

Federal Court



Cour fédérale

Date: 20100125

Docket: T-1983-08

Citation: 2010 FC 81

Toronto, Ontario, January 25, 2010

PRESENT: The Honourable Mr. Justice Zinn

BETWEEN:

**JANSSEN-ORTHO INC. and
ALZA CORPORATION**

Applicants

and

**APOTEX INC. and
THE MINISTER OF HEALTH**

Respondents

REASONS FOR ORDER AND ORDER

[1] Separate motions were heard together in Court files T-1983-08 and T-775-09, which involve the same parties and arise out of twin applications. The applications are made pursuant to the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133, as amended (NOC

Regulations) with respect to a methylphenidate product for which Apotex Inc. (Apotex) seeks Notices of Compliance from the Minister. These applications have been agreed to be consolidated and are scheduled to be heard commencing April 12, 2009. Given the similarity of the motions, the reasons in both are identical, although separate Reasons for Order and Order will issue in each file. Given the short time before hearing of these applications, my reasons will be brief.

[2] The order of evidence in these applications was reversed. Apotex was required to file first its evidence as to validity before the Applicants were required to file their evidence. The normal order of evidence as to infringement was maintained with Apotex responding to the Applicants' evidence.

[3] The Applicants move to strike certain paragraphs and exhibits from the evidence of Apotex. All of the impugned evidence was filed by Apotex in response to the Applicants' evidence on infringement. It is submitted by the Applicants that the impugned paragraphs and exhibits relate to the issue of the invalidity of Canadian Patent No. 2,264,852 (the '852 patent) and not to the issue of infringement of the '852 patent by the Apotex methylphenidate product.

[4] The Applicants assert that invalidity evidence filed by Apotex is interspersed throughout by evidence in respect of non-infringement. If so, it is submitted, this violates the Court's scheduling Orders. The Applicants in their Notices of Motion ask that this evidence be struck. In the alternative, the Applicants seek leave to file reply evidence. If the evidence is not struck, then the Applicants ask that the schedule for the completion of the steps to hearing be revised. This last request for relief in the Notice of Motion was not pursued at hearing; counsel for the Applicants

advised the Court that regardless of the outcome of this motion, the current scheduled hearing dates can be met.

[5] Apotex submits that the impugned evidence is appropriate non-infringement evidence, not invalidity evidence. It submits that “virtually all of the impugned evidence is in direct response to evidence raised for the first time by the Applicants in their non-infringement evidence and Apotex is thus entitled to lead it.” They submit that the Applicants have failed to meet the test for reply evidence and that they should not be granted leave to file the proposed affidavits of Kennerly Patrick and James Swanson.

[6] A few words are in order concerning motions to strike in NOC proceedings. Prothonotary Aalto recently reviewed the jurisprudence of this Court relating to motions to strike affidavit evidence in this context: see *Proctor & Gamble Pharmaceuticals Canada Inc. v. Canada (Minister of Health)*, 2009 FC 113. I agree with his observation that such motions must be the exception and that complaints about the evidence are best left to the hearing judge. In my view, it is only where the evidence challenged is clearly improper, in the sense that it is scandalous or vexatious, or it is without doubt abusive or irrelevant, that the evidence ought to be struck prior to the hearing.

[7] The scheduling Orders of the Court are to be respected. In NOC proceedings, where the order of evidence has been reversed, parties ought not to file evidence in the second tranche that clearly and without question ought to have been filed in the first tranche. To proceed in such a fashion would be a clear abuse of the Court’s Orders and processes. However, in order to warrant a pre-hearing motion and the time of the Court, the evidence about which a party complains must

clearly and without question relate only to the issue on which the party has already filed its evidence. Accordingly, in this case, if the impugned evidence clearly and without question relates only to validity, I am prepared to strike it, notwithstanding that motions of this sort are to be discouraged.

[8] I turn to examine the impugned evidence.

John Hems Affidavit

[9] The Applicants seek to strike paragraph 12 of the affidavit of John Hems and the exhibit referenced therein. That paragraph reads as follows:

I was further asked by Mr. Clarizio [with the firm that is counsel to Apotex] to provide testing data, if available, that Apotex possessed in relation to Ritalin SR. Attached as Exhibit “F” to this my affidavit is a DVD containing a study that was done for Apotex (“the bio-study”). The bio-study involved testing Ritalin SR and a product that was developed by Apotex.

[10] The bio-study attached as an exhibit was not made a part of the record before the Court on these motions but apparently runs to more than 3,000 pages. Apotex asserts that only 20 pages of it, the pages referenced by Dr. Ping Lee, are relevant.

[11] It is not stated by Mr. Hems why he produces the bio-study in his affidavit, except to state that the lawyer for Apotex asked him. It is evident that it was attached to his affidavit in order to properly identify it so others, Dr. Ping Lee in fact, might speak to it. For that reason, the status of the bio-study and paragraph 12 of Mr. Hems’ affidavit stands or falls with the evidence of Dr. Lee that relates to the bio-study document.

David Greenblatt Affidavit

[12] The Applicants submit that paragraphs 7 and 11 to 14 of Dr. Greenblatt's affidavit deal with ambiguity and thus are directed to validity. They point to the following passages to illustrate their allegation:

- “Reference is repeatedly made in these affidavits to the ambiguous and variable language found in the ‘852 Patent.”
- “In the context of the ‘852 Patent, it is my opinion that these terms are ambiguous...”
- “Thus, a phrase such as “sustained ascending dose over time” would also, in my opinion, have been ambiguous to the notional clinical psychologist ...”

[13] I agree with the submissions of Apotex that these paragraphs are made in response to the Applicants' infringement evidence and that they relate to what is meant by the phrase “sustained ascending dose over time” as used in the patent. This evidence goes to the proper interpretation of the patent.

[14] The patent must be interpreted before issues of validity or infringement are determined. There is no question that evidence going to interpretation was put forward by Apotex earlier in its affidavits directed to validity. It was suggested that a party should put all of its evidence on interpretation in the affidavits that it files first, in cases where the order of evidence has been reversed; however, there is no jurisprudence or rule that prevents a party from advancing evidence that goes to interpretation in the second tranche. In my view, the Court ought to consider such

evidence, especially if it responds to something just filed by the party opposite. I am satisfied that the impugned paragraphs meet that test.

[15] The Applicants submit that paragraphs 38 to 45 of Dr. Greenblatt's affidavit relate to validity. Apotex submits that these paragraphs support the Gillette defence it raised in its Notice of Allegation that its product would not infringe the '852 patent because it will be "made, constructed, used and sold in accordance with the teachings of the prior art." Therefore, it submits, it is obligated to discuss that prior art, including Ritalin SR, which is the subject of the paragraphs. The Applicants submitted that it is fallacious to state that evidence related to the Gillette defence must relate to infringement and provided the Court with an interesting interpretation of the grounding of that defence in support of their view. That view is better left to be decided by the hearing judge than a judge on a motion of this sort. I do not find that these impugned paragraphs are clearly and without question related only to validity. It was noted that counsel made the statement at the hearing that the Patrick article cited at paragraph 41 is "in the main" related to invalidity. This suggests that it is related in part to other aspects of the application; if so, it should not be struck. For these reasons these paragraphs will not be struck at this stage.

[16] The Applicants submit that paragraphs 57 and 62 relate to construction of the '852 patent and go to the issue of its validity in that it alleges that the figures in the patent reflect artificial and not real profiles. Again, they relate in part to construction of the claims, and therefore are not struck.

Ping Lee Affidavit

[17] Paragraph 14 is alleged to be a statement that is in the nature of reply evidence and thus inappropriate. Dr. Ping Lee begins this paragraph with the phrase “As with earlier paragraphs, Dr. Davies in his paragraph 60 misses the point that I was conveying...” and he then goes on to reiterate what his point was. I agree with the Applicants that this paragraph is reply; it adds nothing new, and is improper. It is struck.

[18] At paragraph 19, Dr. Lee speaks to two US patents and to the statements made by Dr. Davies, the Applicants’ witness, concerning them. These patents are prior art and it is submitted that the impugned paragraph must be directed to validity. Apotex submits that they relate to its Gillette defence. I am not convinced at this stage that the statements made in this paragraph do relate to the Gillette defence and thus are saved as being directed, in part, to infringement; however, Apotex ought to be able to make that case to the hearing judge based on a complete record including cross-examination and this paragraph is not struck.

[19] The Applicants submit that paragraphs 47 to 49 relate to claim 1 of the ‘852 patent and the construction of the phrase “over time” and they point out that Dr. Lee failed to raise this evidence in his first affidavit on construction. Much of the impugned evidence responds directly to statements made by Dr. Patrick in his affidavit filed on infringement or to its Exhibits “S” and “T”. Further, the evidence appears to have some relevance to the construction of the ‘852 patent and thus will not be struck.

[20] In paragraph 50 Dr. Ping Lee refers to Exhibits “S” and “T” to the affidavit of Dr. Patrick and then states that “these are not the only published papers where Ritalin SR had a plasma profile that peaked at 4 hours or greater” and he then goes on to point out that the article attached as Exhibit “U” to Dr. Patrick’s affidavit also showed patients whose plasma profile peaked at 4 hours or greater and concludes that “it is clear that the plasma levels for Ritalin SR, in some instances, ascended continuously to 4 hours or more.” This statement appears on its face to be responding to Dr. Patrick’s statements; however, it does not challenge his evidence or contradict it. It is in fact not responding at all to Dr. Patrick’s evidence. It’s only obvious relevance would be as evidence of prior art that goes to the issue of validity. It has no obvious connection either to infringement or to interpretation of the patent and is struck. The statements made by Dr. Lee in this paragraph are more appropriate for cross-examination of Dr. Patrick.

[21] At paragraphs 53 and 68 and Exhibit “B” Dr. Lee turns to the Apotex bio-study. The Applicants describe this as evidence that is “post art” as it was done in 2003, well after the ‘852 patent. Apotex submits that this evidence “is in response to paragraphs 99-103, and exhibits “S” and “T”, of Dr. Patrick’s non-infringement affidavit.” It is said that it specifically addresses his statement that “the ‘852 Patent refers to the plasma profile of the Ritalin-SR formulation as “nonascending profile over time.” Through this post art Apotex challenges the assertion that the plasma profile of Ritalin SR is a flat profile and it says that it is a continuously ascending profile.

[22] The Applicants submit that there is no evidence that the Ritalin SR that was the drug studied in the 2003 in the bio-study is exactly the same as that which existed at the time the ‘852 patent

issued and absent such evidence the study cannot assist in interpretation of the '852 patent insofar as it discusses Ritalin SR.

[23] It is not obvious to the Court that the Ritalin SR that was the subject of the bio-study was not the identical formulation referenced in the '852 patent. A more complete record, such as will exist at the hearing is required to assess this submission's merit. It is also not obvious to the Court that the impugned evidence does not go to interpretation. Accordingly, it is not struck.

[24] As a consequence paragraph 12 and Exhibit "F" to the affidavit of John Hems are also not struck.

Christopher Varley Affidavit

[25] A challenge was made to paragraph 30 but was dropped at the hearing when it was conceded by counsel that it could arguably relate to interpretation.

[26] In paragraphs 38 and 39 Dr. Varley discusses Metadate CD. In paragraph 38 his statement regarding it begins with the phrase "I reiterate," being a reference to his earlier affidavit on validity.

[27] Apotex submits that these paragraphs relate to non-infringement. "At page 13 of Apotex's NOAs, Apotex stated that its product will not infringe the '852 Patent because, among other things, it will not regulate and compensate for acquired tolerance. Dr. Varley's impugned affidavit is simply that the Metadate CD product, which has a similar profile to the '852 Patent (and therefore, according to the Applicants' theory, to Apotex's proposed product), does not regulate tolerance."

[28] Infringement requires that the Apotex product be compared to the '852 patent. Whether Metadate CD does or does not regulate tolerance and whether it does or does not have a profile similar to the '852 patent is entirely irrelevant to infringement by the Apotex methylphenidate product. I also reject the submission that this evidence goes to interpretation of the phrase "sustained ascending dose" as not referring to plasma on the basis that Metadate CD has an ascending plasma profile but there is no discussion that it might regulate tolerance. There is no connection between the impugned paragraphs and the interpretation of the '852 patent. It is lastly submitted that these paragraphs respond to Dr. González who introduced Metadate CD in his affidavit. It is true that Dr. González mentions Metadate CD; however, his reference to Metadate CD is at paragraph 11 of his affidavit wherein he describes his experience in the research and development of methylphenidate dosage forms. As such, while it is mentioned in his affidavit, there is nothing therein that requires the response provided.

[29] The Applicants submit that if these paragraphs are permitted to stand then they should be permitted to reply to them as they could not have been reasonably anticipated by them. I agree. However, given the irrelevance of the evidence in these impugned paragraphs to the issue of interpretation or non-infringement, I conclude that the proper course is to strike them.

[30] The Applicants object to paragraph 59. Dr. Varley makes two comments therein. The first is his opinion that the Applicants' experts are giving terms meanings that are "not clearly defined within the body of the '852 Patent." Secondly, he reiterates his position from his first affidavit that

these terms are capable of multiple meanings. While this evidence may be redundant, it goes to interpretation not to validity and is not struck.

[31] In paragraph 61, Dr. Varley returns to the Applicants' experts' evidence and says that he finds it difficult to accept their interpretations "based on what is described in the patent" and concludes that as the '852 patent is "providing 'mixed' messages, the patent simply is not clear on what the invention actually is." This paragraph alleges the patent is ambiguous and thus goes to invalidity. It is struck.

Reza Fassihi Affidavit

[32] The Applicants submit that paragraphs 29 to 31 are improper as relating to validity. Apotex submits that these paragraphs respond to Dr. Davies' affidavit, and in particular to paragraph 22 wherein he discusses the words "dose" and "sustained-ascending dose". While Dr. Davies' affidavit is directed to both validity and infringement, his paragraph 22 is directed to interpretation of the '852 patent, and in my view, Dr. Fassihi is entitled to respond to that interpretation.

Reply Evidence

[33] Rule 312(a) of the *Federal Courts Rules* permits this Court to grant leave to file additional evidence. In *Atlantic Engraving v. Lapointe Rosenstein*, 2002 FCA 503 at paras. 8-9, the Court of Appeal described four requirements that must be met before this Court may permit additional affidavits:

- (a) The evidence to be adduced will serve the interests of justice;
- (b) The evidence will assist the Court;

- (c) The evidence will not cause substantial or serious prejudice to the other side; and
- (d) The evidence must not have been available at an earlier date.

In *Deigan v. Canada (Industry)* (1999), 168 F.T.R. 277 (T.D.) aff'd (1999), 165 F.T.R. 121 (T.D.), a fifth requirement was enunciated: The evidence will not unduly delay the proceeding. These five criteria were applied in *Merck Frosst Canada & Co. v. Canada (Minister of Health)*, 2003 FCT 287 at para. 12 and *Pfizer Canada Inc. v. Canada (Minister of Health)*, 2007 FC 168 at para. 5.

[34] Apotex submits that the proposed reply evidence was available at an earlier date, that supplementing the record will unduly delay the proceeding, that it will result in prejudice to its interests, and that the interests of justice should favour not permitting the filing of the proposed affidavits.

[35] In view of my disposition of paragraphs 38 and 39 of Dr. Varley's affidavit, the Applicants admit that no reply affidavit is required from Dr. Swanson. The Court need only consider Dr. Patrick's proposed reply affidavit.

[36] With one exception, the Applicants have not demonstrated that the proposed evidence of Dr. Patrick was not previously available or could not have been anticipated as relevant. I agree with Apotex that many of the proposed paragraphs from Dr. Patrick simply reiterate or rephrase his earlier evidence. Much of the proposed evidence relates to matters more appropriate for cross-examination of the affiants his proposed affidavit addresses. I have reviewed his proposed affidavit with care and have concluded that the only part of his proposed affidavit that could not be reasonably anticipated by the Applicants to be relevant when they filed their evidence and which

could assist the Court are the paragraphs relating to the Apotex bio-study, i.e. paragraphs 25 to 30. Accordingly, the Applicants are granted leave to file reply evidence from Dr. Patrick consisting of paragraphs 25 to 30 of the proposed affidavit, together with the necessary introductory paragraphs.

Costs

[37] In view of the divided success on the motion, there will be no costs awarded.

ORDER

THIS COURT ORDERS that:

1. Paragraphs 14 and 50 of the affidavit of Dr. Ping Lee are struck;
2. Paragraphs 38, 39 and 61 of the affidavit of Christopher Varley are struck;
3. The Applicants are granted leave to file reply evidence consisting of paragraphs 25 to 30 of the proposed affidavit of Dr. Patrick, together with the necessary introductory paragraphs; and
4. No costs are awarded.

“Russel W. Zinn”

Judge

FEDERAL COURT
SOLICITORS OF RECORD

DOCKET: T-1983-08

STYLE OF CAUSE: JANSSEN-ORTHO INC. and ALZA CORPORATION v.
APOTEX INC. and THE MINISTER OF HEALTH

PLACE OF HEARING: Toronto, Ontario

DATE OF HEARING: January 20, 1020

**REASONS FOR ORDER
AND ORDER:** ZINN J.

DATED: January 25, 2010

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