Federal Court  Cour fédérale

Date: 20191018

Docket: T-353-18

Citation: 2019 FC 1309

Ottawa, Ontario, October 18, 2019

PRESENT: The Honourable Mr. Justice Manson

BETWEEN:

JANSSEN INC.

Plaintiff

and

JANSSEN PHARMACEUTICA N.V.

Plaintiff
(Defendant by Counterclaim)

and

TEVA CANADA LIMITED

Defendant
(Plaintiff by Counterclaim)

JUDGMENT AND REASONS

I. Introduction

[1] This is a motion brought by Teva Canada Ltd [Teva], the Defendant and Plaintiff by counterclaim, seeking leave to serve the reply expert reports of Dr. Suzanne Allain, Dr. James Simm, and Dr. Herman Vromans [the Reply Reports].

[2] Teva's motion arises in the context of a patent infringement action pursuant to subsection 6(1) of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133. The Plaintiffs, Janssen Inc and Janssen Pharmaceutica NV [Janssen] allege infringement of Canadian Patent No. 2,655,335 [the '335 Patent]. Teva denies infringement, and alleges that the patent is invalid for obviousness and lack of patentable subject matter.

[3] The '335 Patent relates to formulations of paliperidone palmitate, a medicine approved for sale in Canada by Janssen for the treatment of schizophrenia and maintenance treatment of schizoaffective disorder. Janssen sells the drug under its INVEGA SUSTENNA® brand.

[4] Teva claims it was unable to fully appreciate Janssen's position on validity of the '335 Patent prior to receiving Janssen's expert reports, and therefore should be allowed to serve the Reply Reports.

II. Background

[5] The parties exchanged expert reports in chief on May 31, 2019. Teva served expert reports on validity of the '335 Patent and Janssen served expert reports on infringement.

[6] The parties exchanged responding expert reports on August 15, 2019. Teva served responding expert reports on infringement, and Janssen served responding expert reports on validity of the '335 Patent.

[7] On September 9, 2019, Teva served the Reply Reports. Janssen objected to the entirety of each of the Reply Reports.

[8] The trial was scheduled to start on September 30, 2019, but has been adjourned until February 3, 2020 by Order of this Court.

[9] Pursuant to the trial management conference held on September 23, 2019, Teva brought this motion for leave to serve the Reply Reports.

[10] Teva's position is that the Reply Reports address issues that were not anticipated when the expert reports in chief were exchanged.

III. Issues

[11] The sole issue for the Court to decide on this motion is whether Teva should be granted leave to serve and file the Reply Reports.

IV. Analysis

[12] Rule 274(1) of the *Federal Courts Rules*, SOR/98-106, sets out the typical order in which parties present their evidence, including reply:

> 274 (1) Subject to subsection (2), at the trial of an action, unless the Court directs otherwise,
>
> (a) the plaintiff shall make an opening address and then adduce evidence;
>
> (b) when the plaintiff's evidence is concluded, the defendant shall make an opening address and then adduce evidence; and

> (c) when the defendant's evidence is concluded, the plaintiff may adduce reply evidence.

[13] This rule is tempered by limits on the introduction of reply evidence imposed by the common law rules of evidence. The general rule is that the plaintiff will not be allowed to split its case (*R v Krause*, [1986] 2 SCR 466 at 473). In other words, the plaintiff cannot adduce evidence on reply that is merely confirmatory of the case in chief. Proper reply evidence must relate to issues raised in the defence's case that were not raised in the plaintiff's case in chief (*Amgen Canada Inc v Apotex Inc*, 2016 FCA 121 at para 12 [*Amgen*]).

[14] Allowing a wide range of evidence could be unfair to a party who relied on opposing evidence in chief to know the case it has to meet. Further, case-splitting could create an unending alternation of successive fragments of the case coming forward (*Amgen*, above at para 12).

[15] Contrary to Teva's submissions, there is no gap in the *Federal Courts Rules* related to reply evidence, and hence the gap rule is not applicable (*Federal Courts Rules*, r 4).

[16] The principles governing the admissibility of reply evidence were aptly summarized by Justice Pelletier, as he then was, in *Halford v Seed Hawk Inc*, 2003 FCT 141 at para 15 [*Halford*]:

> 1. Evidence which is simply confirmatory of evidence already before the court is not to be allowed.
>
> 2. Evidence which is directed to a matter raised for the first time in cross examination and which ought to have been part of the plaintiff's case in chief is not to be allowed. Any other new matter relevant to a matter in issue, and not simply for the purpose of contradicting a defence witness, may be allowed.

> 3. Evidence which is simply a rebuttal of evidence led as part of the defence case and which could have been led in chief is not to be admitted.
>
> 4. Evidence which is excluded because it should have been led as part of the plaintiff's case in chief will be examined to determine if it should be admitted in the exercise of trial judge's discretion.

[17] These principles apply equally to expert reports (*Dow Chemicals Co v Nova Chemicals Corp*, 2014 FC 855 at paras 5-8 of Schedule A). Mere disagreement with statements made by another witness is not proper subject matter for reply evidence. Disagreements between experts can be addressed by cross-examination.

[18] Teva's proposed Reply Reports must comply with these principles. Teva submits that Janssen's pleadings were deficient, leaving Teva to guess at what issues and documents would be relevant to the central issues. Further, Janssen refused to answer certain questions during discovery, indicating that the information sought would be addressed in expert evidence.

[19] Teva's position is that the Reply Reports are its response to information that was not available or known or anticipated to be relevant to the issues in this proceeding prior to Janssen serving its expert reports.

[20] With respect to the pleadings, Janssen argues that Teva bears the burden of establishing invalidity as the plaintiff by counterclaim. Teva, not Janssen, asserted that the '335 Patent is invalid on the basis of obviousness and unpatentable subject matter. After receiving Janssen's Reply and Defence to Counterclaim, Teva did not demand particulars or move to strike any of Janssen's pleadings, but now claims that the pleadings were deficient.

[21] Janssen submits that the discovery refusals referenced by Teva in its written submissions were proper. This position is supported by Teva's lack of success on its motion to compel Janssen with respect to each of these questions.

[22] Janssen further submits that the issue of pharmacokinetic modeling as a part of the inventors' course of conduct forms much of Teva's Reply Reports, and this issue was known to Teva when evidence in chief was filed. Specifically, the '335 Patent refers to population pharmacokinetic analysis, and the figures in the patent are based on population pharmacokinetic modeling. The pharmacokinetic analysis undertaken during the development of paliperidone palmitate is also set out in documents produced by Janssen.

[23] Teva questioned two of the '335 Patent inventors, Dr. Vermeulen and Dr. Samtani, on their involvement in pharmacokinetic and pharmacodynamic modeling during examinations for discovery. Accordingly, Teva could not have been surprised that population pharmacokinetic modeling would be relevant to the issue of the inventors' course of conduct.

[24] In Janssen's view, Teva waited to see how Janssen's experts would address the issue of population pharmacokinetic modeling, and then had its experts address the issue in the Reply Reports. This framing of the exchange of expert reports constitutes case-splitting.

[25] A majority of the proposed Reply Reports amounts to simply disagreeing with Janssen's experts, restating Teva's experts' initial opinion, or Teva's experts stating they are surprised by

statements made by Janssen's experts. These portions of the Reply Reports should not be admissible based on the principles laid out by Justice Pelletier in *Halford*.

[26] However, any evidence that could have been led as part of Teva's case in chief must still be examined to determine if, in the Court's discretion, it should be nevertheless admitted. Given the 4-month adjournment resulting from a medical emergency in this matter, the Court could arguably grant Janssen the right to file sur-reply reports, without running up against the trial date. But to serve what purpose? Absent any new issues raised in Janssen's expert reports, there is no need for an endless cycle of reports, merely as rebuttal of opposing experts' reports or confirmatory evidence already provided in chief.

A. *Proposed Reply Expert Statement of Dr. Suzanne Allain*

[27] In paragraph 1 Dr. Allain states that she has been asked by counsel for Teva to respond to statements in Dr. Ofer Agid's Validity Expert Statement that she could not have anticipated in preparing her first two reports.

[28] In paragraph 3 Dr. Allain responds to Dr. Agid's opinion of her definition of the POSITA. This paragraph is a mere rebuttal or disagreement with Dr. Agid's opinion, and is not proper reply.

[29] Paragraphs 4-6 relate to the inventive concept of the '335 Patent. Dr. Allain disagrees with Dr. Agid's opinion on various aspects of the inventive concept. Teva had the opportunity in

its counterclaim to deal with its version of inventive concept and chose not to do so. Again, these paragraphs merely rebut or disagree with Dr. Agid's opinion, and are not proper reply.

[30] In paragraph 7 Dr. Allain responds to Dr. Agid's statement that risperidone is the most sedating compound in its class. Dr. Allain cites a report discussing sedating effects of various antipsychotics. Teva argues that this statement was not anticipated because it is not correct, and therefore this paragraph constitutes proper reply. I disagree. Teva can address the correctness of this statement during cross-examination of Dr. Agid without the need for reply evidence on this issue.

[31] Paragraph 8 addresses the use of loading dose regimens as discussed by Dr. Agid in his expert report. Again, Dr. Allain states that Dr. Agid's opinion is incorrect and cites various sources. This evidence is merely a rebuttal of Dr. Agid's expert evidence, and could have been led in chief. Teva can cross-examine Dr. Agid on this point. Moreover, the use of loading doses was discussed by Teva's other experts, Dr. Kwon and Dr. Vromans.

[32] In paragraphs 9-12 Dr. Allain addresses Dr. Agid's disagreement with her clinical practices with respect to the loading and maintenance doses of Invega Sustenna. Dr. Allain states she is not "repeating the opinion in [her] earlier reports," and goes on to critique Dr. Agid's prescribing practices. Dr. Allain further states that she prefers the approach employed by Dr. Simm, one of Teva's other experts, over that of Dr. Agid. These paragraphs amount to an attempt to contradict Dr. Agid's evidence, while amplifying the expert testimony of Teva's other witness.

These paragraphs also seek to confirm evidence already before the Court in Dr. Simm's report, and should not be admitted.

[33] In paragraphs 13-15 Dr. Allain disagrees with Dr. Agid's criticisms of Dr. Simm's Expert Report. Again, these paragraphs amount to an attempt to contradict Dr. Agid's evidence, while endorsing Dr. Simm's opinion which is already before the Court, and should not be admitted.

[34] In paragraphs 16-28 Dr. Allain disagrees with Dr. Agid's opinion that prescribing the loading dose of Invega Sustenna does not require judgment. In several places Dr. Allain states that she is surprised by Dr. Agid's opinion. Dr. Allain also states that she disagrees with Dr. Agid's disagreement with passages of her initial expert reports. Dr. Allain is effectively affirming her initial evidence, while attempting to contradict Dr. Agid's opinion. These paragraphs are not proper reply and should not be admitted.

[35] None of the proposed reply report of Dr. Allain constitutes proper reply evidence.

B. *Proposed Reply Expert Statement of Dr. James Simm*

[36] In Paragraph 1 Dr. Simm states that he has been asked by counsel for Teva to respond to statements in Dr. Ofer Agid's Validity Expert Statement that he could not have anticipated in preparing his previous reports.

[37] Paragraph 3 addresses Dr. Agid's statement that risperidone is the most sedating compound in its class. Dr. Simm opines that various other drugs are known to be more sedating

than risperidone, referencing the Centre for Addiction and Mental Health website. Teva advances the same arguments that it advanced on this point with respect to Dr. Allain's report, and for the same reasons, I disagree. Teva can address the correctness of this statement during cross-examination of Dr. Agid, if necessary.

[38] In paragraphs 4-6 Dr. Simm disagrees with Dr. Agid's opinion on use of loading doses in clinical practice. Again, this evidence is merely a rebuttal of Dr. Agid's expert evidence, and could have been led in chief. Teva can cross-examine Dr. Agid on this point. Moreover, the use of loading doses was discussed by Teva's other experts, Dr. Kwon and Dr. Vromans.

[39] In paragraph 7, Dr. Simm disagrees with Dr. Agid's disagreement with Dr. Allain's practice of administering Invega Sustenna. This paragraph is an attempt to contradict Dr. Agid's evidence, while endorsing Dr. Allain's practice. This paragraph seeks to confirm evidence already before the Court in Dr. Simm's report, and should not be admitted.

[40] Paragraphs 8-10 address Dr. Agid's view that Dr. Simm's definition of the POSITA is too restrictive. Dr. Simm disagrees with Dr. Agid's view and goes on to restate part of his initial statement about the POSITA from his initial expert report. Dr. Simm is merely confirming his initial evidence that is already before the Court, and attempting to contradict Dr. Agid. Further, all of Teva's experts provided their opinion on the POSITA in their initial reports. These paragraphs are not proper reply and should not be admitted.

[41] In paragraph 11 Dr. Simm takes issue with Dr. Agid's construction of the term "maintenance dose." Teva asserts that Dr. Agid's view is incorrect, and therefore could not have been anticipated when Dr. Simm's initial report was prepared. Dr. Simm has already provided his view on issues of construction in his initial report, including discussion of the meaning of the term "maintenance dose." Addressing this issue again by way of disagreeing with Dr. Agid's view in reply is not proper. This paragraph should not be admitted.

[42] In paragraphs 12-28 Dr. Simm responds to Dr. Agid's criticisms of Dr. Simm's initial opinion on the use of paliperidone palmitate in practice, including whether or not physicians follow the product monograph. Dr. Simm's view of this issue is already before the Court, and these paragraphs serve no purpose other than to rebut Dr. Agid's criticisms. They should not be admitted.

[43] In paragraphs 29-35 Dr. Simm addresses Dr. Agid's characterization of the inventive concept of the '335 Patent. As with paragraphs 4-6 of Dr. Allain's proposed reply statement, these paragraphs merely rebut or disagree with Dr. Agid's opinion, and are not proper reply.

[44] The proposed reply report of Dr. Simm does not constitute proper reply evidence.

C. *Proposed Reply Expert Report of Dr. Herman Vromans*

[45] In Paragraph 1 Dr. Vromans states that he has been asked by counsel for Teva to respond to statements in Dr. Robert R. Bies and Dr. Larry Ereshefsky's expert reports that he could not have anticipated in preparing his first report.

[46] Paragraphs 4-14 relate to the definition of the POSITA. Dr. Vromans takes issue with Dr. Ereshefsky's comments critiquing Dr. Vromans' definition of the POSITA. As with the proposed reply evidence of Dr. Allain, these paragraphs are mere rebuttal or disagreement with Dr. Ereshefsky's opinion, and are not proper reply. Insofar as they are not already included in the pleadings, the prior art documents attached as Schedules A through C to this report will be added to Appendix B to the Amended Defence and Counterclaim for the limited purpose discussed in paragraph 56 below.

[47] In paragraph 15 Dr. Vromans addresses Dr. Ereshefsky's critiques of his construction of claim 1 of the '335 Patent. Dr. Vromans states that it is unclear to him what Dr. Ereshefsky disagrees with, and goes on to restate and clarify his position on construction. This paragraph amounts to a restatement of evidence before the Court and a rebuttal of Dr. Ereshefsky's evidence, and is not proper reply.

[48] Paragraphs 16-39 relate to the common general knowledge and prior art relating to pharmacokinetics discussed by Dr. Ereshefsky in his report. Dr. Vromans agrees with Dr. Ereshefsky's inclusion of certain concepts and details as part of the common general knowledge, but disagrees on the importance of these concepts and details. Dr. Vromans goes on to restate his opinion on the knowledge of the POSITA at the relevant time that was set out in his initial report, and refine his opinion based on Dr. Ereshefsky's opinion. Nothing contained in these paragraphs constitutes proper reply. Dr. Vromans is simply critiquing Dr. Ereshefsky and restating the original opinion he tendered in Teva's evidence in chief – classic case-splitting.

[49] Insofar as they are not already included in the pleadings, the prior art documents referred to in paragraph 28 and attached as Schedules E through G to this report will be added to Appendix B to the Amended Defence and Counterclaim for the limited purpose discussed below.

[50] Paragraphs 40-46 address the inventive concept of the ‘335 Patent. Dr. Vromans sets out Dr. Ereshefsky’s opinion on the inventive concept, and proceeds to critique it, stating that the opinion is not supported by the patent itself. Dr. Vromans goes on to restate his opinion of the inventive concept. Again, these paragraphs contain nothing more than a disagreement between experts and a restatement of evidence already before the Court, not proper reply.

[51] Paragraphs 47-50 address the extent of the effort required to determine dosing windows and the injection site, as well as the motivation to find the optimal dosing regimen. Dr. Vromans critiques Dr. Ereshefsky’s opinion, and then restates his opinion from his first report. These paragraphs are not proper reply.

[52] Paragraphs 51-53 and 57-76 (critiquing Dr. Bies’ expert statement) are focused on the actual work done by the inventors. Dr. Vromans outlines the opinions of Dr. Ereshefsky and Dr. Bies on this issue, and then states that much of the work outlined in these opinions would have been routine. Dr. Vromans also disagrees with several conclusions made by Dr. Ereshefsky and Dr. Bies. Again, these paragraphs contain nothing more than a disagreement between experts. They are not proper reply.

[53] That said, insofar as they are not already included in the pleadings, the prior art documents referred to in paragraphs 60, 62, 63, 66, 67, and 70, and attached as Schedules H through O to this report will be added to Appendix B to the Amended Defence and Counterclaim for the limited purpose discussed in paragraph 56 below. Paragraphs 54-55 refer to the advantages of Invega Sustenna discussed by Dr. Ereshefsky with reference to two pieces of alleged prior art raised by Teva. Dr. Vromans already referred to both pieces of prior art in his initial report. These paragraphs contain disagreement between experts and a restatement of evidence already before the Court. They are not proper reply.

[54] Paragraph 56 relates to the inventive concept identified by Dr. Bies. Dr. Vromans states that he agrees with the inventive concept identified to the extent that it is consistent with the inventive concept identified in his initial report, but disagrees with certain other aspects. This disagreement is not proper reply evidence.

D. *Amended Statement of Defence and Counterclaim*

[55] Rule 75 of the *Federal Courts Rules* is the applicable rule:

> 75 (1) Subject to subsection (2) and rule 76, the Court may, on motion, at any time, allow a party to amend a document, on such terms as will protect the rights of all parties.
>
> **Limitation**
>
> (2) No amendment shall be allowed under subsection (1) during or after a hearing unless
>
> (a) the purpose is to make the document accord with the issues at the hearing;
>
> (b) a new hearing is ordered; or

> (c) the other parties are given an opportunity for any preparation necessary to meet any new or amended allegations.

[56] Teva also seeks to further amend its Amended Statement of Defence and Counterclaim to include additional prior art documents referenced by Dr. Vromans in his proposed reply evidence. As I indicated to counsel at the hearing, the inclusion of relevant prior art, while late in the day, nevertheless should be considered for the Court to have a complete picture of the state of the art as long as it will not work an injustice on the Plaintiff. The trial is now scheduled for February 2020; this prior art may be contextually relevant for cross-examination of the expert witnesses and for that purpose only should be allowed as an additional amendment to Appendix B of the Amended Statement of Defence and Counterclaim (*Canderel Ltd v Canada* [1994] 1 FC 3 (FCA); *Nidek Co v VISX Inc* (1998) 234 NR 94 (FCA)).

V. Conclusion

[57] This Court cannot allow case-splitting or improper reply evidence seeking to bolster a party's evidence in chief or merely rebut an opposing party's evidence, particularly in light of the "litigation culture change prescribed by the Supreme Court of Canada in Hryniak v Maudlin, 2014 SCC 7" (*Amgen* at para 24).

[58] For the foregoing reasons, Teva's motion to file the reply evidence is dismissed. The motion to amend for the limited purpose set out above is allowed.

JUDGMENT in T-353-18

THIS COURT'S JUDGMENT is that

1. Teva's motion to file reply evidence is dismissed.
2. Teva's motion to amend Appendix B to the Amended Defence and Counterclaim to add the prior art referenced in the Reply Expert Report of Dr. Herman Vromans is allowed for the limited purpose of cross-examination of any expert witness at trial, if deemed necessary by any party.
3. Costs to Janssen assessed at the middle of Column III of Tariff B.

"Michael D. Manson"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

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