Federal Court Cour fédérale

Date: 20260302

Docket: T-1308-24
T-1309-24

Ottawa, Ontario, March 2, 2026

PRESENT: Madam Justice Pallotta

BETWEEN:

TAIHO PHARMACEUTICAL CO., LTD and TAIHO PHARMA CANADA, INC.

Plaintiffs

and

PHARMASCIENCE INC.

Defendant

PUBLIC ORDER AND REASONS
(Confidential Order and Reasons issued February 17, 2026)

[1] This motion relates to the proposed expert evidence on infringement, for a patent trial scheduled to start on February 23, 2026.

[2] In the actions, brought under subsection 6(1) of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133, the plaintiffs (collectively, Taiho) seek to prevent Pharmascience from marketing a generic version of their LONSURF® prescription drug.

LONSURF® tablets containing trifluridine and tipiracil are approved for treating certain cancers. Taiho allege that Pharmascience's proposed generic drug (PMS Product) would infringe:

- certain claims of Canadian patent no. 2,861,480 to oral compositions comprising trifluridine and tipiracil (480 Patent); and
- certain claims of Canadian patent no. 2,914,999 to crystal forms of tipiracil (999 Patent).

[3] Pharmascience alleges (among other defences) that the PMS Product would not infringe the asserted claims of either patent.

[4] In the 480 Patent action, Taiho intend to rely on Dr. Steven Little's opinion evidence and Pharmascience intends to rely on Dr. Colin Rowlings' opinion evidence. Taiho contend that paragraphs 14-16 and 35-79 of Dr. Rowlings' responding report—which is the bulk of his non-infringement opinion—are inadmissible and should be struck. Alternatively, they seek leave to tender a proposed report from Dr. Little to reply to those paragraphs.

[5] In the 999 Patent action, Taiho intend to rely on Dr. Fabia Gozzo's and Dr. Allan Myerson's opinion evidence (Dr. Myerson opines on infringement based on Dr. Gozzo's test results), and Pharmascience intends to rely on Dr. Michael Zaworotko's opinion evidence. Taiho contend that Dr. Zaworotko's responding report on infringement raised unanticipated issues that warrant reply. They seek leave to tender proposed reply reports from both Dr. Gozzo and Dr. Myerson.

[6] Pharmascience does not oppose an order that would grant Taiho leave to tender parts of Dr. Gozzo's proposed reply report at trial but argues that the Court should dismiss the rest of Taiho's motion.

[7] The main legal principles are not controversial.

[8] Admissibility of expert opinion evidence is governed by a two-part test: *White Burgess Langille Inman v Abbott and Haliburton Co*, 2015 SCC 23 at paras 22-24, 54. The first step considers whether the evidence meets the threshold requirements for admissibility of expert opinion: (a) relevance; (b) necessity in assisting the trier of fact; (c) the absence of any exclusionary rule; and (d) a properly qualified expert. The second step balances the potential benefits and risks of admitting the evidence, to determine whether the potential benefits justify the risks. At this point, the threshold factors can continue to play a role in weighing the overall considerations for deciding whether the benefits of admitting the evidence outweigh the risks.

[9] The principles governing admissibility of reply evidence were summarized in *Janssen Inc v Teva Canada Limited*, 2019 FC 1309 at para 16, citing *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.
>
> 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.

[10] As noted in *Merck-Frosst v Canada (Minister of Health)*, 2009 FC 914 at paragraph 10, the Court may consider whether the further evidence serves the interests of justice, whether the further evidence assists the Court in making its determination on the merits, whether granting the motion will cause substantial or serious prejudice to the other side, and whether the reply evidence was available and/or could not be anticipated as being relevant at an earlier date.

A. 480 Patent

[11] Taiho submit that paragraphs 14-16 and 35-79 of Dr. Rowlings' responding report on infringement do not meet the threshold requirements for admitting expert opinion evidence, and the Court should strike them. The challenged paragraphs relate to whether the PMS Product comprises the claim 1 element "a sugar having a critical relative humidity of 85% or more at 25°C as an excipient," or the further limitations of this element in dependent claims.

[12] Taiho contend that Dr. Rowlings relies on newly obtained documents about different forms of sugar to opine that the sugar in the PMS Product is unlikely to have a critical relative humidity of 85% or more at 25°C.

[13] Taiho contend that the challenged paragraphs are irrelevant and unnecessary in that Dr. Rowlings' opinions: (i) raise a new non-infringement defence that was not pleaded, contrary

to rule 279 of the *Federal Courts Rules*, SOR/98-106; and (ii) are not responsive to Dr. Little's infringement opinions, rely on unsupported scientific theories, and are based on a hypothesis that is contradicted by information he relies on (which he cannot explain). Also, the benefit of admitting the challenged paragraphs does not outweigh their prejudice because they are based on new unproduced documents and they are inconsistent with Pharmascience's discovery answers or statements in regulatory submissions to Health Canada. Admitting the challenged paragraphs would prejudice Taiho and offend rules 232, 245, and 248 since Taiho did not have notice of documents or information other than what was in the Abbreviated New Drug Submission (ANDS) that Pharmascience confirmed to be accurate and complete.

[14] In the alternative, Taiho seek leave to tender a reply report from Dr. Little to address the opinions in the challenged paragraphs of Dr. Rowlings' report, all of which are based on newly obtained information. Taiho submit the proposed reply is proper because:

- they and Dr. Little could not have anticipated a need to address opinions based on newly obtained information that goes beyond Pharmascience's ANDS and productions (including information that contradicts Dr. Rowlings' hypothesis), and the opinions could not have been anticipated from Pharmascience's general denial of infringement (*Boehringer Ingelheim (Canada) Ltd v Apotex Inc*, 2024 FC 2025 at para 29);

- Dr. Little's proposed reply is not simply confirmatory of his in chief infringement opinion, which does not address the sugar forms Dr. Rowlings discusses in his responding report;

- the proposed reply is not mere rebuttal—Dr. Little analyzes the sugar forms discussed in Dr. Rowlings' report and provides necessary expert opinion for the Court to consider;

- the Court should exercise discretion to admit the proposed reply because it addresses a critical issue in dispute and Pharmascience will not be unduly prejudiced (*Takeda Canada Inc v Apotex Inc*, 2023 FC 1353 at para 21).

[15] Pharmascience submits that no part of Dr. Rowlings' responding report should be struck, arguing that the Court should not make pre-trial determinations on the admissibility of evidence where context is required, unless this exceptional step is necessary to ensure the just, least expensive, and most expeditious determination of the issues: *McCain Foods v JR Simplot Company*, 2023 FC 1480 at para 24. Pharmascience states it specifically pleaded that its products do not contain a sugar having the requisite critical relative humidity, and it was not required to plead precisely how the PMS Product does not infringe the 480 Patent. Pharmascience also says its productions disclosed the name and the manufacturer of the specific sugar in the PMS Product but Taiho did nothing with the information. Dr. Rowlings relied on publicly available documents and scientific literature—not Pharmascience documents—and it cannot be said that documents were withheld from production.

[16] Pharmascience states that Dr. Rowlings' opinions are necessary to assist the Court in assessing whether the PMS Product comprises "a sugar having a critical relative humidity of 85% or more at 25°C as an excipient" and contends it is ironic that Taiho claim Dr. Rowlings'

opinions, which are based on a thorough investigation and analysis, are not necessary to assist the Court, but Dr. Little's brief analysis without investigation is necessary.

[17] Pharmascience submits that Dr. Little's proposed reply report is improper and leave should be refused because:

- it offends the rule against case splitting and seeks to introduce evidence that ought to have been introduced in chief:
    - Taiho have the burden to prove the PMS Product comprises "a sugar having a critical relative humidity of 85% or more at 25°C as an excipient" with evidence that raises more than a strong possibility of infringement (*Takeda Canada Inc v Apotex Inc*, 2024 FC 106 at para 116); Dr. Little simply did not bother to investigate whether the PMS Product meets this claim element;
    - Taiho should have anticipated Dr. Rowlings' non-infringement opinion; in view of the pleadings, Pharmascience's documentary productions and discovery answers, and the inventor's development work, they should have done more to address the sugar element in chief; instead, Taiho advanced a thin case in chief and seek to supplement it with Dr. Little's proposed reply;
    - Dr. Little's assertion that he could not have anticipated Dr. Rowlings' opinion is of marginal value, particularly since he was not given all

pertinent information (including discovery documents identifying the name and manufacturer of the sugar in the PMS Product); as an expert, Dr. Little should have known that different sugar compositions have different characteristics but he took no steps to investigate the composition of the specific sugar in the PMS Product;

- there is no inconsistency between the ANDS and the information Dr. Rowlings found;

- Dr. Little's proposed reply does not offer the Court any new scientific information or documents about the sugar composition or its moisture behaviour; rather, the proposed reply amounts to a mere disagreement with Dr. Rowlings and reads like a cross-examination outline.

[18] For the reasons below, I will not strike the challenged paragraphs of Dr. Rowlings' reply, and I will grant Taiho leave to tender Dr. Little's reply report at trial.

[19] Taiho have not persuaded me that the challenged paragraphs of Dr. Rowlings' responding report should be struck on the basis that Pharmascience is improperly advancing a new non-infringement position. Pharmascience denied infringement and pleaded, for each claim of the 480 Patent, that the PMS Product would not comprise the elements of the claim. On this motion, Taiho have not shown that Pharmascience admitted that the PMS Product meets the "sugar element" of claim 1 (or in dependent claims) or took a position that implicitly narrowed the infringement issues "in play" prior to the exchange of expert reports. Indeed, Taiho

acknowledged in argument that everything was in play for non-infringement purposes and Pharmascience never suggested that its non-infringement theory turned on a different claim element. Dr. Little's in chief infringement opinion is consistent with this understanding. He addresses every element of every asserted 480 Patent claim, including the sugar element.

[20] Taiho have not shown that the challenged paragraphs of Dr. Rowlings' responding report are irrelevant, unnecessary, or outweighed by their prejudice for the other reasons they advanced. Dr. Rowlings relies on third party documents and other public documents (such as information on the manufacturer's website and scientific journal articles). On this motion, Taiho have not shown that Dr. Rowlings' opinions are inconsistent with Pharmascience's discovery answers, ANDS, or statements to Health Canada, that Pharmascience breached its discovery obligations, or that admitting the challenged paragraphs based on these new documents and information would offend rules 232, 245, or 248. In my view, Dr. Rowlings' opinions are responsive to Dr. Little's infringement opinion, and whether his theories are contradictory or scientifically supportable is an issue that may be explored or argued at trial. Taiho have not shown that any of Dr. Rowlings' paragraphs should be excluded.

[21] While I have found that Pharmascience's general denial of infringement does not justify striking the challenged paragraphs of Dr. Rowlings' responding report, it is a factor in considering whether to allow reply. Dr. Rowlings' opinions are not inconsistent with Pharmascience's discovery answers or documents, but at the same time, I do not agree with Pharmascience that Taiho should have anticipated Dr. Rowlings' responding opinions from the answers or documents.

[22] Pharmascience argues that the standard for anticipation is high, and possibly very high in view of the Court's decision in *Bristol-Myers Squibb Company v Apotex Inc*, 2011 CanLII 11988 (FC) where the Court found that the experts for the party bearing the burden should have anticipated possible responding theories, even if the theories were not considered to be scientifically reasonable. I agree with Taiho that *Bristol-Myers Squibb* turned on specific facts and circumstances. Other decisions of this Court have recognized that a party need not address every anticipated responding argument in chief: for example, see *Pharmascience Inc v Meda AB*, 2021 FC 1209 at para 33. In this case, I disagree with Pharmascience that Taiho should have anticipated Dr. Rowlings' opinions based on the pleadings, Pharmascience's documentary productions and discovery answers, and/or the inventor's development work, and should have done more to address the sugar element in chief. I do not agree that Dr. Little should have focused on any particular claim element any more than he did, and furthermore, I am not persuaded that Dr. Little should have anticipated the details of Dr. Rowlings' responding opinion.

[23] To be clear, I am not suggesting that a general denial relieves the party bearing the burden from the obligation to put forward their full case in chief. Rather, case splitting is evaluated on a case-by-case basis. In this case, based on the motion record before me, I find the proposed reply does not go beyond proper reply and it does not offend the principle against case splitting. In my view, Taiho should have an opportunity to tender expert evidence that replies to Dr. Rowlings' specific opinions and addresses whether the documents he offers support those opinions. Dr. Little's proposed reply report provides such evidence.

[24] I do not accept Pharmascience's argument that I should deny leave because Dr. Little's proposed reply does not offer any new scientific information or documents and amounts to a mere disagreement with Dr. Rowlings. Whether Dr. Little's proposed reply opinions are scientifically supported is an issue for trial, but in my view, his opinions are not mere buttressing of his in chief opinion or mere disagreement with Dr. Rowlings. The proposed reply report explains why Dr. Little disagrees with Dr. Rowlings on questions the Court will have to decide with the aid of technical opinion evidence.

[25] Pharmascience argues that Taiho took an aggressive tactic by bringing a pre-trial motion to strike Dr. Rowlings' evidence, and instead Taiho should have acknowledged a shortcoming of their evidence and sought an indulgence to file reply. Pharmascience argues that the aggressive tactic of seeking to strike Dr. Rowlings' evidence prior to trial should work against Taiho in the Court's weighing of factors and exercise of discretion on whether to admit reply.

[26] I reject this argument. Taiho's motion was not improper. The *Case and Trial Management Guidelines for Complex Proceedings, Proceedings under the PM(NOC) Regulations, and Appeals under Subsection 56(1) of the Trademarks Act* state that objections to expert reports should be raised prior to trial, and the guidelines contemplate a determination of objections before trial or at trial, in the trial judge's discretion. Before bringing the motion, Taiho asked for a trial management conference to discuss the process, and they did not take a hard line on when the motion should be heard. I decided to hear Taiho's motion to strike and for reply together, and prior to trial.

[27] As a final point, I have decided to grant Taiho leave to tender Dr. Little's proposed reply report in its entirety. I do not consider any part of Dr. Little's reply to be materially distinct so as to warrant different treatment or a separate analysis on whether leave should be granted.

B. 999 Patent

[28] For the 999 Patent action, the issues on this motion relate to the expert evidence on whether the PMS Product meets the elements of "Crystal I" claims, which cover a crystal form of tipiracil hydrochloride exhibiting claimed peaks in powder x-ray diffraction tests. Taiho seek leave to tender reply reports from Dr. Gozzo and Dr. Myerson.

[29] Taiho argue they should be permitted to tender a proposed reply report from Dr. Gozzo addressing Dr. Zaworotko's opinions that [redacted] Taiho submit Dr. Gozzo's proposed report is proper reply evidence because:

- Dr. Gozzo could not have anticipated Dr. Zaworotko's opinions—she used a standard protocol, she has never observed [redacted], and Dr. Zaworotko relies on a scientific paper that is about a different experimental technique;

- Dr. Gozzo's proposed reply is not confirmatory or duplicative, but rather it "corrects" Dr. Zaworotko's mischaracterization and misunderstanding of the data

collection process with responsive evidence, in the form of clarifying comments and reprocessed data showing that [redacted]

- the Court should exercise its discretion to admit the proposed reply to ensure it understands the complicated scientific concepts at play (*Meda AB* at paras 35-37; *Akebia Therapeutics, Inc v Fibrogen, Inc*, 2021 FC 171 at para 6); Pharmascience would not be unduly prejudiced because it observed the testing and because the new data are directed to the narrow issue of Dr. Zaworotko's [redacted] hypothesis, and while voluminous, the data can be analyzed with computer software.

[30] Pharmascience does not object to most parts of Dr. Gozzo's proposed reply report, but states that the following are improper reply that should not be permitted:

- Dr. Gozzo's references to the "standard practice" for testing and her references to Dr. Zaworotko's "mischaracterizations" go beyond clarification, are not necessary to assist the Court, are mere disagreements that should be addressed in cross-examination, are seeking the "last word," and/or are needlessly inflammatory; also, Dr. Gozzo's comments on her own experience should have been in her in chief report and they are prejudicial to Pharmascience as they are not reasonably testable on cross-examination and Dr. Zaworotko did not get an opportunity to respond;

- the section in Dr. Gozzo's proposed reply that introduces and analyzes new data (paragraphs 30-36) is not necessary to clarify what she did and what she observed

> with respect to [redacted] during the tests; Dr. Zaworotko and Pharmascience should not be faulted for any lack of clarity or completeness in Dr. Gozzo's first report, and Pharmascience should not have to review new, voluminous data in the short time before trial to prepare for Dr. Gozzo's cross-examination.

[31] For the reasons below, I will grant Taiho leave to tender Dr. Gozzo's reply report at trial.

[32] I am not persuaded by Pharmascience's arguments that Dr. Gozzo's statements about her experience, the standard practice, or what she refers to as Dr. Zaworotko's mischaracterizations constitute improper reply. In my view, the statements in question are not materially different, in terms of their propriety as reply, from the parts of Dr. Gozzo's proposed report that will be tendered without Pharmascience's objection. Moreover, removing selected words or sentences from Dr. Gozzo's reply report, as Pharmascience asks, makes the report difficult to read and sometimes changes Dr. Gozzo's point.

[33] With respect to the data, they are not "new" data in the sense of being data from new tests. Rather, Dr. Gozzo asked a colleague to generate new data files, using data from the prior tests, so she could generate new diffractograms to visualize the data and assess whether they [redacted] over the data acquisition period. The paragraphs of Dr. Gozzo's reply report addressing the data are responsive to Dr. Zaworotko's opinion about [redacted] While admitting the paragraphs presents Pharmascience with voluminous new data files prior to trial, I am not persuaded that this is unduly onerous or prejudicial. The

data are analyzed with computer software. I agree with Taiho's counsel that this is not akin to voluminous pages of materials to review.

[34] Pharmascience's counsel suggested that Dr. Zaworotko's point about [redacted] may not remain in play. Some or all of Dr. Gozzo's proposed reply may become unnecessary if the point is no longer in play, but as things stand, the proposed reply is relevant and will assist the Court.

[35] Taiho seek leave to tender a proposed reply report from Dr. Myerson addressing Dr. Zaworotko's opinions about how Dr. Myerson presented the results from Dr. Gozzo's tests of the PMS Product and ingredients (particularly his use of "zoomed in" diffractograms, and whether the results show [redacted]), and also addressing Dr. Zaworotko's opinions that [redacted] and Dr. Gozzo's test results were likely affected by how the tablets had been prepared. Taiho submit Dr. Myerson's proposed reply report is proper because:

- Dr. Myerson could not have anticipated Dr. Zaworotko's opinions—Dr. Myerson's in chief opinions relied on standard practices, and while criticisms of an experimental method may be expected, it is not possible to foresee every possible theory that may be advanced to explain the results; furthermore, the reason Dr. Zaworotko believes tipiracil [redacted] contradicts information Pharmascience provided on discovery;

- the proposed reply is not simply confirmatory—it is responsive to Dr. Zaworotko's opinions and explains why Dr. Myerson disagrees, and there was no reason for Dr. Myerson to address the issues in chief because they are irrelevant to assessing the experimental results;

- the proposed reply is not mere rebuttal—it seeks to correct inaccuracies and clarify misleading statements to assist the Court's understanding of the pertinent science for adjudicating infringement;

- the Court should exercise its discretion to admit the proposed reply as it is in the interests of justice to have a fulsome record on these issues for the Court's consideration, and Pharmascience would not be prejudiced.

[36] Pharmascience submits that Dr. Myerson's proposed reply report is improper. Leave should be refused because Dr. Myerson's report relates entirely to matters that can be addressed by cross-examination with information that will be in the evidentiary record at trial. He offers opinions that merely observe information on the face of documents that will be in the record, his opinion on whether the experimental results show [redacted] is not directly responsive to Dr. Zaworotko's opinion on [redacted] it is not apparent that Dr. Myerson has the requisite expertise to offer opinions on the force that would induce [redacted] and the proposed reply merely seeks to have the "last word" on a debate started with Dr. Myerson's in chief infringement opinion.

[37] For the reasons below, I will grant Taiho leave to tender Dr. Myerson's reply report at trial.

[38] I agree with Taiho that Dr. Myerson's proposed reply report addresses opinions that he could not have anticipated. Pharmascience did not argue the contrary.

[39] Dr. Myerson's proposed reply report does not merely buttress his in chief opinion and I am not persuaded that he merely seeks to have the last word. Dr. Myerson's proposed reply does not merely disagree with Dr. Zaworotko on points that are more appropriate for cross-examination. The proposed reply relates to three points that Dr. Zaworotko raised, and in my view, it provides responsive evidence that will assist the Court. Whether Dr. Myerson's points are valid or scientifically supported, and whether he (or Dr. Zaworotko) strays outside of his expertise may be issues for trial, but I am not satisfied on the motion before me that these are reasons to deny leave to tender the proposed report.

C. Conclusion

[40] Taiho's motion is granted in part.

[41] Regarding the 480 Patent action, Taiho's request to strike paragraphs 14-16 and 35-79 of Dr. Rowlings' responding infringement report is denied. Taiho's request for leave to tender Dr. Little's proposed reply report at trial is granted.

[42] Regarding the 999 Patent action, Taiho's request for leave to tender the proposed reply reports of Drs. Gozzo and Myerson is granted.

[43] The parties submit that costs of this motion should be in the cause, and I agree.

ORDER in T-1308-24 and T-1309-24

THIS COURT ORDERS that:

1. The plaintiffs are granted leave to tender the proposed reply expert report of Dr. Little at the 480 Patent trial (court file T-1308-24).

2. The plaintiffs are granted leave to tender the proposed reply expert reports of Dr. Gozzo and Dr. Myerson at the 999 Patent trial (court file T-1309-24);

3. The balance of the plaintiffs' motion, specifically the request to strike parts of Dr. Rowlings' report, is dismissed.

4. Costs of the motion are in the cause.

"Christine M. Pallotta"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

DOCKETS:	T-1308-24 AND T-1309-24
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