.

[18] These applications, which in theory are summary in nature, do not even prevent the immediate parties thereto from taking a patent action. A very recent decision on point is that of the Federal Court of Appeal in *Sanofi-Aventis Canada Inc. v. Novopharm Ltd.*, 2007 FCA 163, [2007] F.C.J. No. 548 (QL). In a trial, on the other hand, there is a proper discovery of documents, examination for discovery, and the witnesses appear live before the Court, rather than in affidavit form. The judge has the opportunity of clarifying issues which are incomprehensible to those who do not have a background in the art or science in question. Mr. Justice Hughes pointed out some of the shortcomings of the system in *Eli Lilly Canada Inc. v. Novopharm Ltd.*, 2007 FC 596, [2007] F.C.J. No. 800 (QL) at paragraph 45ff.

[19] Thus, it cannot be said that *res judicata*, issue estoppel or abuse of process applied to the action when instituted.

a. Mootness

[20] Had Apotex obtained judgment before the '751 patent expired, the prohibition order would no longer have been applicable and it would have been able to market its version of omeprazole earlier. AB Hässle argues that that was the only point to the action. The patent having expired, the

prohibition order has lapsed and it follows that Apotex has no standing to set aside an ineffective order. If the action was only forward looking, I would agree. However, section 62 of the *Patent Act* provides:

62. A certificate of a judgment voiding in whole or in part any patent shall, at the request of any person filing it to make it a record in the Patent Office, be registered in the Patent Office, and the patent, or such part as is voided, **shall thereupon be and be held to have been** void and of no effect, unless the judgment is reversed on appeal as provided in section 63.

62. Le certificat d'un jugement annulant totalement ou partiellement un brevet est, à la requête de quiconque en fait la production pour que ce certificat soit déposé au Bureau des brevets, enregistré à ce bureau. Le brevet ou telle partie du brevet qui a été ainsi annulé **devient alors nul et de nul effet et est tenu pour tel**, à moins que le jugement ne soit infirmé en appel en vertu de l'article 63.

[Emphasis added]

[21] In its statement of claim, Apotex recites the then current status of AB Hässle's application for a prohibition order. At the time, Mr. Justice Campbell's decision was under appeal. To my way of thinking, that was a sufficient statement of a material fact so as not to deprive Apotex of standing, or to make the action moot, even though the patent has expired. One must allege material facts; one need not allege the law (*Federal Courts Rules*, Rules 174 and 175).

[22] That allegation allows Apotex to submit that if it succeeds in the impeachment action, the prohibition order of Mr. Justice Campbell falls, and it is entitled to damages running from the time it would have otherwise been on the market with its version of omeprazole. It may be that no damages flow, because Apotex also has to succeed in its parallel impeachment action against the '693 patent. However, it is not for the Court at this stage to assess the case in a positive manner and to consider

the chances of success. Rather, the Court has to look at the case negatively, asking whether it is “plain and obvious” or “beyond reasonable doubt” that the case will not succeed.

[23] The leading case on mootness is *Borowski v. Canada (Attorney General)*, [1989] 1 S.C.R. 342. The doctrine of mootness derives from the general policy that the Court may decline to decide a case which is based on hypothetical or abstract questions. A decision is moot if it will not have the effect of resolving some controversy affecting or potentially affecting the rights of the parties. That live controversy must not only be present when the action was instituted, but also at the time of judgment. There is a two-step approach to mootness. The first is to determine whether the requisite tangible and concrete dispute has disappeared. If so, then and only then may the Court in its discretion decide to nevertheless hear the case.

[24] *Borowski*, above, must be read in conjunction with *Hunt v. Carey Canada Inc.*, [1990] 2 S.C.R. 959, which deals with motions to strike pleadings for failure to disclose a reasonable cause of action. The test as set out at page 980 is whether the outcome of the case is “plain and obvious” or “beyond reasonable doubt”.

[25] It is not “plain and obvious” to me that the case has become moot. It is therefore not necessary for me to exercise any discretion in allowing the case to continue. The case must continue. AB Hässle relies on section 8(1) of the Regulations, which provides that if an application for a prohibition order “...is 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...” Its successful application for a prohibition order was never withdrawn, discontinued, dismissed or reversed. Therefore, there is no legal basis for Apotex’s claim for damages.

[26] As far as the parties are aware, this is the first time a motion has been brought to dismiss an impeachment action because the underlying patent has expired. However, they have brought to the Court’s attention a number of authorities they consider helpful.

[27] On the one hand, Apotex relies upon the decisions of Madam Justice Reed in *Hoffman-La Roche Ltd. v. Canada (Minister of National Health and Welfare)*, [1999] 167 F.T.R. 111, Mr. Justice Blais in *Apotex Inc. v. Syntex Pharmaceuticals International Ltd.* (2001), 16 C.P.R. (4th) 473, aff’d 2002 FCA 222, [2002] F.C.J. No. 800 (QL) and Madam Justice Sharlow in *Apotex Inc. v. AB Hassle*, 2006 FCA 51, 47 C.P.R.(4th) 329.

[28] AB Hässle urges upon me the decision of Mr. Justice Marc Noël in *Sanofi-Aventis Canada Inc. v. Apotex Inc.*, 2006 FCA 328.

[29] To first deal with the decision of Mr. Justice Noël in *Sanofi-Aventis*, although the Court held that the appeal became moot as a result of the expiration of the patent in issue, the appeal was from an order dismissing an application for a prohibition order. That was the only point of the application. The fact that the patent had been listed on the register kept by the Minister could no longer serve to prevent him from issuing a notice of compliance. This case is quite different. It is an

impeachment action, one of the very remedies contemplated by the Federal Court of Appeal for unsuccessful parties in NOC proceedings.

[30] The decision of Madam Justice Reed in *Hoffman-La Roche*, above, arises from peculiar facts. Following the issuance of a prohibition order against the Minister, the patent in question was declared invalid in an impeachment action. Armed with that decision, Apotex, which had been denied a notice of compliance, then sought an order to set aside the prohibition order either pursuant to Rule 399(2) on the grounds that a new matter had arisen or pursuant to the Court's inherent jurisdiction to vary an order when circumstances change. It also sought an order dismissing Hoffman-La Roche's initial application for a prohibition order.

[31] In the circumstances, Madam Justice Reed said she need not decide whether Rule 399(2) was applicable, as she was persuaded that the Court had continuing jurisdiction over the prohibition order. The Minister had been somewhat reluctant to issue a notice of compliance in light of that prohibition. Madam Justice Reed noted that the declaration granted in the impeachment action was that the patent was "invalid, void and of no force and effect". In her view, as in mine, this allowed the Minister to treat the patent as a nullity and to proceed as though it had never been listed. Put another way, it could also be said that the patent expired early.

[32] AB Hässle argues that although in the formal order Madam Justice Reed "dismissed" the application, that word is inconsistent with her reasons in which she actually "set aside" the prohibition order. An order which is set aside is not one that has been withdrawn, discontinued,

dismissed or reversed, and so will not serve as the basis of an action for damages under the Regulations.

[33] I am not persuaded that that is so. In *Hunt v. Carey*, above, Madam Justice Wilson extensively surveyed the jurisprudence pertaining to the disclosure of a reasonable cause of action. She noted at page 972: “Complex matters that disclosed substantive questions of law were most appropriately addressed at trial where evidence concerning the facts could be led and where arguments about the merits of the plaintiff’s case could be made.” The points of law in issue are not as clear cut as sometimes arises, such as when the dispute concerns the Court’s jurisdiction over the subject matter of the action.

[34] To that end, I refer to the decision of Mr. Justice Blais in *Apotex v. Syntex*, above, which dealt with a motion to set aside an order of a prothonotary striking a claim under section 8 of the Regulations. Relying on the decision of Mr. Justice Blanchard in *Apotex Inc. v. Eli Lilly and Co.*, 2001 FCT 636, 13 C.P.R. (4th) 78, Mr. Justice Blais was of the view that contentious legal issues of statutory interpretation should not be dealt with on a motion to strike. His observation that there was not at that time a clear understanding of what section 8 of the Regulations really means is just as true today. In appeal, Mr. Justice Sexton, speaking for the Court, and following *Hunt v. Carey*, above, held that it was not plain and obvious the plaintiff’s claim was certain to fail.

[35] Another case I consider most instructive is the decision of Madam Justice Sharlow, speaking for the Federal Court of Appeal, in *Apotex v. AB Hassle*, above. That was an appeal by Apotex from

the issuance of a prohibition order with respect to the '693 patent, the other currently relevant patent relating to omeprazole. It was Apotex's second unsuccessful attempt to obtain an NOC. The Motions Judge found against Apotex on the grounds of issue estoppel or abuse of process. The Federal Court of Appeal declined to intervene.

[36] However at paragraphs 28 and 29, Madam Justice Sharlow contemplated exactly what Apotex is doing in this case. She referred to the well established doctrine that proceedings under the Regulations are not conclusive for all purposes of validity and infringement and that it was open for Apotex to bring an action under section 60 of the *Patent Act* to impeach the patent. She said at paragraph 29:

...If such an action were to result in a declaration that the 693 patent is invalid, then either the prohibition order in *AB Hassle 2003* would cease to have any effect, or the prohibition order could be set aside under Rule 397 of the *Federal Courts Rules*, SOR/98-106: see *Hoffmann-La Roche Ltd. v. Canada (Minister of National Health and Welfare)* (1999), 167 F.T.R. 111 (F.C.T.D.) (paragraphs 14 to 16).

[37] I imagine the reference to Rule 397 is a reference to Rule 397 and following, more particularly Rule 399. AB Hässle points out that Madam Justice Sharlow's comments are *obiter*. That may be so, but it is not "plain and obvious" to me that she would not use them when required, for instance in an appeal of the order accompanying these reasons. Words deliberately spoken, that need not be spoken, can be very enlightening to a lower court.

[38] Having considered the law, and whether an exercise of discretion would be justified, to borrow the words of Madam Prothonotary Tabib:

...I cannot conclude that it is plain and obvious that a determination of this proceeding can have no legal effect or consequences on the parties and it therefore is moot. For the same reason, I also find that it is not plain and obvious that Apotex no longer has standing to pursue this action.

ORDER

THIS COURT ORDERS that Aktiebolaget Hässle's motion in appeal from the order of Madam Prothonotary Tabib dated 30 March 2007 is dismissed with costs.

“Sean Harrington”

Judge

FEDERAL COURT
SOLICITORS OF RECORD

DOCKET: T-2146-03

STYLE OF CAUSE: *Apotex Inc. v. Aktiebolaget Hässle*

PLACE OF HEARING: Ottawa, Ontario

DATE OF HEARING: June 21, 2007

REASONS FOR ORDER: HARRINGTON J.

DATED: June 27, 2007

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