

CANADA / JUDGMENT

Apotex Inc. v. Canada Inc.

2004 FC 1220

COURT

Federal Court

DECIDED

7 September 2004

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Apotex Inc. v. Canada Inc. Court (s) Database Federal Court Decisions Date 2004-09-07 Neutral citation 2004 FC 1220 File numbers T-485-02 Decision Content Date: 20040907 Docket: T-485-02 Citation: 2004 FC 1220 Ottawa, Ontario, this 7th day of September, 2004 Present: The Honourable Mr. Justice von Finckenstein BETWEEN: APOTEX INC. Plaintiff and HER MAJESTY THE QUEEN, BRISTOL-MYERS SQUIBB CANADA INC. and BRISTOL-MYERS SQUIBB COMPANY Defendants REASONS FOR ORDER AND ORDER (Delivered orally from the bench and subsequently written for precision and clarification)

- [1] This is a motion to brought by Apotex Inc (Apotex) set aside certain parts of the Order of Prothonotary Tabib dated June 4th, 2004, wherein she ordered Ms. Johanna Mercier and Dr. Bernard Sherman to re-attend for examination of discovery to answer specific questions.
- [2] In a companion motion brought by Bristol Myers Squibb Canada Inc. (BMS Canada) and Bristol Myers Squibb Company (BMS US) this Court ordered that the motion to set aside the order of Prothonotary Tabib be adjourned until the second Monday after the Court of Appeal renders a judgment in Apotex v. Eli Lily, 2004 FC 502.
- [3] Equally with respect to section 1 of this motion relating to Prothonotary Tabib's ruling in respect of the discovery of Johanna Mercier regarding questions 34, 37, page 13 lines 4-8, 87-88, 132, 133, 135 and page 42 lines 2-21 this Court orders an adjournment until the second Monday after the Court of Appeal renders a judgment in Apotex v. Eli Lily, 2004 FC 502.
- [4] Appeals from a Prothonotary used to be governed by the standard set out in The Queen v. Aqua- Gem Investments [1993] 2 F.C. 425 where the court stated at p. 454 I am in agreement with counsel for the appellant that the proper standard of review of discretionary orders of prothonotaries in this Court should be the same as that which was laid down in Stoicevski for masters in Ontario. I am of the opinion that such orders ought to be disturbed on appeal only where it has been made to appear that
 - (a) they are clearly wrong, in the sense that the exercise of discretion by the prothonotary was based upon a wrong principle or upon a misapprehension of the facts, or b)in making them, the prothonotary improperly exercised his discretion on a question vital to the final issue of the case.

- [5] In *Merck & Co. v. Apotex Inc.* (2003), 315 N.R. 175, the Court of Appeal recently reformulated the test in *Canada v. Aqua-Gem Investments Ltd.* (supra) when , Décary J.A. stated at para.19: Discretionary orders of Prothonotaries ought not to be disturbed on appeal to a judge unless:
- a) the questions in the motion are vital to the final issue of the case, or
 - b) the orders are clearly wrong, in the sense that the exercise of discretion by the prothonotary was based upon a wrong principle or upon a misapprehension of facts.
- [6] Apotex 's argument in this case is that the Prothonotary applied the wrong principle; i.e. that she erred in finding these questions are relevant to the points in issue.
- [7] There four groups of questions to be determined by this motion, called for convenience by Apotex Groups 1(a), 1 (b), 2 and 3
- [8] Group 1 (a) relates to questions 43, 59, page 23 line 15-19 and 68. All these questions concern the applications filed by Apotex in respect of provincial formularies.
- [9] Group 1(b) relates to questions 31, 32, 52, 53, 65, 72, 409, 410 and 415 which concern questions whether Apotex compared its Apo-Pravastatin to Provachol (the pravastatin product sold by the BMS defendants).
- [10] Group 2 concerns questions 191, 200, 201 and 231 which relate to whether Apotex's Apo-Pravastatin is manufactured by a process that infringed patent 1,150,170 ('170 patent).
- [11] Group 3 consists of questions relating to Apotex's conduct in prosecuting a separate judicial review application that it commenced against Her Majesty (the Crown).
- [12] It is well established that Prothonotaries are the prime managers of interlocutory matters. They should be given ample elbow and their findings should only be upset if they clearly violate the rule set out in *Aqua-Gem*,(supra) as modified by *Merck & Co. v. Apotex* (supra).
- [13] As to Group 1(a) , i.e. questions 43, 59, page 23 line 15-19 and 68. , one of the issues in contention is whether there was an obligation on Apotex to send a notice of allegation before the Minister could issue a Notice of Compliance both before and after the October 1999 amendments to the regulations. (See BMS US Statement of Defense para 12 , Apotex Motion record p. 85.)
- [14] The BMS defendants therefore wanted to know if such comparisons were made in applications filed by Apotex in respect of provincial formularies. On page 24 of the discovery of Dr. Sherman (Apotex Motion record p. 24) counsel for Apotex gave an undertaking to peruse provincial submissions in respect of comparative bioavailability studies. Such undertaking had, as of the date of hearing the motion, not been complied with. Apotex cannot have it both ways, i.e. giving an undertaking regarding provincial formularies (thereby implicitly recognizing that provincial formularies are relevant) and moving to strike questions regarding provincial formularies as being not relevant.

- [15] In light of these facts I cannot see how the Prothonotary's decision to find these questions relevant and requiring them to be answered can be considered to amount to an error in principle.
- [16] Group 1(b) i.e. questions 31, 32, 52, 53, 65, 72, 409, 410 and 415 relate to whether Apotex compared its Apo-Pravastatin to Provachol in its federal filing. Apotex alleges that such questions only relate to its claim against the crown, not to its claim against the BMS defendants. It is thus not relevant to the defense of the BMS defendants. In support it cites *Steinberg v. Regent Construction* [1966] 2 O.R. 864 where at p. 865 Stewart J. Observes " In *Madge v. Odeon Theatres (Ontario) Ltd* [1953] O.W.N. 103 at p. 104 the Senior Master{Marriott} said:... it appears to be settled that a party cannot be required to give discovery relating only to matters between the party examining and another party....."
- [17] However Apotex asserts in its Statement of Claim in paragraph 25 "The Minister had previously indicated to Apotex that the foreign product was an unacceptable reference point. Being a foreign product, the reference product referred to by Apotex in its ANDS was therefore not a Canadian Patented Product. As a result , the Apotex ANDS did not make a direct reference or comparism to a Canadian patented product." (underlining added)
- [18] Both the BMS US Statement of Defense at paras 12-16 and the BMS Canada Statement of Defense at paras 9-17 dispute this fact vehemently.
- [19] It is well established that discovery is limited to the pleadings. See *Steinberg supra* at p. 866 for instance. Given that we are dealing here with a fact raised by Apotex in its pleadings that is disputed by both BMS defendants in their statements of defense, it is clearly relevant to this dispute. Accordingly, again I cannot see how the Prothonotary's decision to find these questions relevant and requiring them to be answered can be considered to amount to an error in principle.
- [20] Group 2 concerns questions 191, 200, 201 and 231 which relate to whether Apotex's Apo-Pravastatin is manufactured by a process that infringed the so called '170 patent.
- [21] Apotex points out that the '170 patent expired some seven month before the occurrence of the delay of seven days (allegedly caused by BMS) which is the subject matter of this litigation. No claim is advanced by Apotex against the BMS defendants in respect of the '170 patent.
- [22] However Apotex in para 21 of its Statement of Claim makes the following assertion: "To avoid infringement of the '170 patent , Apotex arranged for the production by fermentation using a non-infringing process at Apotex's sister company Apotex Fermentation Inc ("AFI") in Wiinipeg , Manitoba. The non-infringing process was developed using a microbe of a different genus from that covered by the '170 Patent. The development was done with the collaboration pf Prof. A. Demain of the Massachusetts Institute of Technology "MIT") and U.S. and Canadian Patents were obtained covering the new process. AFI holds the exclusive license under these patents. "

- [23] The Statement of Defense of BMS US in para 17 specifically denies this allegation. The Statement of Defense of BMS Canada in paragraph 18 does likewise. Since Apotex has not withdrawn this assertion or in any limited it to its allegation against the Crown, it must now answer any questions regarding a fact that is in dispute as a result of the pleadings.
- [24] Thus as with groups 1(a) and 1 (b) again I cannot see how the Prothonotary's decision to find these questions relevant and requiring them to be answered can be considered to amount to an error in principle.
- [25] Finally Group 3 concerns questions 271, 272 and 273 relating to Apotex's conduct in prosecuting a separate judicial review application that it commenced against Her Majesty (Crown).
- [26] As part of its claim against the Crown Apotex produced document 28 which is a mandamus application Apotex brought against the Crown on Nov. 25, 1999. The application refers to a supporting affidavit of Dr. Bernard Sherman. Upon questioning by counsel for both BMS Canada and BMS US Apotex refused to produce the affidavit. Apotex claims it is not relevant to the proceedings against BMS US or BMS Canada.
- [27] I find it difficult to accept this argument. Having produced the mandamus application (which it intends to rely on for some purpose) which refers to the supporting affidavit, it is incumbent on Apotex to produce this referenced affidavit. It may well be totally irrelevant to BMS Canada and BMS US as Apotex claims. However without examining that document it is impossible to determine its relevance. At this point only Apotex knows the contents of the affidavit and its relevance.
- [28] It may or may not be relevant for instance, to an assessment of the conduct of Apotex. This litigation is based on s. 8 of the Patented Medicines (Notice of Compliance) Regulations. In such proceedings, the conduct of the first or second person which contributed to the delay is relevant to the quantum of damages. The affidavit in question may or may not shed light on the conduct of Apotex. As long as Apotex does not withdraw this document, it must produce supporting documents referenced therein.
- [29] Thus as with groups 1(a), 1 (b) and 2 again I fail to see how the Prothonotary's decision to find these questions relevant and requiring them to be answered can be considered to amount to an error in principle.
- [30] Accordingly Apotex's motion in respect of the issues set out in section 2 of its notice of motion cannot succeed. ORDER THIS COURT ORDERS that:
1. In respect to the issues raised in section 1 of the Notice of Motion, this motion is adjourned until the second Monday after the Court of Appeal renders a judgment in *Apotex v. Eli Lilly*, 2004 FC 502.
 2. In respect of the issues raised in s. 2 of the Notice of motion, this motion is dismissed.

3. Cost in favour of the Defendants Bristol Myers Squibb Company and Bristol Myers Squibb Canada Inc " Konrad von Finckenstein " F.C.J. FEDERAL COURT Solicitors of Record DOCKET: T-485-02 STYLE OF CAUSE: APOTEX INC. and HER MAJESTY THE QUEEN, BRISTOL-MYERS SQUIBB CANADA INC. and BRISTOL-MYERS SQUIBB COMPANY DATE OF HEARING: AUGUST 23, 2004 PLACE OF HEARING: TORONTO, ONTARIO REASONS FOR ORDER AND ORDER BY: VON FINCKENSTEIN J. DATED: SEPTEMBER 7, 2004 APPEARANCES BY: Julie Rosenthal FOR THE PLAINTIFF Frederick Woyiwada FOR THE DEFENDANTS Patrick Smith FOR THE DEFENDANTS Cristin Wagner SOLICITORS OF RECORD: JULIE ROSENTHAL FOR THE PLAINTIFF Goodmans, LLP Toronto, Ontario MORRIS ROSENBERG FOR THE DEFENDANTS Deputy Attorney General for Canada (Her Majesty the Queen) Ottawa, Ontario PATRICK SMITH & CRISTIN WAGNER FOR THE DEFENDANTS Gowling Lafleur Henderson LLP (for Bristol-Myers Squibb) Ottawa, Ontario FEDERAL COURT Date: 20040907 Docket: T-485-02 BETWEEN: APOTEX INC. Plaintiff and HER MAJESTY THE QUEEN, BRISTOL-MYERS SQUIBB CANADA INC. and BRISTOL-MYERS SQUIBB COMPANY Defendants REASONS FOR ORDER AND ORDER

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