

Federal Court



Cour fédérale

Date: 20260519

Docket: T-846-26

Toronto, Ontario, May 19, 2026

PRESENT: The Honourable Madam Justice Furlanetto

BETWEEN:

**NOVARTIS PHARMACEUTICALS CANADA INC.
AND NOVARTIS AG**

Plaintiffs

and

ZYDUS LIFESCIENCES LIMITED

Defendant

ORDER

[1] This is an action under subsection 6(1) of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 [*PM(NOC) Regulations*] involving two patents and the medicine sacubitril-valsartan. The Defendant Zydus Lifesciences Limited [Zydus] seeks to bring a motion for summary trial on the issue of infringement involving one of the patents. The Plaintiffs, Novartis Pharmaceuticals Canada Inc and Novartis AG [collectively, Novartis], contest the request, asserting that it will not serve to streamline the proceeding. For the reasons set out below, the summary trial shall be scheduled.

[2] The action was commenced on February 20, 2026. On March 19, 2026, Associate Judge Crinson, the Case Management Judge [CMJ], issued a scheduling order setting out deadlines for the action and identifying the parties' availability for a 10-day trial. As part of the schedule, the CMJ ordered that any party proposing to bring a motion for summary trial or summary judgment notify the Court and opposing counsel by March 31, 2026. On March 23, 2026, the Judicial Administrator issued an Order setting the trial down for the following dates: October 19-22, 25-28, and November 3-4, 2027. On March 31, 2026, counsel for Zydus advised that Zydus was seeking to bring a motion for summary trial and asked for a case management conference [CMC].

[3] A preliminary CMC was convened with the CMJ on April 14, 2026 in which the parties agreed to have the Court consider Rule 216(5)(b) of the *Federal Courts Rules* (i.e., the efficiency of bringing the motion for summary trial) and determine whether the summary trial should proceed. The parties agreed to provide brief written submissions, that Zydus provide a draft notice of motion, and that a further case management conference be convened with the Trial Judge on April 30, 2026. Following that CMC, further brief written submissions were provided by the parties on May 8, 2026 to address specific questions raised by the Court.

[4] Determining whether to allow a summary trial to proceed is a discretionary decision that must be considered based on the facts of the particular case. Determination is guided by the objectives of Rule 3 of the *Federal Courts Rules*, and principles of proportionality and fair access to the affordable, timely and just adjudication of claims: *Viiv Healthcare v Gilead Sciences*, 2021 FCA 122 at paras 29, 36-42. The Court will consider various factors, including

whether summary trial would result in a significant savings of time and cost, whether the summary trial will result in efficiencies, and whether the summary trial could resolve the entire proceeding or whether it would lead to piecemeal litigation: *Wenzel Downhole Tools v National-Oilwell*, 2010 FC 966 at paras 37-38; *Hoffmann-La Roche Limited v Pfizer Canada Inc*, 2018 FC 932 at para 5.

[5] For the merits of a summary trial to be considered, the presiding judge must be satisfied that the issues raised are suitable for summary trial and that the summary trial will assist with the efficient resolution of the action: Rule 216(5), *Federal Court Rules*.

[6] As noted, this proceeding involves two patents: Canadian Patent Nos. 2,590,511 [511 Patent] and 2,703,598 [598 Patent]. The proposed summary trial deals with infringement of the 598 Patent only. The 511 Patent will expire on November 8, 2026 before any proposed summary trial will be heard. The issues for summary trial are directed at whether Zydus' proposed drug product includes a hemipentahydrate salt of the specific active pharmaceutical ingredient which Zydus pleads is an essential element of each of the asserted claims of the 598 Patent.

[7] As the 511 Patent will have expired, Zydus asserts that a summary trial on this issue has the potential to bring the entire action to an end as there would be no need to address the validity of the 598 Patent. While the schedule proposed would require discovery to proceed on infringement and validity issues, Zydus asserts that the summary trial has the potential to eliminate further expenses associated with expert reports which are not due to be exchanged under the current timetable until April 9, 2027 (reports in chief) and July 16, 2027 (responding

reports). Even if unsuccessful, Zydus contends that the determinations on the summary trial will narrow the remaining issues on the 598 Patent and any issues that could require determination on the 511 Patent. Zydus asserts that it will suffer prejudice if the summary trial is not permitted to proceed as the market has already gone generic and therefore the timing of their market entry is critical.

[8] As the proposed summary trial does not address the 511 Patent and there has been no concession regarding section 8 of the *PMNOC Regulations*, Novartis asserts that there would be no efficiencies gained as a summary trial would not resolve the entire proceeding. It asserts that the issues of infringement and validity of the 511 Patent are not rendered moot by the expiration of the 511 Patent: *Astrazeneca Canada Inc v Sandoz Canada Inc*, 2020 FC 635 [*Astrazeneca*]. Rather, a summary trial would amount to litigation in slices, duplicative expert evidence, and wasteful use of judicial and party resources. If the summary trial were not successful, Novartis asserts that there are also other infringement issues relating to the 598 Patent that would have to be addressed. Novartis asserts that Zydus is unlikely to be successful on summary trial as they were unsuccessful in establishing that they did not have the hemipentahydrate salt of sacubitril/valsartan in the United States.

[9] While the parties do not agree that a summary trial should proceed, if one is ordered they agree that it should be set down for 4 days in January 2027. Included in their submissions is a joint schedule for the summary trial which provides for production of samples for testing (if deemed necessary by Novartis), testing on the samples by Novartis and responsive testing by Zydus, completion of discovery of Zydus in relation to the 598 Patent, and exchange of expert

evidence on the summary trial issues. The parties have also discussed and agreed on the nature of the fact and expert evidence that may be expected.

[10] I have considered the arguments made by the parties and am satisfied that the issue raised by Zydus is appropriate for summary trial, that a summary trial has the potential to save the parties time and cost overall, and that there is a likelihood of overall efficiencies to be gained by proceeding with the summary trial.

[11] I agree with Zydus that it is not a foregone conclusion that the 511 Patent will need to be litigated. As submitted by Zydus, once expired, the 511 Patent only remains relevant if Zydus is successful with respect to the 598 Patent, the Zydus Product is approvable before the expiry of the 511 Patent, and Zydus brings a claim pursuant to section 8 of the *PMNOC Regulations*. Unlike *Astrazeneca*, which dealt with an unopposed motion, Zydus has made representations that section 8 may *not* be an issue between the parties as it relates to the 511 Patent.

[12] Moreover, even if the above conditions were met, once the 511 Patent expires and if Zydus were successful on summary trial, there would be no impediment to Zydus entering the market and any issues relating to the 511 Patent could be dealt with outside the statutory 24-month time-period. Indeed, as it is Zydus who requests the summary trial in this proceeding, they would be hard-pressed to argue otherwise. Thus, in my view, there is no necessity to complete all steps relating to the 511 Patent at the same time as the 598 Patent.

[13] In any event, Zydus clarifies that on May 20, 2026 they will provide an affidavit of documents that includes all documents relevant to both the 598 Patent and the 511 Patent, allowing Novartis to discover on both patents if they so choose.

[14] With respect to the remainder of the schedule for the action, while discovery on the validity issues relating to the 598 Patent will need to proceed, on agreement of the parties this discovery will be on a later track. I note that Zydus has the burden on these issues and shall be encouraged to streamline their approach. Despite this discovery, I am satisfied that the savings that could result from elimination of the need to prepare and file further expert reports is sufficient to create efficiencies that justify proceeding with the summary trial.

[15] With respect to the outcome of litigation in the United States, this is not binding on this Court. Nor can I draw any conclusions on the Zydus drug product or the likelihood of success in the proposed summary trial based on the materials filed.

[16] I am satisfied that the proposed summary trial raises a discrete infringement issue with the potential for associated savings of time and cost, which will allow for the possibility of more efficient use of the Court's and parties' resources. These circumstances are sufficient to justify allowing Zydus to move for summary trial.

THIS COURT ORDERS that:

1. The Defendant is permitted to move for summary trial on the issues set out in the proposed notice of motion submitted on April 27, 2026. The notice

of motion shall be formalized and served and filed within seven (7) days of the date of this Order.

2. The Defendant shall serve its affidavit of documents by May 20, 2026.
3. Within seven (7) days of the date of this Order, the parties shall submit their joint availability for a further case management conference with the Case Management Judge to set the remainder of the schedule for the summary trial, including dates for any contemplated motions to compel, and alternative dates for steps in the event that samples of the Defendant's product and/or testing is not requested. The parties shall advise of their joint availability in January 2027 for summary trial and on earlier dates in the event that the schedule is accelerated.
4. The remaining steps in the timetable set out in the Defendant's April 27, 2026 letter shall apply until a formal timetable is set by the Case Management Judge.

"Angela Furlanetto"

Judge