

Federal Court



Cour fédérale

Date: 20240229

**Dockets: T-1484-22
T-1607-22**

Citation: 2024 FC 344

Ottawa, Ontario, February 29, 2024

PRESENT: The Honourable Mr. Justice Fothergill

BETWEEN:

**GILEAD SCIENCES, INC. and
GILEAD SCIENCES CANADA, INC.**

Plaintiffs/Moving Parties

and

JAMP PHARMA CORPORATION

Defendant/Responding Party

ORDER AND REASONS
(MOTIONS TO STRIKE RESPONDING EXPERT EVIDENCE
AND FOR LEAVE TO FILE EXPERT REPLY)

I. Introduction

[1] The Plaintiffs Gilead Sciences, Inc. and Gilead Sciences Canada, Inc. [collectively Gilead], claim ownership of Canadian Patent No 2,845,553, titled “Tenofovir Alafenamide

Hemifuramate” [553 Patent], and No 2,990,210, titled “Pharmaceutical Formulations Comprising Tenofovir and Emtricitabine” [210 Patent].

[2] The Defendant JAMP Pharma Corporation [JAMP] has developed a product containing the medicinal ingredient tenofovir alafenamide hemifuramate. In the underlying actions, Gilead seeks declarations of infringement of the 553 Patent and 210 Patent under ss 6(1) of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 [Regulations], as well as injunctive relief. JAMP denies infringement of the 210 Patent, and alleges that both the 553 Patent and the 210 Patent are invalid.

[3] On September 27, 2023, Gilead served its expert reports addressing infringement of the 553 and 210 Patents. The same day, JAMP served its expert reports addressing infringement and invalidity.

[4] The following expert reports are relevant to these motions:

- a) Report of Dr. [REDACTED], expert witness for Gilead, regarding the person of ordinary skill in the art [PSA], the common general knowledge pertaining to the 553 Patent, and infringement by JAMP’s product;
- b) Report of Dr. [REDACTED], expert witness for Gilead, regarding the relevant background in chemistry, the PSA, the common general knowledge pertaining to the 553 Patent, claims construction, and infringement by JAMP’s product;

- c) Report of Dr. [REDACTED], expert witness for Gilead, regarding the relevant background in dosage forms and formulation, the PSA, the common general knowledge pertaining to the 210 Patent, and claims construction;
- d) Report of Dr. [REDACTED], expert witness for JAMP, regarding the PSA, the common general knowledge pertaining to the 553 Patent, and invalidity; and
- e) Report of Dr. [REDACTED], expert witness for JAMP, regarding the PSA, the common general knowledge pertaining to the 210 Patent, the meaning of certain terms in the 210 Patent, and invalidity.

[5] On December 19, 2023, before they exchanged responding expert reports, the parties entered into a Stipulation and Agreement [REDACTED]

[REDACTED] According to the Stipulation: [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[6] Footnote 4 to the Stipulation provided:

[REDACTED]

[7] The parties served their responding expert reports on January 3, 2024. The following reports tendered by JAMP are relevant to these motions:

- a) responding expert report of Dr. [REDACTED], addressing the expert reports of Drs. [REDACTED] and [REDACTED]; and
- b) responding expert report of Dr. [REDACTED], addressing the expert report of Dr. [REDACTED], with additional comments on infringement.

[8] According to Gilead, Dr. [REDACTED] response (a) amounts to improper case-splitting; (b) is not responsive to the evidence, given the Stipulation; and (c) will cause prejudice to Gilead. Gilead maintains that Dr. [REDACTED] response (a) amounts to improper case-splitting; and (b) constitutes mere disagreement, which is better addressed in cross-examination at trial.

[9] If the Court is not prepared to strike the impugned portions of Dr. [REDACTED] responding report, Gilead requests leave to file an expert report in reply from Dr. [REDACTED]

II. General Principles

[10] The admissibility of responding expert reports is to be determined in accordance with the following guiding principles (*Canadian Pacific Railway v Canada*, 2020 FC 690 [*Canadian Pacific*] at para 34):

- i. a plaintiff is not obliged to call primary expert evidence on an issue the burden of which lies with the defendant; if the

plaintiff, however, chooses to do so, it must exhaust any evidence on the point, lest the case be split;

- ii. the notion of a “response” or “rebuttal” is not to be applied in such a narrow sense so that the responding expert must accept the way the primary expert has defined the question; a responding report may also include background and incidental information, and need not be tied word for word to the primary expert report. Fairness is maintained due to the opportunity for reply (or surrebuttal) report;
- iii. there will nonetheless be occasions where a rebuttal (or part of it) is not responsive to the primary opinion, veering into non-responsive areas, thereby exceeding its proper domain, and as a result all or part of the report may be determined to be inadmissible; and
- iv. the Court retains the discretion to admit any non-conforming sections of the responding expert report, taking into consideration any prejudice that will result to the other side from its admission.

[11] Reply evidence is treated differently from responding evidence. The later stage of its receipt, in addition to the rule against case-splitting, means the rules on reply evidence are more restrictive than for responding evidence (*Canadian Pacific* at para 31).

III. Analysis

A. Dr. [REDACTED] *Responding Expert Report*

[12] Gilead objects that Dr. [REDACTED] responding expert report: (a) amounts to improper case-splitting; (b) is not responsive to the evidence, given the Stipulation; and (c) will cause prejudice to Gilead.

[13] JAMP notes that expert witnesses are expected to identify areas of agreement or disagreement with opposing experts. I agree with JAMP that Dr. [REDACTED] responding expert report reiterates his previous views or offers “new” opinions in this context. This does not amount to case-splitting or “veering into non-responsive areas”.

[14] Gilead asserts that several paragraphs of Dr. [REDACTED] responding expert report are “simply confirmatory of evidence already given”. Gilead relies on *Merck-Frosst v Canada (Health)*, 2009 FC 914 at paragraph 23, which concerned reply evidence rather than responding evidence. The two should not be confused (*Bauer Hockey Ltd v Sport Masko Inc*, 2020 FC 212 at para 33). Gilead has not demonstrated any prejudice arising from the confirmatory evidence, which is at worst repetitive and redundant.

[15] The parties agreed in the Stipulation that Gilead would [REDACTED] [REDACTED]. Gilead therefore maintains that Dr. [REDACTED] comments in paragraph 32 of his responding report regarding these claims are inadmissible. Based upon a cursory review, the paragraph is directed towards [REDACTED] [REDACTED]. Gilead has not demonstrated prejudice.

[16] The responding expert report of Dr. [REDACTED] will therefore be admitted. Gilead retains the right to address questions of relevance in closing argument.

B. Dr. [REDACTED] *Responding Expert Report*

[17] Gilead objects that Dr. [REDACTED] responding expert report: (a) amounts to improper case-splitting; and (b) constitutes mere disagreement, which is better addressed in cross-examination at trial.

[18] According to Gilead, Dr. [REDACTED] first report addressed the PSA's understanding of certain terms selected by counsel. He did not construe the claims of the 210 Patent, nor was he asked to identify the essential elements of any of the claims. None of the terms Dr. [REDACTED] was asked to consider in his first report are related to a [REDACTED] nor did he provide an opinion with respect to the PSA's understanding of a [REDACTED] in relation to any of the claims.

[19] Gilead says that Dr. [REDACTED] is providing new opinions in his responding report on the meaning of the claims. In particular, Dr. [REDACTED] states in his responding report that [REDACTED] and [REDACTED] and JAMP's product therefore does not infringe these claims.

[20] JAMP notes that Gilead is seeking to strike most of Dr. [REDACTED] opinion on infringement, depriving it of any opportunity to respond to Dr. [REDACTED] opinion on infringement. It is contrary to the interests of justice to adjudicate an issue with evidence from only one party. JAMP maintains that Dr. [REDACTED] could not have anticipated Dr. [REDACTED] opinion on infringement, and his responding report cannot be fairly described as case-splitting.

[21] JAMP asserts that Dr. [REDACTED] was aware, when he prepared his first report, of the indications in the proposed JAMP product monograph, and knew at the time that JAMP's product was [REDACTED]. JAMP therefore disputes Gilead's assertion that Dr. [REDACTED] could not have anticipated JAMP's position that its product would not infringe claims that [REDACTED].

[22] JAMP argues that the proposed reply report of Dr. [REDACTED] should not be permitted, because it amounts to mere disagreement and discusses matters that should have been anticipated in Dr. [REDACTED] first report. The proposed reply therefore does not satisfy the well-established principles applicable to the admission of reply expert evidence (*Janssen Inc v Teva Canada Limited*, 2019 FC 1309 at paras 16-17 [*Janssen*], citing *Halford v Seed Hawk Inc*, 2003 FCT 141 (TD) at para 15).

[23] These motions were submitted barely one week before the commencement of trial. "Courtesy copies" of the full expert reports, all of which are lengthy and complex, were provided subsequently. The reports that are the subject of these motions were delivered at the beginning of January 2024. There can be no excuse for waiting until the eve of trial to submit contested motions of this nature. The Court's opportunity for reasoned analysis has been severely curtailed.

[24] It is not possible in the limited time available to make complete sense of the parties' arguments respecting Dr. [REDACTED] responding expert report, or the 106 paragraphs that are in dispute. It seems clear that Dr. [REDACTED] is advancing new opinions respecting the meaning of certain

claims of the 210 Patent. It is less clear whether Dr. [REDACTED] should have anticipated these opinions and addressed them when he prepared his first report.

[25] While I have misgivings about admitting the proposed reply report of Dr. [REDACTED], I conclude that it is in the interests of trial fairness to do so. JAMP has not asserted that it will be unduly prejudiced by the proposed reply; only that the reply does not conform to the *Janssen* criteria.

[26] The *Janssen* criteria for admitting expert evidence in reply are not exhaustive. Other pertinent considerations include the relevance of the impugned evidence to the case (*Abbott Laboratories v Canada (Health)*, 2006 FC 823 at para 26); whether it will unduly delay the proceeding (*Janssen-Ortho Inc v Apotex Inc*, 2010 FC 81 at para 33); and the recognition that parties cannot be expected to anticipate every argument (*Takeda Canada Inc v Canada (Minister of Health)*, 2014 CarswellNat 8773 at paras 7-8). The Court retains a discretion to admit evidence and weigh the factors differently on a case-by-case basis (*Solvay Pharma Inc v Apotex Inc*, 2007 FC 913 at paras 9-12).

[27] In the result, the responding expert report of Dr. [REDACTED] will be admitted. The brief reply report of Dr. [REDACTED] will also be admitted. Both parties retain the right to address questions of relevance in closing argument.

IV. Conclusion

[28] Gilead's motions to strike the responding expert reports of Drs. [REDACTED] and [REDACTED] are refused. Gilead's request, in the alternative, to admit the expert reply report of Dr. [REDACTED] is granted.

[29] As success in these motions is divided, there will be no order as to costs.

ORDER

THIS COURT ORDERS that:

1. Gilead's motions to strike the responding expert reports of Drs. [REDACTED] and [REDACTED] are refused.

2. Gilead's request, in the alternative, to admit the expert reply report of Dr. [REDACTED] is granted.

3. No costs are awarded.

“Simon Fothergill”

Judge

FEDERAL COURT
SOLICITORS OF RECORD

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STYLE OF CAUSE: GILEAD SCIENCES, INC. AND GILEAD
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**MOTIONS TO STRIKE RESPONDING EXPERT EVIDENCE
AND FOR LEAVE TO FILE EXPERT REPLY**

ORDER AND REASONS: FOTHERGILL J.

DATED: FEBRUARY 29, 2024

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