Date: 20070618

Docket: T-1171-06

Citation: 2007 FC 649

Ottawa, Ontario, June 18, 2007

PRESENT: The Honourable Madam Justice Hansen

BETWEEN:

PFIZER CANADA INC. and
WARNER-LAMBERT COMPANY, LLC

Applicants

and

THE MINISTER OF HEALTH,
RANBAXY LABORATORIES LIMITED and RANBAXY INC.

Respondents

REASONS FOR ORDER AND ORDER

Introduction

[1] Ranbaxy Laboratories Ltd. (Ranbaxy) brought a motion under section 6(5)(*b*) of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 (Regulations) to dismiss the within application in its entirety. Prothonotary Tabib concluded that it was not plain and obvious

the application is frivolous, vexatious or an abuse of process and dismissed the motion. Ranbaxy appeals from this Order.

Background Facts

[2] The within application arises from Ranbaxy's proposed sale of generic atorvastatin calcium tablets, Ran-Atorvastatin, to compete with Pfizer's LIPITOR product. By letter dated May 23, 2006, Ranbaxy made allegations of non-infringement of Canadian Patent nos. 2,450,111 (‘111 Patent), 2,521,953 (‘953 Patent) and 2,521,933 (‘933 Patent) (NOA) added to the Patent Register by Pfizer Canada Inc. (Pfizer). These patents claim crystalline Forms VII, X and XII of atorvastatin calcium respectively. In its NOA, Ranbaxy stated that its Ran-Atorvastatin Tablets will comprise only the amorphous form of atorvastatin calcium and not any of the crystalline forms. Ranbaxy also stated that it would not make, construct, use or sell the claimed crystalline forms of atorvastatin calcium.

[3] In response, the Applicants filed the within Notice of Application for an order of prohibition on the basis that Ranbaxy's allegations of non-infringement are not justified. Pfizer alleges that the Ran-Atorvastatin Tablets will “contain, will convert to or will be made by processes that use or produce [the claimed crystalline forms] as an intermediate and/or a final product.”

[4] It is not disputed that Ranbaxy has two processes to make Ran-Atorvastatin: first, the one filed with Health Canada as part of its Abbreviated New Drug Submission (ANDS) at issue in this

proceeding and, second, a process not on file with Health Canada that according to Pfizer's experts uses intermediates that are or contain crystalline Form VII atorvastatin.

[5] Although Ranbaxy states that it has not made a decision as to whether it will commercialize with the process on file with Health Canada or with the second process, Pfizer maintains that there is "more than enough" evidence on the record from which it can be concluded that Ranbaxy will change its manufacturing process on file with Health Canada to the second process if it is issued a Notice of Compliance (NOC). From this, Pfizer argues that there is credible evidence that Ranbaxy will infringe its patent for crystalline Form VII atorvastatin if it is issued a NOC.

[6] On the motion to dismiss, Ranbaxy argued that "an application for a prohibition order pursuant to section 6(5) of the Regulations is necessarily limited to and defined by the submission on file with Health Canada, and the only issues that can be considered by the Court or that can be relevant in such an application are whether, on the basis of the materials filed by the second party with Health Canada, the second person's allegations of non-infingement are justified." (Prothonotary's reasons para. 14)

[7] In reaching her decision that it is not "plain and obvious" the application is redundant, scandalous, frivolous, vexatious or an abuse of process, Prothonotary Tabib took into account the fact that Ranbaxy's NOA does not specifically refer to the process on file with Health Canada as

defining its allegations and that there is no jurisprudence directly addressing the issue of whether a first person is limited in attempting to show that the allegations of non-infringement are not justified to only the material filed with Health Canada.

[8] Before Prothonotary Tabib, Ranbaxy also argued that Pfizer's Rule 306 evidence contained no contention that the '953 or the '933 Patents would be infringed by the making, constructing, using, or selling of the Ran-Artorvastatin Tablets. On the basis that Ranbaxy only sought a dismissal of the application in its entirety and not in part and since these matters were clearly secondary involving little or no evidence and none controversial, Prothonotary Tabib declined to exercise her discretion to consider whether the application should be dismissed in part. This was not contested on appeal. Finally, for the sake of completeness, it should also be noted that Prothonotary Tabib rejected Pfizer's argument that she did not have the jurisdiction to hear motions to dismiss under section 6(5)(*b*) of the Regulations. Pfizer did not appeal the ruling on this issue.

Standard of Review

[9] Both parties agree that since the questions raised in the motion are vital to the final issue of the case, the Court is to consider the merits of the motion *de novo* (*Merck & Co. v. Apotex Inc.*, 2003 FCA 488 at paragraph 19).

Burden of Proof

[10] Section 6(5)(*b*) of the Regulations provides that a court may dismiss an application that is redundant, scandalous, frivolous or vexatious, or is otherwise an abuse of the court's process. As a motion pursuant to section 6(5)(*b*) has been held to be akin to a motion to strike, the second person must establish that it is "plain and obvious" the application has no chance of success. It is also well established that the summary dismissal of an application before hearing is an extraordinary remedy that should only be granted in limited circumstances (*Norton v. Via Rail Canada Inc.*, 255 D.L.R. (4th) 311 at paragraph 15).

Analysis

[11] Ranbaxy's position that the within application is bereft of any possibility of success is mainly grounded on its assertion that the overall intent and the specific language of the Regulations dictate that a notice of allegation of non-infringement must relate to the submission filed with Health Canada. Thus, on an application for an order of prohibition, the court is limited to a consideration of the material forming part of the submission to Health Canada. In particular, in its consideration of whether the allegations of non-infringement are justified, the court may only have regard to the process Ranbaxy has on file with Health Canada. For this reason, Ranbaxy argues that its future intention as to which process it will use for the manufacture of Ran-Atorvastatin, is not relevant to this proceeding. As Pfizer's contentions of infringement of the '111 Patent that claims Form VII do not relate to the process on file with Health Canada and Pfizer has not contended that the '933 and '953 Patents will be infringed, it is "plain and obvious" that the application cannot succeed.

[12] As an aside, Ranbaxy acknowledges that there is no jurisprudence on the question of whether on an application for an order of prohibition a court may consider a process that does not form part of the submission to Health Canada.

[13] Ranbaxy also takes the position that even if its future intentions regarding the manufacturing process are considered by the court, Pfizer cannot succeed. Pfizer must show that the allegations of non-infringement are not justified. Factual allegations are presumed to be true and the onus is on the first person to disprove the allegation. Merely showing the possibility of infringement is not sufficient to disprove the allegations. In the present application, according to Ranbaxy, all Pfizer can do is raise the possibility of infringement since no decision has been taken regarding the process that it will use if a NOC is issued.

[14] In my view, Ranbaxy has failed to meet its burden on this appeal that it is "plain and obvious" that the application cannot succeed. First, the legal assertion underlying its position that the court hearing the application will be limited to a consideration of the material on the Health Canada file has never been judicially determined. In fact, there is case law from which it could be argued by analogy to the contrary. This is not the forum to decide controversial questions of law.

[15] Second, if it is determined that the second process is a relevant consideration, there is a factual dispute between the parties as to whether Ranbaxy will use the second process if it is granted a NOC. Any finding on this point is best left to the applications judge before whom there will be a complete record.

[16] Finally, the interpretation of the Regulations urged upon the Court by Ranbaxy could lead to a conclusion directly at odds with the purpose of the Regulations, namely, to prevent patent infringement. In my opinion, questions of statutory interpretation ought to be determined in a factual context and not in a vacuum.

[17] Although in its written submissions Ranbaxy took the position that the post-October 5, 2006 Regulations were applicable, at the hearing it became evident that the parties may not be in agreement on this point. I indicated to them that if any part of this decision should turn on the language of the Regulations that has changed as a result of the amendment, I would give them an opportunity to make written submissions. In light of the above reasons, the opportunity to make further submissions on this question is unnecessary.

[18] For the above reasons, the appeal is dismissed with costs to Pfizer.

ORDER

THIS COURT ORDERS that the appeal is dismissed with costs to Pfizer Canada Inc.

"Dolores M. Hansen"

Judge

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-1171-06
STYLE OF CAUSE:	Pfizer Canada Inc. and Warner-Lambert Company LLC v. The Minister of Health, Ranbaxy Laboratories Limited and Ranbaxy Inc.
PLACE OF HEARING:	Vancouver, BC
DATE OF HEARING:	June 5, 2007
REASONS FOR ORDER AND ORDER:	HANSEN, J.
DATED:	June 18, 2007

APPEARANCES:

Mr. Peter Wilcox	FOR THE APPLICANTS
Mr. David Reive Ms. Angela Furnaletto	FOR THE RESPONDENT RANBAXY LABORATORIES LIMITED

SOLICITORS OF RECORD:

Torys LLP Toronto, Ontario	FOR THE APPLICANTS
Dimock Stratton LLP. Toronto, Ontario	FOR THE RESPONDENT RANBAXY LABORATORIES LIMITED