

Federal Court



Cour fédérale

Date: 20200121

Docket: T-353-18

Citation: 2020 FC 87

Ottawa, Ontario, January 21, 2020

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)**

ORDER AND REASONS

I. Introduction

[1] In the underlying action, the Plaintiffs [collectively Janssen] seek a declaration pursuant to subsection 6(1) of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 that the Defendant [Teva] will infringe any of claims 1 to 48 of Canadian Patent No. 2,655,335 [the '335 Patent].

[2] Janssen claims that the making, constructing, using or selling of Teva's proposed paliperidone palmitate product, TEVA-PALIPERIDONE INJECTION, by Teva will directly and/or indirectly infringe claims 1 to 48 of the '335 Patent.

[3] The '335 Patent is listed on the Patent Register in respect of Janssen's INVEGA SUSTENNA[®] product, a long-acting injectable drug product for the treatment of schizophrenia and schizoaffective disorder.

[4] The parties submitted a joint statement of issues on September 16, 2019. The contentious issues that remain are:

- i. Construction of the asserted claims of the '335 Patent
- ii. Infringement of the '335 Patent
- iii. Whether any of the asserted claims of the '335 are invalid for obviousness or lack of patentable subject matter (method of medical treatment).

II. Background

[5] On August 23, 2019, a Trial Management Conference was held to discuss objections to expert reports, expert qualifications, and potential proposed reply expert reports. The parties made submissions on their objections in September 2019, but the trial, initially scheduled to start on September 30, 2019, was adjourned until February 3, 2020 by Order of this Court.

[6] The Court dealt with the admissibility of Teva's reply reports by way of a separate motion (*Janssen Inc v Teva Canada Limited*, 2019 FC 1309). With the new trial date upcoming, this Order addresses the parties' hearsay and expert qualification objections.

III. Hearsay Objections

A. *Janssen's Objections & Teva's responses*

[7] The parties exchanged a first set of expert reports on May 31, 2019. Of these reports, Janssen objects to certain paragraphs of the Expert Report of Dr. Suzanne Allain dated May 21, 2019 [the Allain Report], the Expert Report of Dr. James Simm dated May 31, 2019 [the Simm First Report], and the Expert Report of Dr. Glenn Kwon dated May 31, 2019 [the Kwon Report].

[8] The parties exchanged a second set of expert reports on August 15, 2019. Of these reports, Janssen objects to certain paragraphs of the Responding Expert Report of Dr. James Simm dated August 14, 2019 [the Simm Second Report] and the Expert Report of Dr. Adil Virani dated August 13, 2019 [the Virani Report].

[9] I have considered the impugned paragraphs of the Reports and I find as follows:

(1) Paragraphs 13, 38, and 39 of the Allain Report

[10] Paragraph 13 is hearsay. Dr. Allain states she was informed by a Janssen sales rep that many psychiatrists use maintenance doses greater than 75 mg-eq and that the doses are administered as frequently as every two weeks. Teva argues this paragraph is offered to support the opinion that Dr. Allain provides in the preceding section, where she notes, “the maintenance dose I prescribe for my treatment-resistant patients is typically 100 or 150 mg-eq every 2 to 4 weeks.” This paragraph is not admissible.

[11] Paragraph 38 is not hearsay. Dr. Allain merely states that sales reps provide her with information and free samples. Janssen submits that this paragraph provides the context for the hearsay statements in paragraph 39. Regardless of the contents of paragraph 39, the information in paragraph 38 is not hearsay.

[12] Paragraph 39 is hearsay. Dr. Allain states the Janssen rep informed her of the maintenance doses that many psychiatrists are using. As with paragraph 13, this is hearsay and is inadmissible.

(2) Paragraphs 22, 48 (last sentence), and 50 of the Simm First Report

[13] Paragraph 22 is not hearsay. The recommendations referred to in this paragraph were made directly to Dr. Simm, and as such he has direct knowledge of what the recommendations

were, and this information is reliable. These statements are not tendered to establish the recommended loading and maintenance doses, but rather that Janssen reps have recommended these doses to Dr. Simm. To the extent this evidence has been tendered to establish what Janssen recommends to physicians through its representatives, the statements in paragraph 22 and 50 only establish what doses were recommended to Dr. Simm. This evidence is admissible, and any concerns about the reliability of the evidence will go to weight.

[14] Paragraph 48 (last sentence) is hearsay. Dr. Simm states that he “has heard” of some colleagues that have prescribed as frequently as every two weeks. This last sentence is hearsay and is inadmissible.

[15] Paragraph 50 is not hearsay. As with paragraph 22, these are recommendations made directly to Dr. Simm.

(3) Paragraph 119, footnote 61 of the Kwon Report

[16] Paragraph 119, footnote 61 is hearsay. The press release is an out of court statement, and the footnote appears to be included to establish the number of mental health professionals who attended the Congress. Therefore, the statement was submitted for the truth of its contents. Teva submits that this is allowable hearsay as it relates to Dr. Kwon’s opinion that all of the art he cites would have been found by the skilled person. I find that while hearsay, I will address any concerns with respect to the weight to be given to Dr. Kwon’s opinion evidence about what prior art a person of ordinary skill would have found at the relevant date.

(4) Paragraph 21 (third sentence) of the Simm Second Report

[17] This sentence is hearsay. The wording is obscured, however the statement is tendered to show that Dr. Simm was informed by his hospital that the most used doses are 150 and 100 mg-eq. This evidence is neither necessary or reliable and should have been introduced by direct knowledge of hospital personnel.

(5) Paragraphs 26 and 27 of the Virani Report

[18] Paragraph 26 is hearsay. As submitted by Janssen, the statements are intended to prove how hospital pharmacists at Dr. Virani's hospital respond to questions regarding a generic product. This is hearsay and inadmissible.

[19] Paragraph 27 is hearsay. As in paragraph 26, the impugned information is based on responses from the nine pharmacists to questions about how they use generic products. The paragraph is inadmissible.

IV. Objections for Opinions beyond the Expert's Qualifications

A. *Teva's Objections & Janssen's Responses*

[20] As noted above, the parties exchanged a first set of expert reports on May 31, 2019. Of these reports, Teva objects to paragraphs 24(a) and (b), 425, 429, 433—7, 446, 476, 477, 479, 482, 484 and 489-91 of the Validity Expert Statement of Dr. Ofer Agid dated August 15, 2019 [the Agid Validity Statement].

[21] Many of these paragraphs contain similarly worded statements about the prescribing practices of physicians in Canada. For example, in paragraph 24(a), Dr. Agid states:

In my opinion, [Dr. Allain's prescribing practices] are not representative of the prescribing practices of the majority of physicians in respect of the majority of patients.

(emphasis added)

[22] As identified by Janssen in its responding submissions, Teva provided the same rationale for objecting to each impugned paragraph of the Agid Validity Statement:

Dr. Agid cannot possibly know what the majority of physicians do when prescribing any medications, this statement can only be Dr. Agid's opinion, and it is not an opinion he is qualified to give.

[23] Janssen agrees that Dr. Agid is providing his opinion, but argues that these are opinions that he is qualified to provide based on his qualifications and professional experience. Teva did not object to Dr. Agid's initial expert report in which he stated that he is qualified to opine on the prescribing practices of physicians in Canada with respect to antipsychotic drugs.

[24] Based on the various positions Dr. Agid holds, Janssen submits that it is evident that he frequently interacts with other psychiatrists and healthcare professionals involved in the treatment of schizophrenia. Because of these frequent interactions, Dr. Agid is well positioned to learn and understand the prescribing practices of many other psychiatrists and healthcare providers in Canada.

[25] I am prepared to admit these paragraphs as evidence, and any concerns about the potential overstatement of the "majority of physicians in respect of the majority of patients" can

go to weight. These statements could be better understood as the majority of physicians in Canada *that Dr. Agid knows*, which, based on his expert qualifications, appears to be many, but certainly would not be all.

[26] In addition to objecting to opinions allegedly outside of Dr. Agid's qualifications, Teva submits that Dr. Agid's characterization of himself as a "key opinion leader" is unhelpful, unsupported, and self-serving. I agree. Absent evidence from others in the medical community in the field of schizophrenia that Dr. Agid's opinion is held in higher regard than others, this statement seems like an attempt to boost Dr. Agid's opinion evidence over that of other experts. I give this self-characterization no weight.

V. Objections to Expert Qualifications

A. *Teva's Objections & Janssen's Responses*

[27] Teva objects to the expert qualifications of Dr. Barrett Rabinow as including "expertise in the properties of pH, particle size distribution and viscosity and isotonicity."

[28] Teva submits that Dr. Rabinow should be qualified as follows:

Expert in pharmaceutical formulation development and manufacturing, including with respect to liquid formulations for parenteral administration and the preparation and use of suspensions and nanosuspensions in formulations and dosage forms (including injectable dosage forms).

[29] Janssen submits that in light of Dr. Rabinow's education, training, and professional experience, he is in a position to provide the Court with information "which is likely to be outside the experience and knowledge of a judge or jury" (*R v Mohan*, [1994] 2 SCR 9 at 23).

[30] I agree that pH, viscosity, and isotonicity are fundamental principle of chemistry that would be within Dr. Rabinow's expertise. Similarly, I agree that particle size distribution is a concept within Dr. Rabinow's expertise based on his extensive experience in the field of pharmaceutical nanosuspensions.

[31] Given Dr. Rabinow's qualifications, I am satisfied that Dr. Rabinow is qualified to give expert opinion evidence on pH, particle size distribution, viscosity, and isotonicity.

ORDER in T-353-18

THIS COURT ORDERS that

1. With respect to Janssen's hearsay objections:
 - Paragraphs 13 and 39 of the Allain Report are hearsay and are inadmissible. Paragraph 38 is not hearsay, but is limited to providing context for paragraph 39 and therefore of limited weight.
 - Paragraphs 22 and 50 of the Simm First Report are not hearsay.
 - The last sentence of paragraph 48 of the Simm First Report is hearsay and is inadmissible
 - Paragraph 119, footnote 61 of the Kwon Report is hearsay. This paragraph is only admissible for the limited purpose of supporting Dr. Kwon's opinion about what prior art a skilled person would have found.
 - The third sentence of paragraph 21 of the Simm Second Report is hearsay and is inadmissible.
 - Paragraphs 26 and 27 of the Virani Report are hearsay and are inadmissible.
2. With respect to Teva's objections for opinions beyond Dr. Agid's qualifications:
 - The impugned paragraphs are admissible as expert evidence, and any concerns about the potential overstatement of the "majority of physicians in respect of the majority of patients" goes to weight to be given to this evidence.
 - Dr. Agid's self-characterization as a "key opinion leader" is given no weight.
3. With respect to Teva's objections to Dr. Rabinow's expert qualifications:
 - Dr. Rabinow is qualified to give expert opinion evidence on pH, particle size distribution, viscosity, and isotonicity.

"Michael D. Manson"

Judge

FEDERAL COURT
SOLICITORS OF RECORD

DOCKET: T-353-18

STYLE OF CAUSE: JANSSEN INC. AND JANSSEN PHARMACEUTICA
N.V. v TEVA CANADA LIMITED

**MOTION DEALT WITH IN WRITING, WITHOUT APPEARANCE OF THE PARTIES,
AT OTTAWA, ONTARIO**

ORDER AND REASONS: MANSON J.

DATED: JANUARY 21, 2020

WRITTEN SUBMISSIONS BY:

Peter Wilcox
Marian Wolanski

FOR THE PLAINTIFFS

Jonathan Stainsby
William P. Mayo
Lesley Caswell

FOR THE DEFENDANT

SOLICITORS OF RECORD:

Belmore Neidrauer LLP
Barristers and Solicitors
Toronto, Ontario

FOR THE PLAINTIFFS

Aitken Klee LLP
Barristers and Solicitors
Toronto, Ontario

FOR THE DEFENDANT