Date: 20090304

Dockets: T-876-08
T-886-08

Citation: 2009 FC 226

Ottawa, Ontario, March 4, 2009

PRESENT: The Honourable Mr. Justice Harrington

BETWEEN:

PFIZER CANADA INC., PFIZER LIMITED, and PFIZER IRELAND PHARMACEUTICALS

Applicants

and

APOTEX INC. and THE MINISTER OF HEALTH

Respondents

REASONS FOR ORDER AND ORDER

[1] In the course of an application to prohibit the Minister from issuing a Notice of Compliance with respect to a generic version of a medicine referenced by a patent listed in the Minister's Register, the Court may order the generic drug manufacturer to produce any portion of the submission it filed with the Minister. Pfizer moved that Apotex produce portions of such submissions. Prothonotary Aalto dismissed its motion. This is the appeal thereof.

[2] There are two passages from Prothonotary Aalto's order which set out the rationale of his decision:

> On my view of the evidence, Pfizer has not met, on a balance of probabilities, its burden of demonstrating that disclosure is required and important, especially in light of the substantial voluntary disclosure made to date by Apotex.
>
> …
>
> On my view of the evidence of Dr. Klibinov, Mr. Terrill, their cross-examinations and the evidence of Dr. Byrn, I am not persuaded that the information sought on this motion is either relevant, important or required. There is no evidence that Apotex is infringing.

[3] The order was discretionary. It is well established that such orders are not to be disturbed unless they could have been vital to the final issue of the case or, failing that, unless the order was clearly wrong as based either upon a wrong principle of law or upon a misapprehension of the facts. In such cases the judge hearing the appeal is required to exercise his or her discretion *de novo* (*Merck & Co. v. Apotex Inc.*, 2003 FCA 488, [2004] 2 F.C.R. 459, 30 C.P.R. (4th) 40 and *Fieldturf Inc. v. Winnipeg Enterprises Corp.*, 2007 FCA 95, 58 C.P.R. (4th) 15, 360 N.R. 355). Pfizer submits both that the issue decided was vital to the outcome of the case and that the Prothonotary was clearly wrong.

BACKGROUND

[4] Apotex has served Pfizer with two Notices of Allegation pursuant to the *Patented Medicines (Notice of Compliance) Regulations* with respect to its submissions to the Minister of Health for approval of its tablets comprising amlodipine for use as an antihypertensive-antianginal.

[5] Pfizer has two patents on the Register maintained by the Minister. Apotex alleges with respect to patent 1,321,393 (‘393) that no claim for the medicinal ingredient, for the formulation, for the dosage form, or for the use of the medicinal ingredient would be infringed by its making, constructing, using or selling its tablets. It alleges that the relevant claims of the ‘393 patent are limited to the besylate salt of amlodipine, or a composition or formulation comprising same. Apotex will not infringe because its tablets will not contain that salt, nor will that salt be used in any way in the manufacturing process. More particularly, only amlodipine will be the medicinal ingredient.

[6] With respect to the second patent, 2,170,278 (‘278), similar allegations are made on the basis that the patent is limited to the R(+) isomer of amlodipine or salt thereof. There will be no infringement because Apotex’s tablets will use the racemate, not the R(+) isomer. There is also an undertaking that the Notice of Compliance it seeks will not include an indication for treatment of conditions requiring inhibition of vascular smooth muscle cell migration.

[7] As Apotex was not content to await the expiry of the two patents before marketing its product, Pfizer has applied for a prohibition order against the Minister. Section 6(7)(*a*) of the *PM (NOC) Regulations* provides:

(7) On the motion of a first person, the court may, at any time during a proceeding,	(7) Sur requête de la première personne, le tribunal peut, au cours de l’instance :
(*a*) order a second person to produce any portion of the submission or supplement filed by the second person for a notice of compliance that is relevant to the	*a*) ordonner à la seconde personne de produire les extraits pertinents de la présentation ou du supplément qu’elle a déposé pour obtenir un avis de

disposition of the issues in the proceeding and may order that any change made to the portion during the proceeding be produced by the second person as it is made;	conformité et lui enjoindre de produire sans délai tout changement apporté à ces extraits au cours de l'instance;

[8] During the course of the proceedings and before the motion was heard, Apotex voluntarily disclosed to Pfizer a good portion of its New Drug Submissions filed with the Minister. The Prothonotary ordered that these productions be deemed to have been made pursuant to s. 6(7), required Apotex to promptly produce any changes that were made thereto and ordered that the Minister verify that these productions, and any changes thereto, corresponded fully to the information on file with him. Those portions of the order are not under appeal.

[9] It is common ground that the active ingredients, as opposed to the ultimate formulation, are supplied to Apotex by two Indian corporations. They provided what may be the relevant portions of their Drug Master Files to the Minister on a "closed" or confidential basis. Apotex does not have these closed portions in its possession or control. All that Apotex could be ordered to do would be to use its "best efforts" to encourage its Indian suppliers to provide that documentation, which documentation would be covered by confidentiality orders already in place or, if appropriate, by more expansive orders.

[10] The other documentation Pfizer seeks is the entire Chemistry and Manufacturing Section contained in Apotex's New Drug Submissions. That is information within Apotex's possession and control. Certainly parts thereof have already been voluntarily produced.

[11] The evidence before Prothonotary Aalto comprised the affidavit of Dr. Steven Byrn, a medicinal chemist called by Pfizer, and reply evidence of Dr. Alexander Klibanov, a professor of chemistry and bioengineering and Dwayne Terrill, Manager of Regulatory Affairs for Apotex. Dr. Byrn was not cross-examined; the other two affiants were. Dr. Byrn focused on that portion of Apotex's submissions to the Minister which states:

> Alternate processes and explanation of their use:
>
> This information is not provided in the open part of either of the Drug Master Files. Please refer to the closed portion of the Drug Master Files.

[12] Dr. Byrn speculates that there may be such alternative processes used by the Indian suppliers and that they might infringe the patents. Dr. Klibanov counters that such a scenario is highly unlikely and would make no sense.

[13] More to the point, however, is that Dr. Klibanov recounts in his affidavit that upon his review of those portions of Apotex's New Drug Submissions with which he had been provided he was of the opinion that: "None of the documents suggests that Apotex is seeking to market amlodipine besylate or the R(+) enantiomer of amlodipine." He went on to explain why, in his opinion, "nothing in the documents would support [Dr. Byrn's] speculation."

[14] In my opinion, on the facts before the Prothonotary, there is nothing to indicate that his decision was vital to the outcome of the case. Apotex has disclosed the process by which it says it will prepare its tablets. The Applications Judge will have to decide on the merits whether Apotex's allegations of non-infringement are justified. The Applications Judge is not called upon to decide whether some other process might infringe.

[15] However, in support of its submission that the Prothonotary erred in law, Pfizer seizes upon the following sentence in his order: "There is no evidence that Apotex is infringing". It is submitted that that is the very point to be decided by the Applications Judge. Pfizer is correct.

[16] However, Prothonotary Aalto's words have to be considered in context. He immediately added:

> Indeed, the thrust of the evidence of Dr. Klibinov, which undermines Dr. Byrn's theorizing, is that it would be essentially nonsensical with absolutely no commercial advantage for Apotex to create amlodipine besylate in its manufacturing process and then destroy it in the course of producing amlodipine maleate. Similarly, the evidence is that with respect to the R(+) isomer, it is highly illogical for a manufacturer to create R(+) amlodipine when such a process would make no chemical sense, would cause additional regulatory hurdles, would add expense and be contrary to the manufacturer's goal of not producing an infringing product.

[17] In his affidavit for the purposes of the production motions, Dr. Byrn does not opine that the material already produced by Apotex evidences an infringement. Rather, he submits that alternate processes by the Indian suppliers might infringe. On the other hand Dr. Klibanov, whose evidence

Prothonotary Aalto preferred, clearly is of the view that the material produced so far establishes a non-infringing process.

[18] Judicial prowess aside, I think the following passage from Lord Devlin's speech in *The Amstelslot*, [1963] 2 Lloyd's Rep. at page 234 drives home the point:

> There was a suggestion in the Court of Appeal that Mr. Justice McNair, who tried the case, got his law wrong on the elementary point about the burden of proof. The suggestion is based on a passage in his judgment that has, for the purpose of the argument, to be isolated from his other statements of the law. For myself, I should want more than a piece of textual criticism as a bait before I was tempted to swallow the idea that Mr. Justice McNair, who is the greatest English authority on the Hague Rules and more experienced than any other Judge in their application, misunderstood where the burden of proof lay in a "due diligence" case.

[19] Prothonotary Aalto's sentence cannot be taken to mean that he intended to decide the case on the merits. On the contrary, his was clearly an interlocutory order and it cannot be suggested that he did not know that he did not have jurisdiction to issue a prohibition order.

[20] A good deal of the argument before me attempted to identify the test to be applied by the Court in determining whether a second person within the meaning of the Regulations, i.e. Apotex, should be ordered to produce portions of its New Drug Submissions to the Minister as part of the approval process for its generic version of a drug. In *Biovail Corp. v. Canada (Minister of National Health and Welfare)*, 2002 FCT 1143, 22 C.P.R. (4th) 503, Mr. Justice Simon Noël stated at paragraph 40:

> In order to be able to justify the application of subsection 6(7) of the Regulations, a party must convince the Court on three matters:

a) That the request for disclosure is done in a timely manner; and
b) That the information already provided is not sufficient to deal with the issues at stake; and
c) That the disclosure of the required information is necessary because it is relevant to the disposition of the issues in the proceeding.

[21] However, in appeal, 2003 FCA 406, 29 C.P.R. (4th) 129 at para. 33, and basing himself on the earlier decision of the Court of Appeal in *Novartis Pharmaceuticals Canada Inc. v. Abbott Laboratories, Ltd.* (2000), 7 C.P.R. (4th) 264, Mr. Justice Nadon held that the first and foremost consideration is whether the documents sought to be produced are relevant:

> …Once satisfied that the documents sought are relevant, a judge may consider a number of factors in deciding whether he or she ought to order production, one of these factors being, in my view, whether the application was brought in a timely manner. To hold otherwise would, in my respectful view, make no sense.

[22] Prothonotary Aalto did not rule against Pfizer on the timeliness point. Rather, he was not persuaded that the information sought was relevant, important or required. In so doing he preferred the evidence of Dr. Klibanov over that of Dr. Byrn. Pfizer submits that he "erred in law in usurping the function of the applications judge by resolving conflicting expert evidence." I fail to appreciate this submission. Although interlocutory motions in applications are often left to be decided by the Applications Judge, that is not the case here. Pfizer could, and did, bring on its application which the Regulations say could be brought on "at any time" or at least in a timely manner. In considering whether the documentation might be relevant, the Prothonotary had to take into account the opinions of the experts. This was a pre-requisite to exercising his discretion, which discretion ought to have been exercised before the hearing on the merits. His preference is not to be disturbed

because he did not make a palpable or overriding error (*Housen v. Nikolaisen*, 2002 SCC 33, [2002] 2 S.C.R. 235, applied to interlocutory decisions of Prothonotaries in *Hershkovitz v. Tyco Safety Products*, 2006 FC 1228, 56 C.P.R. (4th) 47 and *Tazco Holdings Inc. v. Advantage Products*, 2008 FC 464, 65 C.P.R. (4th) 390).

[23] Indeed, like him, I cannot see how the information is relevant. The issue to be determined by the Applications Judge is whether the process Apotex states it will use would infringe, not whether some other process might infringe. Even if it could be said that the information might be relevant, a production order does not automatically follow. This is an application which is intended to be heard in a summary manner, not an action in which a party in its affidavit of documents must reveal all (Rules 222 and 223 of the *Federal Courts Rules*). In exercising his discretion, Prothonotary Aalto properly took into account Apotex's productions to date, and was not clearly wrong in deciding that the information was not relevant, was not important or was not required.

[24] Even if Prothonotary Aalto could be taken to task, which he should not, for accepting the hearsay evidence from Apotex's Mr. Terrill that the Indian suppliers did not have an alternate process, he acted within his discretion, particularly considering the wealth of material Apotex has already provided.

[25] In the circumstances, it is not necessary in this case to consider what "best efforts" would have to be undertaken by Apotex to endeavour to persuade its suppliers to disclose the closed

portion of their Drug Master Files (*PharmaScience Inc. v. Canada (Minister of Health)* 2003 FCA 333, 28 C.P.R. (4th) 27).

[26] As to production of the entire Chemistry and Manufacturing Section of Apotex's New Drug Submissions, again given Apotex's extensive productions to date, the Prothonotary's refusal was not based on an error of fact or law.

[27] In conclusion, the Prothonotary's decision was not, and could not have been, vital to the outcome of the case. Furthermore, the exercise of his discretion was not clearly wrong. However, should I have misapplied the test stated by the Court of Appeal in such cases as *Merck v. Apotex*, above, so that I am required to exercise my discretion *de novo*, for the reasons set out herein I would also dismiss the motions.

ORDER

THIS COURT ORDERS that:

1. The appeal from the order of Prothonotary Aalto in Court file T-876-08 dated 19 January 2009 is dismissed.
2. The appeal from the order of Prothonotary Aalto in Court file T-886-08 dated 19 January 2009 is dismissed.
3. Apotex shall have its costs, calculated on a single motion in appeal.

"Sean Harrington"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

DOCKETS:	T-876-08 T-886-08
STYLE OF CAUSE:	Pfizer Canada Inc. *et al*. v. Apotex Inc. and the Minister of Health
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APPEARANCES:

W. Grant Worden	FOR THE APPLICANTS
Andrew Brodkin Daniel Cappe	FOR THE RESPONDENT APOTEX INC.
No one appeared	FOR THE RESPONDENT THE MINISTER OF HEALTH

SOLICITORS OF RECORD:

Torys LLP 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