Date: 20090331

Dockets : T-371-08
T-372-08

Citation: 2009 FC 269

Ottawa, Ontario, March 31, 2009

PRESENT: The Honourable Mr. Justice Harrington

Docket: T-371-08

BETWEEN:

ASTRAZENECA CANADA INC. AND
ASTRAZENECA AKTIEBOLAG

Applicants

and

APOTEX INC. AND
THE MINISTER OF HEALTH

Respondents

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ASTRAZENECA AB

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APOTEX INC. AND
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PUBLIC VERSION OF THE CONFIDENTIAL REASONS FOR ORDER AND ORDER ISSUED 17 MARCH 2009

[1] March 7, 2010. Prothonotary Aalto surely had that date in mind when he dismissed AstraZeneca's motion for an order requiring Apotex to provide certain portions of the Abbreviated New Drug Submission it filed with Health Canada. This is an appeal of that decision. On March 7, 2008 AstraZeneca filed applications under these two docket numbers, as well as five others, for orders prohibiting the Minister from issuing Apotex a Notice of Compliance with respect to its generic esomeprazole magnesium tablets for the treatment of gastric ulcers, and other conditions requiring a reduction in gastric acid secretion, until patents on file with the Minister expired. Under the *Patented Medicines (Notice of Compliance) Regulations*, those applications have the effect of preventing the Minister from issuing Notices of Compliance until March 7, 2010, the date by which, in the normal course, the Court is expected to have rendered its decision as to whether the various allegations in Apotex's Notices of Allegations are justified.

[2] The PM (NOC) Regulations provide at s. 6(7) that a party such as AstraZeneca may seek an order from a party such as Apotex for the production in whole or in part of the documentation it filed with Health Canada in support of its application for approval of its generic version of a drug, which approval takes the form of a Notice of Compliance.

[3] It is well known that these applications are complex and time consuming, with the clock always running. In December 2007, the Chief Justice issued a Notice to the Parties and the Profession directing that all such proceedings forthwith continue as specially managed proceedings.

These two applications are specially managed. Prothonotary Aalto is the case manager. As case manager he convened a conference at an early date which dealt with a number of issues, such as fixing schedules and "other matters useful to ensure the just, most expeditious and least expensive disposition of the proceeding." Indeed it is a general principle, as enunciated in Rule 3 of the *Federal Courts Rules*, that the rules "…shall be interpreted and applied so as to secure the just, most expeditious and least expensive determination of every proceeding on its merits."

[4] Although in taking stock of all the applications, matters of both patent invalidity and non-infringement are in issue, the motions before Prothonotary Aalto only dealt with Apotex's allegations that it would not infringe Canadian patents 2,290,963 ('963) and 2,139,653 ('653). The title of patent '963 is S- Omeprazole Magnesium Trihydrate. Its very title indicates a water content. The title of patent '653 is "Optically Pure Salts of Pyridinylemethyhl sulfinyl-1H-Benzimidazole Compounds." The words "optically pure" suggest enantiomers as indeed disclosed in the background portion of the patent.

[5] In its Notices of Allegation, Apotex states that it will not infringe patent '963 because its product is not a trihydrate. However, if it is, it suggests a purposeful, and perhaps limiting, meaning to be given to the claims of the invention, particularly as regards crystalline forms. As regards patent '653, the basic allegation is that the patent will not be infringed as its product will be the Mg^{2+} salt of esomeprazole.

[6] As ultimately argued before Prothonotary Aalto, AstraZeneca's motions were primarily limited to: 1) the water content of certain material manufactured by a supplier to Apotex, and 2) the infrared (IR) spectroscopy analysis referred to in the Abbreviated New Drug Submission and details pertaining thereto.

[7] AstraZeneca relied upon an affidavit from Dr. Stephen Byrn, an expert chemist, while Apotex relied upon the affidavit of Dr. Michael Cima, another expert chemist. Neither was cross-examined. Dr. Byrn's point was that without the requested information he could not assess whether or not Apotex's allegations of non-infringement were justified. Dr. Cima, on the other hand, was of the view that the documentation voluntarily provided by Apotex permitted such an assessment to be made, and that it was unnecessary to obtain further production. Prothonotary Aalto preferred the evidence of Dr. Cima.

[8] Basing himself upon *Biovail Corp.* v. *Canada (Minister of National Health and Welfare)*, 2002 FCT 1143, 22 C.P.R. (4th) 503 at paragraphs 40-43, he was of the view that AstraZeneca had the onus to demonstrate:

a. The request for disclosure was made in a timely manner.
b. The information already provided is not sufficient to deal with the issues at stake.
c. The disclosure of the required information is necessary because it is relevant to the disposition of the issues in the proceeding, and is required and important.

[9] Although that decision was affirmed by the Court of Appeal, 2003 FCA 406, 29 C.P.R. (4th) 129, in speaking for the Court, Mr. Justice Nadon did not set out a formal tri-partite test. He held that relevancy is the prime consideration. This point was taken by Prothonotary Aalto since he noted that while relevance of the information is a condition precedent to the Court exercising its discretion to direct disclosure, it was not necessary for the purposes of the disposition of the motion to determine whether the information was also required and important. Put another way, the court will not order disclosure of documents it considers irrelevant, but on the other hand it may not order the production of relevant documents that are not necessary to a determination of the case on its merits

[10] Prothonotary Aalto was of the view that sufficient information had been provided to allow AstraZeneca to file its record. He left the door open that following production of Apotex's record, a fresh motion for production could be filed. He said: "Suffice it to say that once evidence has been filed in this proceeding, if there is information that AstraZeneca still requires that it is both relevant, required and important, they may be able to pursue it."

DISCUSSION

[11] Prothonotary Aalto's decision, whatever it might have been, could not have been vital to the outcome of the case. His decision was discretionary and is only to be disturbed if the exercise of that discretion was based on a wrong principle or misapprehension of the facts (*Merck & Co. v. Apotex Inc.*, 2003 FCA 488, 30 C.P.R. (4th) 40).

[12] AstraZeneca submits that Prothonotary Aalto erred both in fact and in law. The flaw in his legal reasoning is said to be that he should not have effectively adjourned the motion. I see no merit in this submission as there is nothing in s. 6.(7) which fetters a decision maker's discretion to adjourn.

[13] As to factual error, it is submitted that the Prothonotary could not have given proper consideration to the facts. The prime fact relied on is that one of Apotex's suppliers appears, on its face, to begin its process with something that falls squarely within one of the patent claims. If that is so, it must be borne in mind that Dr. Byrn's complaint is that the Notice of Allegation does not give him sufficient information to assess possible water content and crystalline forms. If that is ultimately found to be so, then Apotex's Notices of Allegation may not be a detailed statement as contemplated by the Regulations, as indeed AstraZeneca alleges in its own applications. If the Applications Judge finds that the patent is valid and interpreted the way AstraZeneca would like, and if the products supplied at an earlier stage constitute a claim for the medicine itself, then Apotex is in considerable difficulty, as per the decision of the Court of Appeal in *Abbott Laboratories v. Canada (Minister of Health)* 2006 FCA 187, 56 C.P.R. (4th) 387.

[14] Given schedules and given deadlines, Prothonotary Aalto's order was not clearly wrong; it was eminently reasonable. There is no basis to interfere (*Sawridge Band v. Canada*, 2001 FCA 338, [2002] 2 F.C. 346 and *Apotex Inc. v. Lundbeck Canada Inc.*, 2008 FCA 265).

[15] It must be borne in mind that parties to an application, as opposed to an action, are under no obligation to voluntarily produce documentation which may be relevant. Indeed, this was also the situation in actions before the former Court Rules were amended in 1991. Under former Rule 447, a party needed only to disclose documents that might be used in evidence to assist in establishing any of its allegations of fact, or to assist in rebutting any allegation of fact of an opposing party. The rationale therefor, which I think still applies in applications which are intended to be summary in nature, was set out by Chief Justice Jackett in the "Little Red Book" (Manual of Practice) issued in 1971:

> …The reason for thus curtailing the ambit of discovery as of right is the purely practical one that while, on the one hand, it is felt that there are relatively few cases where a party can be building his case on documents that he hopes to get from his opponent, on the other hand it is very onerous, tedious and a difficult task, involving considerable expense and delay, to prepare a list of documents that would, conceivably, be of aid to one's opponent… On balance, it seems probable that the costs and delays of making such discovery outweigh, in most cases, the theoretical advantages obtained from it.

[16] The old rules had a fallback position in that the Court could nevertheless order full discovery under Rule 448. Currently, apart from s. 6(7) of the *PM (NOC) Regulations*, Rule 313 of the *Federal Courts Rules* also permits the Court to require the filing of additional material if it considers the record is incomplete.

[17] As a matter of caution, should I have erred and the circumstances require me to exercise my discretion *de novo*, for the reasons given above, I would have done exactly what Prothonotary Aalto did.

ORDER

THIS COURT ORDERS that:

1. The appeal of the order of Prothonotary Aalto is dismissed.

2. Apotex shall have its costs, calculated on the basis of a single motion in appeal.

"Sean Harrington"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-371-08 and T-372-08
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APPEARANCES:

Ms. Yoon Kang Ms. Urszula Woytyra	FOR THE APPLICANTS
Mr. Andrew Brodkin Mr. Daniel Cappe	FOR THE RESPONDENT APOTEX INC.
No one appeared	FOR THE RESPONDENT THE MINISTER OF HEALTH

SOLICITORS OF RECORD:

Smart & Biggar Barristers & Solicitors Toronto, Ontario	FOR THE APPLICANTS
Goodmans LLP Barristers & Solicitors Toronto, Ontario	FOR THE RESPONDENT APOTEX INC.
John H. Sims, Q.C. Deputy Attorney General of Canada	FOR THE RESPONDENT THE MINISTER OF HEALTH