

Federal Court



Cour fédérale

Date: 20220817

Docket: T-1869-21

Citation: 2022 FC 1187

Ottawa, Ontario, August 17, 2022

PRESENT: Case Management Judge Mireille Tabib

BETWEEN:

BAYER INC. AND ADVERIO PHARMA GMBH

Plaintiffs

and

SANDOZ CANADA INC

Defendant

AMENDED REASONS FOR ORDER AND ORDER

[1] The Defendant, Sandoz Canada Inc. (“Sandoz”), brings this motion for leave to amend its Statement of Defence. The Plaintiffs, Bayer Inc. and Adverio Pharma GmbH, (collectively, “Bayer”), have consented to some amendments but object to most, on the basis that there is insufficient time left before trial for them to adequately defend the new allegations.

[2] For the reasons below, the motion is granted, but on condition that if Sandoz chooses to make some of the proposed amendments, the trial dates will be adjourned and the 24-month stay contemplated in the *Patented Medicines (Notice of Compliance) Regulations* will be extended.

I. Procedural Context and Relief Sought

[3] This action was brought pursuant to subsection 6(1) of the *Patented Medicines (Notice of Compliance) Regulations* SOR/93-133 (the “*Regulations*”). At the end of June 2022, over six months after the beginning of the action and less than 15 months before the trial of this matter (scheduled to begin September 25, 2023), Sandoz for the first time proposed to amend its Statement of Defence to include new defences of invalidity of the patent at issue. Sandoz’s Notice of Allegations (“NOA”) alleged that its product will not infringe the ‘852 Patent. In the alternative, the NOA alleged that if the product does fall within claims 1, 3, 4, 5, 7 or 8 of the Patent, these claims would then be invalid in accordance with the principles established in *Gillette Safety Razor Co. v Anglo Trading Company limited* (1913), 30 our PC for 65 (H. L.), because the processes claimed therein were disclosed in five pieces of prior art. No other allegations of invalidity or ineligibility for listing were made. Because of the nature of the *Gillette* defence, Sandoz did not, in its NOA, ask for production of the invention documents.

[4] The Statement of Defence filed in early February 2022 asserts only the defences set out in the NOA.

[5] In June 2022, after a schedule had been set for all steps leading up to the September 2023 trial, and after affidavits of documents and oral discovery plans had been exchanged, Sandoz

changed its Solicitors of record, and shortly afterwards, advised Bayer that it intended to amend its Statement of Defence to correct clerical errors, make the pleadings consistent with respect to the relevant dates, contest Bayer's entitlement to the equitable relief sought in the action, clarify Sandoz's position on non-infringement, and clarify Sandoz's existing pleading of the *Gillette* defence. The proposed amendments would also add a suite of new invalidity defences including:

- Improper priority claim;
- Anticipation based on new prior art;
- Obviousness based on 38 new pieces of prior art;
- Insufficiency of disclosure;
- Lack of utility; and
- Claims broader than the invention made or disclosed.

[6] Sandoz also proposes to add allegations that the patent is ineligible for listing because, *inter alia*, Bayer's product is not obtained by the processes claimed in the Patent.

II. The Parties' Positions and Issues to Be Determined

[7] Prior to the hearing, Bayer indicated that it consented to all clarifications, with the exception of those relating to the *Gillette* defence, but contested all other proposed amendments. In the course of the hearing, however, Bayer conceded that the new allegations relating to the improper priority claim, anticipation, and the clarifications to the *Gillette* defence could, despite the lateness of the amendments, be briefed and ready to proceed to trial on the currently scheduled dates. As such, Bayer conceded that these amendments, if permitted, would not cause it prejudice that cannot be compensated in costs.

[8] As for all remaining amendments, Bayer maintained its vigorous opposition, on the basis that there is insufficient time left in the schedule for it to reasonably defend these new allegations and still meet the scheduled trial dates. Simply adjourning the trial dates would threaten the Court's ability to determine the action within the 24-month period contemplated in the *Regulations* and, unless the 24-month stay were extended commensurately, any delay in the trial would cause it prejudice that cannot be compensated in costs.

[9] Sandoz does not dispute that amendments that necessitate the adjournment of a trial in an action under the *Regulations* are inherently prejudicial to the first person, unless there is a concomitant extension of the 24-month period. What Sandoz submits is that there is sufficient time before the September 2023 trial for the parties to take all the steps required, even with the addition of the new issues.

[10] With over 13 months left before trial, it may technically be possible to write a new schedule that would see the pleading and discovery stages related to the new issues catch up with the ongoing schedule to meet the trial dates. The question, as always, is whether shoehorning a compressed schedule for new issues into an already established schedule still provides a fair opportunity for the opposing party to fully defend against the new allegations. Lack of sufficient time to defend, or an unreasonably compressed schedule, constitutes prejudice that cannot be compensated in costs.

[11] The central issue to be determined on this motion is thus whether Bayer can fairly defend the new allegations within the time remaining before the September 2023 trial. If it cannot, then

the disputed amendments must either be refused, or permitted on condition that the trial be adjourned and the 24-month period extended.

III. Preliminary Comments on the Eligibility for Listing Issue

[12] I entertain considerable doubts as to whether a patent's ineligibility for listing is a substantive defence that can properly be raised in a statement of defence. Section 6.07 of the *Regulations* contemplates that ineligibility for listing can only be raised as part of a motion in the context of a subsection 6(1) action and that the Court cannot dismiss an action, in whole or in part, solely on the basis that a patent is ineligible for inclusion on the register. This suggests that eligibility for listing is not a matter to be determined on the merits of an action, and that it does not therefore raise a reasonably arguable defence to the merits of the action.

[13] Bayer did not raise this argument in response to the motion to amend. I raised it myself at the hearing, and while counsel did their best to address the issue, the submissions received are insufficient for a proper determination of that question. As Sandoz indicates that it does intend to seek discovery of Bayer on the issue of eligibility if its amendments are permitted, I have assumed, for the purposes of this motion, that it forms a proper defence entitling Sandoz to discovery. Nothing in these reasons should, however, be taken as a determination of the validity of that assumption, one way or the other. Because Bayer failed to raise the issue in answer to the motion to amend, it is precluded from making a motion to strike if the amendments are ultimately made. However, Bayer's right to raise the validity of the defence and the effect of its inclusion in the Statement of Defence for any other purpose is reserved, as is Sandoz' right to

argue that it is at law entitled make a motion pursuant to section 6.07 of the *Regulations* without having pleaded the issues in its Statement of Defence.

IV. Discussion

[14] As at the party seeking to amend, Sandoz bears the burden of proving that its proposed amendments should be permitted. That includes demonstrating, to the satisfaction of the Court, that Bayer will not be prejudiced. I acknowledge that proof of a negative can be difficult, and that Bayer is in a far better position than Sandoz to determine how it might suffer prejudice if it has to meet the new allegations in the time remaining before trial. That, however, does not throw the entire burden of proof back onto Bayer, nor does it permit the Court to draw an adverse inference from Bayer's failure to adduce evidence as to any specific form of prejudice.

[15] Sandoz has filed no evidence to establish circumstances from which it would be reasonable to infer that Bayer was already aware of the potential new allegations or has already marshalled and considered information and documents relevant to defending the new allegations. On the contrary, Bayer has led evidence to the effect that Sandoz's NOA was the first and only NOA delivered in respect of the '852 Patent and that this action is the first and only litigation involving this patent.

[16] Given that Sandoz has not sought from Bayer documents relating to the invention as part of its NOA, and that the NOA does not raise any invalidity issue other than the *Gillette* defence, I conclude, on the balance of probability, that Bayer was not aware of the potential new causes of invalidity or of the ineligibility for listing issue before the draft Amended Statement of Defence

was delivered to it on June 29, 2022. Bayer has likely not gathered any documents relating to the invention, contacted the inventors reviewed or considered any of the new prior art alleged, or collected documents relevant to the manner in which its product is manufactured. It is clear that Bayer cannot begin to formulate a defence strategy to the new allegations until it has collected and reviewed that information.

[17] At the 11th hour, Sandoz offered as a compromise to defer the production of invention documents to October 31, 2022, to forgo discovery of the inventors and to limit its discovery of Bayer's representatives on the new invalidity issues to five pages of written questions, to be provided on November 28, 2022, and answered by January 13, 2023. This, it says, would give Bayer nearly 90 days to collect and deliver the invention documents, which is equivalent to the total time contemplated by the *Regulations* and the *Federal Courts Rules* from the delivery of a NOA to the delivery of affidavits of documents (e.g., 45 days from the NOA to the commencement of the action, 30 days for a statement of defence, 10 days for a reply and 30 days for the affidavit of documents).

[18] Sandoz's proposed compromise is unrealistic. It ignores the fact that the parties to section 6(1) actions rarely, if ever, hold to the strict deadlines for filing replies and for serving affidavits of documents. The proposal does not take into account the fact that parties do not typically devise their infringement and liability cases independently of each other and it glosses over the need, in complex and streamlined proceedings, for parties to develop a coherent theory of the case and litigation strategy before proceeding to discoveries. Sandoz's proposed compromise would force Bayer to plead over and to gather and analyze the information necessary for the

invalidity case at the same time as it is preparing for and conducting discoveries on the infringement issues.

[19] Litigation schedules in section 6(1) actions are elaborated carefully, and map out all the steps leading up to the trial, taking into account the parties' and their counsel's often busy schedules and the competing demands on their time. Adding, with significantly compressed timelines, an entirely new defence of invalidity to a case previously focused on infringement can be expected to bring significant strain on Bayer and its litigation team. Given the nature of the new issues raised, it is also reasonable to believe that Bayer would need to retain different experts to those needed for its infringement case and to consider calling the inventors to testify at trial. It is late in the day to guarantee the required experts' and witnesses' presence at trial. Furthermore, the insufficient disclosure allegations are of a nature that may call for testing, for which the existing schedule would almost certainly be insufficient. The potential for significant prejudice is evident.

[20] Sandoz points out that Bayer did not file evidence establishing that it would indeed need to conduct testing or retain new experts, or that any potential inventor or expert would not be available for the September 2023 trial. However, Bayer had barely three weeks between the time Sandoz first disclosed its proposed amendments and the time it had to serve and file its responding motion record. It would be unreasonable to expect that it could, in that short time, consider and map out its defence strategy and verify its feasibility.

[21] Sandoz has also argued that the initial schedule contemplated two fairly time-consuming motions that have now been resolved or withdrawn, such that there is now more time in the schedule to brief the new allegations. There was indeed a motion for further production of documents from the ANDS, but that motion was meant to be briefed and heard in the course of the summer months. While its resolution provides some relief, I am not satisfied that the amelioration is such as to counterbalance the burdens and schedule disruption that the amendments are otherwise likely to cause. As for Sandoz's proposed motion for summary trial, it was never formally scheduled. Indeed, the issue of whether it should be allowed to proceed so late in the day remained to be determined. I do not consider that Sandoz's decision not to proceed with that motion constitutes a saving of time.

[22] In conclusion, the contested amendments are lengthy and raise complex and multifaceted arguments. The factual foundation for allegations of obviousness, claims broader than the invention made, inutility, insufficiency and ineligibility for listing is as broad as it is potentially complex. Given the challenges discussed above, and the fact that Bayer has only just been apprised of the new issues, the suggestion that it could reasonably be prepared to plead to such issues, conduct discovery and prepare for trial within less than 15 months defies common sense. Sandoz bore the ultimate burden of demonstrating that, in spite of all appearances, Bayer would be in a position to fairly defend the new allegations within the time remaining before trial. I find that Sandoz has not met its burden.

V. Remedy

[23] Bayer submits that Sandoz could and should have been aware of all facts giving rise to the new defences at the time it served its NOA. Because Sandoz failed to satisfactorily explain why its proposed amendments were not included in the NOA, Bayer urges the Court, on the authority of *Sunovion Pharmaceuticals Canada Inc v Taro Pharmaceuticals Inc*, 2021 FCA 113, to dismiss the motion on the basis that permitting the amendments would not serve the interest of justice.

[24] The argument that was before the Federal Court of Appeal in *Sunovion* was that a second person could seek to profit by withholding invalidity allegations from its NOA and introducing them only after an action had been started. The Federal Court of Appeal acknowledged a potential for abuse from the fact that a first person would then be exposed to section 8 damages based on allegations that were not included in the NOA. It is in that context that the Federal Court of Appeal held, at paragraph 8, that:

A second check on a strategy based on the introduction of new invalidity allegations after the commencement of an action under the Regulations is the Court's discretion to grant or dismiss a motion to amend a pleading. If a Court is convinced that a proposed amendment seeks to introduce invalidity allegations of which the moving party was aware when its NOA was served, the Court may dismiss the motion on the basis that permitting the amendment would not serve the interests of justice. The second person would then be denied the right to make its case based on the omitted allegations.

(Emphasis added)

[25] I agree with Bayer that Sandoz could probably have included all of the proposed new allegations in its NOA. There is, however, nothing on the record to suggest that Sandoz was in fact aware of the invalidity allegations and that it withheld them with a view to gaining an advantage in a subsequent section 8 claim. The fact that a second patent is listed against Bayer's reference product, which Sandoz has not addressed and which expires in April 2023, negates that motivation in the circumstances of this case.

[26] Still, the strategic and tactical gains that a second person may seek to obtain from the late introduction of invalidity defences, by splitting its case and disrupting its opponents' litigation schedule, should not be discounted. In the circumstances of this case, any procedural or substantive prejudice caused by the late amendments can be alleviated by the adjournment of the trial and a commensurate extension of the 24-month period. There is also still sufficient time before the trial that the adjournment can be made without wasting Court resources. The dismissal of the motion to amend is not indicated in the circumstances of this case.

[27] Sandoz advised in the course of the hearing that a delay in the trial accompanied by an extension of the 24-month period would be prejudicial to it, such that it may not pursue any amendments made contingent on such an extension of time. The Order therefore grants Sandoz leave to make the proposed amendments, but on condition that if the Amended Statement of Defence it serves includes any of the allegations related to eligibility for listing, invalidity on the grounds of obviousness, claims broader than the invention made, insufficiency of disclosure, or lack of utility, the trial dates will be adjourned and the 24-month period will be extended commensurately. This will allow Sandoz to choose whether it wishes to make the disputed

amendment, at the cost of a delayed trial and extended stay of the 24-month period, or to forego those amendments in favour of keeping the trial dates.

VI. Costs

[28] The motion to amend was untimely. All of the proposed amendments could, with the exercise of diligence, have been included in Sandoz's original Statement of Defence. The lateness of the motion was due solely to Sandoz's change of heart and/or of solicitors. Bayer was justified in opposing Sandoz's motion as initially proposed. While Sandoz's position and strategy changed over the course of briefing and hearing the motion, Bayer was still substantially successful in the outcome.

[29] Taking all those factors into consideration, costs of this motion are awarded in Bayer's favour, whether or not Sandoz chooses to avail itself of the leave to amend granted. I do not, however, find that there are grounds to order those costs payable forthwith.

ORDER

THIS COURT ORDERS that:

1. The Defendant has leave to serve and file, within 14 days of the date of this Order, an Amended Statement of Defence containing the allegations and modifications set out in Schedule “A” to its Notice of Motion, subject to the conditions outlined in this Order.
2. Should the Defendant choose to include in its Amended Statement of Defence any of the following modifications, the trial of this matter, currently scheduled to begin on September 25, 2023, shall be adjourned to a date to be fixed:
 - a) The addition in paragraph 7, of the words “(but denies it that the ‘852 Patent is eligible for listing on the Patent Register in respect of ADEMPAS, as discussed below)” ;
 - b) The modifications to paragraphs 10 and 35;
 - c) The addition of paragraphs 46 to 68 and their related headings;
 - d) The inclusion, in paragraph 69, of the words “or obviousness” and of the words “made or”;
 - e) The inclusion, in paragraph 70, of the words “made or” and of the words “, and the named inventors had not demonstrated or soundly predicted the relevance and practical utility of the subject-matter of the Asserted Claims over their scope”
 - f) The addition of paragraph 71 and of paragraphs 72 to 76, including related headings.
3. In the event the September 2023, trial is adjourned, the 24-month statutory stay pursuant to section 7(8) of the *Patented Medicines (Notice of Compliance)*

Regulations shall be extended by the same number of days as there are between September 25, 2023, and the start of the rescheduled trial.

4. The Plaintiffs shall serve and file a reply to the Amended Statement of Defence no later than 14 days from the day of service thereof.
5. The parties shall, no later than 14 days following the service of the Plaintiffs' reply, having consulted with each other, file written submissions as to any amendments to the existing schedule, up to and including trial, their mutual dates of availability for trial if the amendment results in the adjournment of the trial, and their mutual dates of availability to participate in a case management telephone conference to discuss and approve the proposed revised schedule.
6. Costs, in the amount of \$3,800.00, shall be paid by the Defendant to the Plaintiffs.

"Mireille Tabib"

Case Management Judge

FEDERAL COURT
SOLICITORS OF RECORD

DOCKET: T-1869-21

STYLE OF CAUSE: BAYER INC. ET AL. v. SANDOZ CANADA INC.

PLACE OF HEARING: OTTAWA, ONTARIO

DATE OF HEARING: JULY 25, 2022

**REASONS FOR ORDER
AND ORDER:** TABIB P.

DATED: AUGUST 10, 2022

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