Federal Court  Cour fédérale

Date: 20200915

Dockets: T-97-19
T-98-19
T-503-19
T-504-19

Citation: 2020 FC 897

Ottawa, Ontario, September 15, 2020

PRESENT: The Honourable Mr. Justice Zinn

Docket: T-97-19

BETWEEN:

BRISTOL-MYERS SQUIBB CANADA CO. AND BRISTOL-MYERS SQUIBB HOLDINGS IRELAND UNLIMITED COMPANY

Plaintiffs

and

PHARMASCIENCE INC.

Defendant

Docket: T-98-19

AND BETWEEN:

BRISTOL-MYERS SQUIBB CANADA CO. AND BRISTOL-MYERS SQUIBB HOLDINGS IRELAND UNLIMITED COMPANY, AND PFIZER INC.

Plaintiffs

and

PHARMASCIENCE INC.

Defendant

Docket: T-503-19

AND BETWEEN:

BRISTOL-MYERS SQUIBB CANADA CO. AND BRISTOL-MYERS SQUIBB HOLDINGS IRELAND UNLIMITED COMPANY, AND PFIZER INC.

Plaintiffs

and

SANDOZ CANADA INC.

Defendant

Docket: T-504-19

AND BETWEEN:

BRISTOL-MYERS SQUIBB CANADA CO. AND BRISTOL-MYERS SQUIBB HOLDINGS IRELAND UNLIMITED COMPANY

Plaintiffs

and

SANDOZ CANADA INC.

Defendant

AMENDED ORDER AND REASONS

[1] Before the Court are motions by the Defendants, Sandoz Canada Inc. [Sandoz] and Pharmascience Inc. [PMS] for leave to serve and file reply reports in these matters. These motions arise in the context of a patent infringement action pursuant to subsection 6(1) of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133. At issue are two patents: Canadian Patent No. 2,791,171 [the 171 Patent], and Canadian Patent No. 2,461,202 [the 202 Patent].

[2] As I noted in *Bristol-Myers Squibb Canada Co v Apotex Inc*, 2019 FC 1379 at paragraphs 4 and 5, the principles governing the admissibility of reply evidence has been examined by Justice Manson in *Janssen Inc v Teva Canada Limited*, 2019 FC 1309 at paras 16 and 17, citing Justice Pelletier in *Halford v Seed Hawk Inc*, 2003 FCT 141, at para 15:

> 1. Evidence which is simply confirmatory of evidence already before the court is not to be allowed.
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> 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.
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> 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.
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> 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.

Justice Manson further observed at paragraph 17: “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.”

[3] The Plaintiffs remind me that at paragraph 25 of *Merck-Frosst v Canada (Health)*, 2009 FC 914 [*Merck-Frosst*], I noted that a party is to put its best case forward at the first instance and is not to lie in the weeds until after the other party has responded, and then file additional evidence to bolster its case in light of the defence that has been mounted.

[4] Sandoz seeks leave to file the reply expert report of Dr. Eliot H. Ohlstein [the Ohlstein Reply], and Dr. Arthur Hamilton Kibbe [the Kibbe Reply]. The Plaintiffs object to paragraphs 4-6 and 8-21 of the Ohlstein Reply, and to all of the Kibbe Reply.

[5] PMS seeks leave to file the reply expert report of Dr. Michael Rieder [the Rieder Reply], and the reply expert report of Dr. Stephen Hanessian [the Hanessian Reply], and the reply expert report of Dr. Paul A. Laskar [the Laskar Reply]. The Plaintiffs object to all of the Rieder Reply and the Laskar Reply, and paragraphs 20-36 of the Hanessian Reply.

The Ohlstein Reply

[6] In paragraphs 4-6 and 8-21, Dr. Ohlstein provides an opinion on how a skilled person would interpret page 6 of the 202 Patent. Dr. Ohlstein attests at paragraph 8 of the Ohlstein Reply that he “could not have anticipated that anyone reading the ‘202 Patent … would interpret the criteria listed on page 6 in the manner in which Dr. Taft has interpreted those words.”

[7] However, he has already addressed page 6. In his original expert report at paragraph 93, he excerpts page 6 and describes it as a "'wish list' of desirable and preferable features." In my view, the Ohlstein Reply Report constitutes a disagreement with Dr. Taft's opinion and is a reiteration of the original opinion. It constitutes improper reply. This reiteration is also evident from his statement in paragraph 15 of the Ohlstein Reply, where he writes, "as stated in my First Report…"

[8] The objection of the Plaintiffs to paragraphs 4-6 and 8-21 of the Ohlstein Reply is upheld.

The Kibbe Reply

[9] Dr. Kibbe attests that he "could not have anticipated Dr. Davies' opinion that the ruggedness studies conducted by the '171 Patent inventors and BMS personnel, as summarized in the Ruggedness Report were non-routine." Sandoz, at paragraph 5 of its submissions say that this reply evidence ought to be admitted because it addresses "evidence regarding productions he has not previously seen and which were relied upon in the Davies Report…"

[10] Sandoz's principal submission on admissibility of the Kibbe Reply is that this is "new evidence on tests included in the Formulation Ruggedness Study, because it was not previously considered by Sandoz to be relevant." It cites *Merck-Frosst* at para 24 in support:

> If the evidence to which the reply is proposed relates to evidence that is new and was not previously considered relevant by that first party, then it may well be proper reply evidence.

[11] Sandoz says that it did not previously consider the Ruggedness Report to be relevant because neither it nor the Apixaban Formulation Ruggedness Study to which it relates, are mentioned in the 171 Patent, and the alleged relevance is not evident from the pleading, as they do not particularize the specific formulation studies or tests conducted.

[12] The Plaintiffs submit that both of these latter statements are factually incorrect. It notes that in response to discovery questions as to Figures 3 and 4 of the 171 Patent, it identified the Ruggedness Report as the source of the data. It says that there is "no argument that Sandoz could have anticipated the Plaintiffs' reliance on the Ruggedness Study as part of their case." I agree with this conclusion.

[13] I also agree with the Plaintiffs that Dr. Kibbe has already offered his opinion on whether the formulation tests were routine work and the balance referred to in the Kibbe Reply "could have and should have been addressed in Dr. Kibbe's report in chief." It was not provided to him by Sandoz. That was a decision made by Sandoz as part of its litigation plan. To attempt now to address it in reply, is case-splitting and is impermissible.

The Rieder Reply

[14] It is proposed that Dr. Rieder respond to Dr. Weitz's comments regarding two of the Plaintiff's documents. He attests that he could not have anticipated this opinion evidence, as he was unaware of these documents. They were not provided to him by PMS which noted that they were "but two of the tens of thousands of documents" produced by the Plaintiffs, and it could not have known which of those documents the Plaintiffs would rely on.

[15] I agree with the Plaintiffs that this submission cannot be seriously maintained; it is not supported by the record. Specifically, as the Plaintiffs note at paragraph 30 of their memorandum, it is belied by the following:

> (a) Both the Pharmacology Report and the PowerPoint Presentation were expressly produced and identified to Pharmascience on January 15, 2019 in the Plaintiffs' initial productions pursuant to 6.03(1)(a) of the PM(NOC) Regulations, which comprised a sum total of 26 documents in respect of the 202 Patent; and
>
> (b) The Pharmacology Report was the subject of discovery answers provided by the Plaintiffs.

[16] In any event, the proposed evidence of Dr. Rieder adds little or nothing to his already expressed opinion. He says at paragraph 11 of the Rieder Reply, "they do not change my view."

[17] For these reasons, the Rieder Reply is inadmissible.

The Hanessian Reply

[18] Paragraphs 31-36 of the Hanessian Reply also purport to speak to the two documents referenced immediately above, and for the reasons therein set out, those paragraphs are inadmissible.

[19] Paragraphs 20-29 of the Hanessian Reply purport to speak to page 6 of the 202 Patent. Much of the reasoning above regarding the Ohlstein Reply apply here. Further, Dr. Hanessian refers to page 6 in his initial report at paras 198-199, and 252. The Hanessian Reply appears

merely to repeat his opinion in the initial report and constitutes a mere disagreement with the Plaintiffs' expert. These paragraphs are inadmissible.

[20] At paragraph 30, Dr. Hanessian addresses paragraph 98 of the report of Dr. Greenlee. The Plaintiffs submit that he has misunderstood the evidence of Dr. Greenlee and that his misunderstanding may be appropriately dealt with in cross-examination. Dr. Greenlee will obviously speak for himself as to what he meant; however, at this time that is unknown. In my view, this paragraph may be proper and thus is admissible.

The Laskar Reply

[21] In paragraphs 5-10 of the Laskar Reply, he says that Dr. Davies has mischaracterized his evidence in chief. I agree with the Plaintiffs that Dr. Laskar does restate his initial evidence; however, this alone does not make these paragraphs inadmissible because this is not a mere disagreement between experts; rather it is the first asserting that the second has misinterpreted his opinion. In my view, that evidence is admissible for that purpose.

[22] In paragraphs 11-23 of the Laskar Reply, he addresses certain prior art attached to and referenced in Dr. Davies Report. It is his opinion that they do not support Dr. Davies opinion and he had not previously addressed them in his initial report.

[23] I agree with PMS that if these portions of the Laskar Reply are not admitted, it may prove impossible to achieve the same result through cross-examination. In my view, these paragraphs may prove useful to the trial judge, and thus they are admissible.

AMENDED ORDER IN T-97-19, T-98-19, T-503-19 and T-504-19

THIS COURT ORDERS that:

1. Sandoz Canada Inc. is granted leave to file a Reply Report of Dr. Ohlstein consisting of paragraphs 1-3, 7, and 22-23 of the proposed reply report of Dr. Ohlstein; in all other respects its motion is dismissed.

2. Pharmascience Inc. is granted leave to file a Reply Report of Dr. Hanessian consisting of paragraphs 1-19, and 30 of the proposed reply report, and leave to file a Reply Report of Dr. Laska consisting of paragraphs 5-10 and 11-23 of the proposed reply report of Dr. Laskar; in all other respects its motion is dismissed;

3. Each party shall bear its own costs.

"Russel W. Zinn"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

DOCKETS:	T-97-19 BRISTOL-MYERS SQUIBB CANADA CO ET AL v PHARMASCIENCE INC T-98-19 BRISTOL-MYERS SQUIBB CANADA CO ET AL v PHARMASCIENCE INC T-503-19 BRISTOL-MYERS SQUIBB CANADA CO ET AL v SANDOZ CANADA INC T-504-19 BRISTOL-MYERS SQUIBB CANADA CO ET AL v SANDOZ CANADA INC
MOTION DEALT WITH IN WRITING, WITHOUT APPEARANCE OF THE PARTIES	
AMENDED ORDER AND REASONS:	ZINN J.
DATED:	SEPTEMBER 15, 2020

WRITTEN SUBMISSIONS BY:

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