

Federal Court



Cour fédérale

Date: 20150414

Docket: T-1472-13

Citation: 2015 FC 458

Montreal, Québec, April 14, 2015

PRESENT: The Honourable Mr. Justice Locke

BETWEEN:

SHIRE CANADA INC.

Applicant

and

**COBALT PHARMACEUTICALS COMPANY
AND THE MINISTER OF HEALTH**

Respondents

and

SHIRE LLC

Patentee/Respondent

ORDER AND REASONS

I. Background

[1] This is a motion by the applicant, Shire Canada Inc. (Shire), to appeal an Order of Prothonotary Tabib dated October 9, 2014 (Prothonotary Tabib's Order) which dismissed Shire's

motion to strike certain affidavit evidence submitted by the respondent Cobalt Pharmaceuticals Company (Cobalt) in the present application pursuant to the *Patent Medicines (Notice of Compliance) Regulations*, SOR/93-133 (the *PM(NOC) Regulations*). Specifically, Shire sought to strike the affidavit of Michael Stewart and certain portions of the affidavit of Peter Rue. In the alternative, Shire sought to file further evidence in the form of a reply affidavit of James Polli.

II. Standard of Review

[2] The standard of review of a discretionary decision of a prothonotary is as argued by Cobalt and as acknowledged by Shire at paragraphs 30 and 31 of its written representations in support of the present motion: such decisions should not be disturbed unless (a) the questions raised in the motion are vital to the final issue of the case, or (b) the order is 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: *Merck & Co. Inc. v Apotex Inc.*, 2003 FCA 488 at para 19. There is no argument that the questions raised in the present motion are vital to the final issue of the case. Therefore, this motion is to be decided on the basis of whether Prothonotary Tabib's Order was clearly wrong.

[3] At the hearing of the present motion, Shire strayed from its written representations and argued that a less deferential standard of review should apply because, in addition to hearing this motion, I will be the judge hearing the present application on its merits. Shire cited no authority for such an exception to the well-settled test for appeal of a prothonotary's decision. I do not accept Shire's argument on this point because there are many reasons for showing deference to prothonotaries' decisions, some of which are unrelated to whether the judge on the appeal is also the judge on the merits.

III. Applicable Law

[4] There appears to be agreement between the parties that the question of whether the evidence at issue should be struck is to be determined in accordance with the decision of the Federal Court of Appeal in *AB Hassle v Canada (Minister of National Health and Welfare)* (2000), 7 CPR (4th) 272 (*AB Hassle*). In that decision, the Court observed that the nature of proceedings under the *PM(NOC) Regulations* requires that the Notice of Allegation (NOA) communicated by the “second person” prior to the commencement of the proceeding raise all factual and legal arguments upon which it relies to support its allegations. As stated by Justice Hughes in *Bayer Inc. v Cobalt Pharmaceuticals Company*, 2013 FC 1061 at para 34, the second person “cannot craft new arguments, or raise new allegations or new facts or new prior art documents not set out in the Notice of Allegation.” However, the parties appear to be agreed that this prohibition does not prevent a second person from responding to evidence adduced and issues raised by the first person.

[5] Therefore, the present motion is to be decided, at least in part, on the basis of whether Cobalt’s evidence in dispute raises new allegations or new facts, or if it is merely responsive to Shire’s evidence.

IV. Prothonotary Tabib’s Order

[6] Prothonotary Tabib concluded that the Stewart Affidavit could be responsive to Cobalt’s affidavit of Beth Burnside, and found no prejudice to Shire in letting the judge on the merits consider the admissibility of the evidence. Prothonotary Tabib rejected Shire’s argument that the Stewart Affidavit was tendered to support a new ground of invalidity of the patent in suit, Canadian Patent No. 2,348,090 (the 090 Patent).

[7] With respect to the Rue Affidavit, Prothonotary Tabib concluded similarly, finding that the portions in dispute do not concern a new argument that the 090 Patent was improperly listed.

[8] Accordingly, Prothonotary Tabib refused to strike the evidence in question. She also refused to allow the filing of Shire's proposed reply evidence since it concerned the alleged new argument of improper listing.

V. Analysis

[9] The present motion comes down to whether Prothonotary Tabib was clearly wrong in determining that:

- i. the Stewart Affidavit could be responsive to the Burnside Affidavit and did not otherwise raise new factual or legal arguments;
- ii. the portions of the Rue Affidavit at issue do not raise new factual or legal arguments; and
- iii. the proposed reply evidence concerns only an issue that is not in dispute.

A. *Stewart Affidavit*

[10] Mr. Stewart is a patent agent registered in Canada and the U.S. His affidavit puts in evidence the file history of the 090 Patent, as well as a number of U.S. patents that are related to the 090 Patent together with their file histories. The Stewart Affidavit also comments on these file histories.

[11] Shire argues that Prothonotary Tabib was clearly wrong in determining that the Stewart Affidavit could be responsive to the Burnside Affidavit. Shire notes correctly that the Stewart Affidavit makes no mention of the Burnside Affidavit and that Mr. Stewart was not even shown

the Burnside Affidavit. Shire also notes correctly that Cobalt's NOA makes no mention of the documents attached to the Stewart Affidavit.

[12] Cobalt argues that the Stewart Affidavit is admissible on a number of grounds. One of these is that the Burnside Affidavit refers to corrections made to the 090 Patent and to "corresponding" U.S. patents and various corrections made to them, but does not provide the underlying documents. Cobalt argues that it is appropriate to put the documents and facts properly in evidence, and that these documents and facts are relevant for a number of reasons. Much of the information Cobalt seeks to keep in evidence concerns figure 7 of the 090 Patent which, by virtue of the position Shire has taken in the present proceeding, has become central to the asserted invention of the 090 Patent. Cobalt wishes to establish that figure 7 was introduced after the claimed priority date, which may affect the claim date of certain claims, and hence the citability of certain asserted prior art. Cobalt also wishes to show that it was not necessary to draft claims in relation to figure 7, which could support its allegation that the 090 Patent violates subsection 86(1) of the *Patent Rules*, SOR/96-423. Moreover, figure 7 is relevant to Cobalt's argument of avoidable ambiguity. Still further, Cobalt wishes to establish that the y-axis in figure 7 measures a single enantiomer of amphetamine, rather than the total amount of amphetamine, which may be relevant to the issue of infringement. Without deciding whether these various arguments have merit, I am not prepared to find that Prothonotary Tabib was clearly wrong in finding that the Stewart Affidavit could be responsive to the Burnside Affidavit. I am also not inclined to make a different decision at this stage as the judge who will hear the application on the merits.

[13] Shire argues that it is well-accepted in Canada that claims are to be construed without reference to extrinsic evidence, such as the prosecution history of the 090 Patent or of related

foreign patents, and therefore the file histories in question are not relevant. Cobalt counters that recent authorities cast doubt on whether the prohibition against extrinsic evidence is as broad as Shire asserts. Cobalt argues that it should be allowed to explore this argument and to adduce the necessary supporting evidence on the issue. Again, without deciding whether Cobalt's position on this point has merit, I am of the view that it should be allowed to make the argument.

[14] Shire points out that Mr. Stewart, as a patent agent, has no expertise concerning how the claims in issue should be construed, and argues that his evidence should be struck on this basis. While I acknowledge the limited scope of Mr. Stewart's expertise, it is my view that this goes more to the weight to be given to his testimony rather than its admissibility.

[15] Finally, Shire cites the rule in *Browne v Dunn* (1893), 6 R 67 (HL) to argue that the Stewart Affidavit is inadmissible to counter the Burnside Affidavit since it was not put to Dr. Burnside during her cross-examination. I am not satisfied that this rule applies to the present situation. After having heard Shire on this point, it is not clear to me what aspects of the Stewart Affidavit should have been put to Dr. Burnside and what sorts of clarifications she might have been able to offer if those aspects of the Stewart Affidavit had been put to her.

B. *Rue Affidavit*

[16] Shire argues that the portions in dispute of the Rue Affidavit assert that its patented product, Adderall XR, does not fall within the scope of claim 22 of the 090 Patent. Since this assertion was not made previously, Shire argues that it goes to a new argument, possibly but not necessarily an improper listing argument. Shire argues that the portions in dispute should therefore be struck.

[17] Having read the portions in dispute, I am satisfied that they do not assert that Adderall XR actually falls outside the scope of claim 22. Rather, they are part of an argument that the claim construction in the affidavit of James Polli should not be followed because it leads to the conclusion that Adderall XR is outside the scope of claim 22.

[18] In light of this, as well as the explicit indication by Cobalt that improper listing is not in issue, I am not prepared to find that Prothonotary Tabib was clearly wrong in refusing to strike the portions in dispute of the Rue Affidavit.

C. *Reply Evidence*

[19] In view of my finding concerning the Rue Affidavit, it follows that Prothonotary Tabib was not clearly wrong when she found that the proposed reply evidence was not necessary or relevant. She did not err in failing to conduct an assessment using the four-point test set out in *Merck-Frosst v Canada (Health)*, 2009 FC 914 at para 10.

VI. Conclusion

[20] For the reasons set out above, I have concluded that Prothonotary Tabib made no error in her Order, and that the present motion should be dismissed with costs. Because time did not permit during the hearing of the present motion, I agreed to allow the parties to make written representations as to costs after release of the present decision.

ORDER

THIS COURT ORDERS that:

1. The present motion is dismissed.
2. Cobalt shall have its costs of this motion from Shire in an amount to be determined following the receipt of representations from the parties as follows:
 - a. Cobalt may submit written representations of no more than three (3) pages no later than one week following the date of this Order;
 - b. Shire may submit written representations of no more than three (3) pages no later than one (1) week following submission of Cobalt's written representations; and
 - c. Cobalt may submit written representations in reply of no more than two (2) pages no later than four (4) days following submission of Shire's written representations.

"George R. Locke"

Judge

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET: T-1472-13

STYLE OF CAUSE: SHIRE CANADA INC. v COBALT
PHARMACEUTICALS COMPANY AND THE
MINISTER OF HEALTH AND SHIRE LLC

PLACE OF HEARING: TORONTO, ONTARIO

DATE OF HEARING: APRIL 2, 2015

ORDER AND REASONS: LOCKE J.

DATED: APRIL 14, 2015

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