Federal Court Cour fédérale

Date: 20250410

Docket: T-732-22

Citation: 2025 FC 669

2025 FC 669 (CanLII)

Ottawa, Ontario, April 10, 2025

PRESENT: The Honourable Mr. Justice Zinn

BETWEEN:

PHARMASCIENCE INC

Plaintiff

and

JANSSEN INC, JANSSEN ONCOLOGY, INC AND BTG INTERNATIONAL LTD

Defendants

ORDER AND REASONS

[1] The Plaintiff, Pharmascience Inc., [Pharmascience or PMS] moves for leave to file three reply reports in this litigation: The Hollis Reply Report, the Ferriera Reply Report, and the Soriano Reply Report. The Defendants do not oppose the filing of the Ferriera Reply Report or the uncontested paragraphs of the Hollis Reply Report and the Soriano Reply Report. The Defendants contest the following paragraphs of those two proposed reply reports:

a. The Hollis Reply Report paragraphs 27-80, 83-84, and

b. The Soriano Reply Report paragraphs 3.2 and 3.32-3.33

[2] The challenged paragraphs of the Soriano Reply Report rely on the challenged paragraphs of the Hollis Reply Report. They stand or fall together. I find that the challenged paragraphs of the Hollis Reply Report are all directed to the same issue—the selection of representative drugs from the data set used by both parties' experts. Accordingly, they too stand or fall together.

[3] Previously, the Defendants unsuccessfully asserted Canadian Patent No. 2,661,422 in actions against Pharmascience under the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133, which delayed Pharmascience from entering the abiraterone market from September 2019 to January 2021 [*Janssen Inc. v Apotex Inc*., 2021 FC 7; aff'd *Janssen Inc. v Apotex Inc*., 2022 FCA 184]. As a result of this delay, Pharmascience seeks damages in this action from the Defendants caused by the delay pursuant to section 8 of the *Patent Act*, RSC, 1985, c P-4.

[4] The trial is scheduled for 11 days of evidence and closing submissions commencing on May 26, 2025.

[5] On September 13, 2024, the Plaintiff served three in-chief expert reports: (i) the Hollis Report; (ii) the Ferreira Report; and (iii) the Soriano Report.

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[6] On December 16, 2024, the Defendants served their responding expert reports: (i) the Cockburn Report (responding to Dr. Hollis); (ii) the Monteith Report (responding to Ms. Ferreira); and (iii) the Hamilton Report (responding to Mr. Soriano).

[7] On February 7, 2025, the Plaintiff served its proposed reply reports from its three experts. Shortly thereafter, the Defendants advised the Plaintiff that they did not object to portions of the Hollis Reply Report and the Soriano Reply Report, and they did not object to any part of the Ferreira Reply Report. Objections were only raised regarding the specific paragraphs identified above. The Plaintiff filed this motion on March 4, 2025, seeking leave to file the three reply reports in their entirety.

[8] Dr. Hollis' mandate was to "estimate the 'but-for' sales volume of the Plaintiff's abiraterone product if it had not been excluded from the market." The Plaintiff argues that one consequence of being prevented from entering the market was that it then had to enter with other generics and thus lost its first mover advantage. Dr. Hollis conducted an analysis of the first mover advantage to predict the Plaintiff's market share had it launched as the first and sole generic product in the market.

[9] The methodology used by Dr. Hollis in his Expert Report is summarized in the Defendants' memorandum at paragraph 5, as follows:

> In his First Report, Dr. Hollis calculated the first mover advantage as follows:
>
> a. Dr. Hollis requested, and PMS produced, data on drugstore sales of all solid oral dose drugs between 2012 and July 2024 (the **2012-2024 Data Set**). The 2012-2024 Data Set contained data for over 500 drugs;

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> b. Dr. Hollis applied a single criterion to the 2012-2024 Data Set to identify representative drugs to analyze the first mover advantage: whether the drug had "a sole generic entrant followed by other generic competitors;"
>
> c. Dr. Hollis identified 39 drugs from the 2012-2024 Data Set meeting this single criterion; and
>
> d. Dr. Hollis then calculated the first mover advantage as the average first mover's market share across these 39 drugs.

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[10] Dr. Cockburn in reply observed that Dr. Hollis missed 45 other generic drugs in this data set that was "a sole generic entrant followed by other generic competitors." When these were included, the first mover advantage was less than Dr. Hollis had predicted.

[11] I agree with the following description provided in paragraph 26 of the Defendants' memorandum:

> Dr. Cockburn's analysis was simple. He examined the 2012-2024 Data Set and included all 83 drugs that fit Dr. Hollis' stated selection criterion to understand the FMA. In other words, Dr. Cockburn merely applied Dr. Hollis' stated selection criterion to the data set that Dr. Hollis requested. Dr. Cockburn did not apply or suggest any new criteria for selecting drugs to be included in the FMA analysis, or introduce any new data. (emphasis in original)

[12] The Plaintiff provided Dr. Cockburn's Expert Report to Dr. Hollis and asked that he "respond to any new and unanticipated opinions expressed in Dr. Cockburn's report and to revise my report based on new data available since I wrote my report".

[13] Counsel for the Plaintiff described what Dr. Hollis does in his proposed Expert Reply Report as correcting "mistakes" made by Dr. Cockburn and himself. Counsel for the Defendants

says it is “an entirely new approach to the selection of representative drugs from the 2012-2024 Data Set.”

[14] I agree with the Defendants.

[15] Under Rule 274(1) of the *Federal Courts Rules*, SOR/98-106, and the common law principle against case-splitting outlined in decisions such as *R v Krause*, [1986] 2 SCR 466 and *Halford v Seed Hawk Inc*, 2003 FCT 141, reply evidence is admissible only if (i) it is responsive to a truly new matter raised by the defendant, and (ii) that matter could not reasonably have been anticipated when the plaintiff submitted the evidence in-chief: *Merck Sharp & Dohme Corp. v Wyeth LLC*, 2020 FC 1087 [*Merck Sharp*] at paras 7-14.

[16] If the evidence constitutes case-splitting, meaning it merely bolsters or repackages the plaintiff’s original theory, it is inadmissible unless the Court, in its discretion, concludes that the interests of justice and lack of prejudice clearly favour admission: *Merck Sharp* at para 10, citing *Merck-Frosst v Canada (Health)*, 2009 FC 914 at para 10.

[17] Applying this analytical framework, I fail to see how what Dr. Cockburn provided in his expert report is something completely new such that Dr. Hollis could not have anticipated it. In my view, it was entirely foreseeable that Dr. Hollis’ counterpart would apply the *same* criterion to the *same* data that he had used to verify whether the drugs he selected met his criteria, and whether additional drugs met that criterion. This was exactly what Dr. Cockburn did when he offered his opinion on the first mover advantage.

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[18] Faced with Dr. Cockburn's differing opinion and results derived using the same methodology, Dr. Hollis set about examining all of the drugs in some detail, which he describes as a "closer review." The result of this closer review was that he retained the original data for only 13 of the 39 drugs, excluded all or part of the data for the remaining 26, and added 15 brand-new drugs. With respect, those changes reflect nothing more than a tactical decision to revisit his own dataset and results in a strengthening of the Plaintiff's case after seeing how Dr. Cockburn's application of his own criteria weakened his calculated first mover advantage.

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[19] Moreover, as noted by the Defendants, Dr. Hollis introduced ten new selection criteria for determining which drugs to include when calculating the FMA: "whether: (i) the first mover had a sufficient head start; (ii) a molecule has different drug products; (iii) DINs were transferred between companies; (iv) pseudo generics competed in the market; (v) the drug is a special access drug; (vi) a drug was included in the Apotex 2014 import ban; (vii) a generic had a drug shortage; (viii) a generic was found to infringe a patent; (ix) a first mover or second mover exited the market; and (x) the drug was genericized before 2012." These new selection criteria, in my view, are not responsive to any new matter raised by the Defendants. Therefore, the resulting data and opinions based on these criteria cannot be admitted as proper reply evidence.

[20] The Defendants submit that, in seeking to have this reply report admitted, the Plaintiff is splitting its case, and they cite the decision of Mr. Justice Michael Manson in *Janssen Inc v Teva Canada Limited*, 2019 FC 1309 at para 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 [*sic*], 2014 SCC 7" …

[21] The Plaintiff submits that the proposed reply evidence does not constitute case-splitting as it does not bolster Dr. Hollis' expert opinion. I find this argument disingenuous given that his opinion on the first mover advantage increased by some $2.5 Million in the proposed reply report. Seeing that Dr. Hollis now asks the Court to accept a *new* dataset that is selected by a *different* criteria and results in *increased* damages, I find it difficult to accept that these changes do not constitute a bolstering of his previous opinion.

[22] Finally, I accept that this Court has discretion to admit reply evidence even if it is case-splitting. However, I am unable to find that admitting this reply evidence would serve the interests of justice in this particular case, considering (i) the closeness to trial, (ii) the burden imposed by the approximately 4,000 additional pages of documentary evidence contained in around 900 new documents to be digested and reviewed by Dr. Cockburn and counsel, and (iii) the fact that this evidence and the treatment of it was publicly available and known to Dr. Hollis when he offered his original opinion. Admitting such evidence would introduce precisely the prejudice and inefficiency that the prohibition against case-splitting aims to prevent: *T-Rex Property AB v Pattison Outdoor Advertising Limited Partnership*, 2022 FC 1008 at para 42.

[23] Accordingly, other than those portions of the reply evidence to which the Defendants have no objection, this motion will be dismissed, with costs to the Defendants.

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ORDER in T-732-22

THIS COURT ORDERS that:

1. The Plaintiff is granted leave to serve and file (a) the Ferriera Reply Report, (b) the uncontested paragraphs of the Hollis Reply Report and (c) the uncontested paragraphs of the Soriano Reply Report [the Reply Evidence];
2. The Defendants are granted leave to file sur reply evidence in response to the Reply Evidence; and
3. The Defendants are awarded their costs of this motion.

"Russel W. Zinn"
Judge

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FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-732-22
STYLE OF CAUSE:	PHARMASCIENCE INC v JANSSEN INC, JANSSEN ONCOLOGY, INC AND BTG INTERNATIONAL LTD
PLACE OF HEARING:	HELD BY VIDEO-CONFERENCE
DATE OF HEARING:	MARCH 27, 2025
ORDER AND REASONS:	ZINN J.
DATED:	APRIL 10, 2025

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APPEARANCES:

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