Federal Court  Cour fédérale

Date: 20190801

Dockets: T-1960-18
T-2093-18
T-435-19
T-806-19

Citation: 2019 FC 1039

Ottawa, Ontario, August 1, 2019

PRESENT: Mr. Justice Pentney

Docket: T-1960-18

BETWEEN:

BAYER INC. and
BAYER INTELLECTUAL PROPERTY GMBH

Plaintiffs

and

TEVA CANADA LIMITED

Defendant

Docket: T-2093-18

AND BETWEEN:

BAYER INC. and
BAYER INTELLECTUAL PROPERTY GMBH

Plaintiffs

and

APOTEX INC.

Defendant

Docket: T-435-19

AND BETWEEN:

**BAYER INC. and
BAYER INTELLECTUAL PROPERTY GMBH**

Plaintiffs

and

TARO PHARMACEUTICALS INC.

Defendant

Docket: T-806-19

AND BETWEEN:

**BAYER INC. and
BAYER INTELLECTUAL PROPERTY GMBH**

Plaintiffs

and

SANDOZ CANADA INC.

Defendant

ORDER AND REASONS

I. Introduction

[1] The question before the Court is whether to add Taro Pharmaceuticals Inc. (Taro) and Sandoz Canada Inc. (Sandoz) as Defendants in the trial of common issues currently set for Bayer Inc. and Bayer Intellectual Property GMBH's (Bayer) claims against Teva Canada Limited (Teva) and Apotex Inc. (Apotex). The Bayer claims against Taro and Sandoz relate to the same drug, the same patents, and same issues of invalidity as those raised in the Teva and Apotex actions. The difference between the actions is primarily a question of timing. The Teva and Apotex actions were commenced within a month of each other, while the Taro and Sandoz actions were not launched until approximately four and six months later, respectively.

II. Background

[2] The background to these cases is set out in the February 14, 2019 Order issued by the Case Management Judge, Mireille Tabib, reported at 2019 FC 191 (the February 2019 Order). A brief summary will assist in understanding the issue before the Court. Bayer launched actions under the *Patented Medicine (Notice of Compliance) Regulations*, SOR/93-133 [the *Regulations*] against Teva and Apotex arising from their applications for approval to produce and market a generic version of the drug rivaroxaban. Bayer claims that these products will infringe several of its patents.

[3] In the February 2019 Order, the Case Management Judge directed that there be a hearing on the common issues of claims construction and invalidity in the Teva and Apotex actions. The following passages capture the essence of the reasoning for making this order:

> [22] … [T]he common trial of issues in these complex cases constitutes the most efficient use of the Court and the parties' time and resources. Where, as here, two actions raising the same invalidity issues in respect of the same patents are instituted and must be resolved within a scant month of each other, prohibiting the Court from ordering the common trial of these issues would force the Court to hear essentially duplicate trials within a month of each other, requiring the same lawyers, the same inventors and perhaps the same experts to make themselves available for trial for twice the amount of time as a joint trial would require, increasing the difficulty of finding common availability dates and leading to unnecessary delays in scheduling. Ensuring the same Judge's availability for both trials in the time permitted by the *Regulations* may also prove impossible, leading to the loss of the efficiencies that come from assigning the same Judge and potentially increasing the time required for adjudication. The prospect of a joint trial also serves as an incentive for the parties in the two actions to coordinate and hold joint discoveries of inventors, eliminating potential delays in attempting to schedule repeated attendance of multiple inventors at two sets of discoveries.
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> …
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> [24] The reasons provided above also lead to the inescapable conclusion that such an order will also lead to the just, most expeditious and least expensive determination of the issues in both actions on their merits, and meet the interest of justice.

[4] As noted by the Case Management Judge, the actions in Teva and Apotex were launched within one month of each other, following service by the defendants of their Notices of Allegation (NOA) on Bayer. In contrast, the NOAs filed by Taro and Sandoz were served several months later, and so the actions launched by Bayer were also launched months later. The table below sets out the relevant dates:

Defendant	**NOA Served**	**Statement of Claim**	**24 months**
Teva	Sept. 28, 2018	Nov. 9, 2018	Nov. 9, 2020
Apotex	Oct. 23, 2018	Dec. 7, 2018	Dec. 7, 2020
Taro	Jan. 23, 2019	Mar. 8, 2019	Mar. 8, 2021
Sandoz	Apr. 2, 2019	May 17, 2019	May 17, 2021

[5] The backdrop to this is the expiry of another patent related to the drug in issue (the 561 Patent) – a patent whose validity is not being challenged by any defendant, and which expires on December 11, 2020. For the Teva and Apotex matters, this timing roughly coincides with the expiry of the 24-month timeline which the *Regulations* set for the determination of these claims. Teva and Apotex agree that neither of them will have a "first mover advantage" in coming to market after the expiry of the 561 Patent if they succeed at their trials, because they will each have had a determination of their claims involving the other related patents shortly before December 11, 2020. They argue that the timing of the service of their NOAs were aligned to correspond to the expiry of the 561 Patent, and that they should not lose the commercial advantage that they thereby gained over Taro and Sandoz, who failed to move in a timely manner.

III. Arguments of the Parties

[6] Teva and Apotex submit that they will be prejudiced by the addition of new defendants at this stage of the proceedings, in view of the very tight timelines for trial preparation and for the completion of the trials in their proceedings. They note that recent decisions of this Court relating to the hearing of common issues in other Patented Medicine (Notice of Compliance) cases all involve claims launched very close in time; they point to the February 2019 Order in this case, as well as a similar Order in *Biogen Canada Inc v Taro Pharmaceuticals Inc*, 2018 FC 1034 [*Biogen*], where the statements of claim against the two defendants were launched just over five weeks apart. In cases where the claims must be resolved so close in time to each other, there is an obvious benefit to coordination between the parties in regard to trial preparation and the trial itself, which can be achieved by an order for a hearing of common issues. In practical terms,

none of the defendants in any of these cases stood to gain a significant commercial advantage by being first to market by virtue of the timing of these trials.

[7] In this case, however, Teva and Apotex argue that they will be prejudiced in several ways if Taro and Sandoz are added as defendants to the hearing of common issues. First, as noted earlier, they submit that Taro and Sandoz did not align the service of their NOAs on Bayer with the expiry of the 561 Patent, and thus they have ceded a potential commercial advantage. Adding Taro and Sandoz now as defendants to the common hearing would allow them, in effect, to "leapfrog" the expected sequence of events within the 24-month timeline fixed by the *Regulations*, and thereby re-gain the commercial advantage they have lost.

[8] In addition, Teva and Apotex note that the initial schedules for their actions were fixed by the Case Management Judge before the statements of claim were even issued in the Taro and Sandoz matters. The four actions, therefore, are at very different points in the schedule, which must work within the very tight timelines set by the *Regulations.* They argue that adding the two latecomers now will inevitably add complexity, cost, and delay to the trial preparation currently underway, as well to the actual the trial of common issues.

[9] Teva and Apotex contend that they have worked to collaborate on preparation for the trial of common issues, and to align their pleadings. This involves a certain added time and expense to their efforts, but it may also lead to some savings for each of them, or at the least the possible sharing of costs associated with trial preparation and the trial itself. Tentative dates have already been set for the hearing, and trial preparations are well underway.

[10] Teva and Apotex further submit that any additional costs to Bayer associated with not adding Taro and Sandoz to the trial of common issues is simply the result of the decision taken by Bayer to launch these actions against all four defendants, and are a natural consequence of the scheme set out in the *Regulations*.

[11] Bayer argues that Taro and Sandoz should be added to the hearing of common issues, since all of the actions will advance during the same general time frame, and there should be no significant delay associated with adding the two defendants to the trial of common issues currently scheduled. Bayer submits that it will be in a position to continue its trial preparation and to meet its obligations towards all of the parties in relation to the production of documents and discoveries, and that adding two more defendants will not cause delay on its part. Bayer also points out the obvious advantages of a common trial involving all four defendants, a trial which will likely involve the same issues, the same witnesses and the same or very similar legal arguments on behalf of Bayer, and all four defendants. There is also an interest in avoiding different results flowing from separate trials where the issues of claims construction and invalidity are virtually identical.

[12] Bayer submits that it will be prejudiced if the other defendants are not joined, because it will have to bear the extra cost and burden of multiple and overlapping document disclosure, examinations for discovery, and related trial preparation obligations for each of the different trials. Bayer points out that the trial preparations will occur during the same general time frame, given the necessity to deal with all of the cases within the timeline fixed by the *Regulations*.

[13] Bayer submitted that the Court should reject the argument that Teva and Apotex will lose their "first mover advantage" if Taro and Sandoz are added to the trial of common issues, for the reasons given by the Case Management Judge in the February 2019 Order(at para 7):

> [7] The parties in *Biogen* did not argue that a common trial of some issues would constitute a joinder of actions prohibited by s 6.02 of the *Regulations*. Taro, however, did object to the proposed common hearing on the basis that doing so might result in concurrent judgements, and the loss by it of the commercial advantage of being first to market with a generic version of its product. The Court considered Taro's arguments and concluded that an order directing the common hearing of invalidity issues would not necessarily result in Apotex having its judgement at the same time as Taro, just as the converse would not guarantee that Taro would be first to come to market. In any event, the Court held that nothing in the *Regulations* entitled a generic that is first to send out a notice of allegation in respect of a particular medicine to be the first to obtain a judgement in an action taken pursuant to the *Regulations*.

[14] Bayer also notes that in the present case, Apotex filed its Abbreviated New Drug Submission with Health Canada in 2015, but delayed serving its NOA until late in 2018. This is an indication that the timing of matters is dictated by a number of considerations, and that the Court should not be unduly influenced by arguments that parties who file first should thereby gain a commercial advantage.

[15] Taro submits that the argument by Teva and Apotex that they should gain a commercial advantage because of the timing of their filings should be rejected because it is based on the assertion that first movers have an entitlement to a period of exclusivity in the market, but Parliament did not provide for such a period in the amendments to the *Regulations*. While the framework set by the *Regulations* reflects a desire to achieve certainty and efficiency, it does not extend to a guarantee of a period of exclusivity for the first generic to serve an NOA. Such a

provision was expressly not included in the amendments to the *Regulations* adopted recently, and the Court should not create such a guarantee by its procedural rulings.

[16] Furthermore, Taro argues that it has, in fact, "caught up" to Teva and Apotex in its trial preparations, and that there would be no delay involved in adding it as a defendant at this stage. A trial of common issues aligns with the overall goals of Rule 3 of the *Federal Courts Rules*, SOR/98-106, since it would "secure the just, most expeditious and least expensive determination" on the merits of the common issues. Taro notes that its pleadings are simpler than those of other parties, since it alleges invalidity of only one of the relevant patents, while the other defendants allege invalidity of three patents. Experienced and responsible counsel can work to align the pleadings and timing of trial preparations, as is done in many other cases. Any additional time, expense or complexity involved in adding Taro as a defendant at this stage is more than off-set by the savings and benefits associated with a trial of the issues which are common to all of these cases.

[17] Taro submits that the most important consideration is that they have caught up procedurally to Teva and Apotex in relation to the trial preparation schedule set for their matters, and therefore there will be no delay if it is added as a defendant. This is the most efficient, effective, and least expensive means of dealing with these common issues.

[18] Sandoz adopts the arguments of Bayer and Taro, and contends that it will be prepared to abide by the trial preparation schedule currently fixed for Teva and Apotex. Sandoz also argues that it would be unfair for it to be bound by determinations of claims construction and invalidity without having an opportunity to lead evidence or make submissions on these questions. If Sandoz is not added as a defendant now, it is almost certain that the decisions in the Teva and

Apotex trial on the common issues will be issued before Sandoz has the opportunity to make submissions on these matters. This will prejudice Sandoz, and is not necessary given that Sandoz can meet the timelines set by the current schedule.

[19] In reply, Teva and Apotex submit that the addition of two other defendants will inevitably add time, complexity and cost to the common proceedings. Furthermore, a defendant has no right to be heard in a separate trial involving different parties, even if the factual and legal issues are the same. All parties to litigation may have to live with the consequences of decisions in separate proceedings (whether separate trials or appeals) involving other parties but similar factual or legal issues. That is not inherently unfair to any party.

[20] Teva and Apotex also contend that if Taro and Sandoz are not added as defendants, they may take the benefit of any ruling that is favourable to their interests, and either avoid a trial completely and simply prepare to move to market if the patents are declared invalid, or take the benefit of a shorter trial on specific issues that have not been resolved in the prior proceeding, if that is the result of the decision. Either way, Taro and Sandoz are not prejudiced by not being able to participate in the currently-scheduled trial of common issues.

IV. Analysis

[21] The decision whether to add Taro and Sandoz as defendants to the hearing of common issues currently set for Teva and Apotex involves the exercise of the Court's inherent jurisdiction to control its own proceedings. There is no doubt that the Court possesses such jurisdiction: see, for example: *Lee v Canada (Correctional Service)*, 2017 FCA 228; *Canada (Human Rights Commission) v Canadian Liberty Net*, [1998] 1 SCR 626. In assessing the arguments, the Court

must be guided by the general principles set out in Rule 3 (seeking "to secure the just, most expeditious and least expensive determination" of the merits), as applied within the particular framework fixed by the *Regulations* for the determination of these sorts of claims.

[22] Two considerations arising from this framework are particularly relevant here: (i) the requirement to determine these matters within the 24-month timeline, and (ii) the overall balance of interests as between innovators, generics, and their respective commercial interests and realities, and the wider public interest, that is reflected in the *Regulations* (see *Bristol-Myers Squibb Co v Canada (Attorney General)*, 2005 SCC 26).

[23] While I find that the balance of interests and commercial realities underlying the regime set out in the *Regulations* is a relevant background consideration in this case, I do not accept the argument of Teva and Apotex that the Court should be guided by seeking to protect any "first mover advantage" as a general principle. I agree in general with the reasons expressed by the Case Management Judge in *Biogen* on this issue. No party is guaranteed that their hearing and decision will proceed before any other, and the timing of the launch of an action does not serve to bind the Court to deal with the cases in sequence.

[24] I find that this decision requires a consideration of what is in the interests of justice for all of the parties in the particular circumstances of these cases. There are persuasive arguments on both sides of the question before the Court. On the one hand, Teva and Apotex have been cooperating with Bayer to prepare for trial in accordance with the schedule set by the Case Management Judge. These preparations are well underway, and I have no doubt that continuing to meet their respective obligations within the short timelines set in the schedule involves considerable cooperation and collaboration amongst the parties. It is worth recalling that the

initial schedule in this matter was set by the Case Management Judge on December 13, 2018, prior to the launch of the actions against Taro and Sandoz. Adding two new defendants at this stage of the proceeding will inevitably add a degree of complexity to the preparations for – and conduct of – the trial of common issues.

[25] In addition, Taro and Sandoz may have an advantage by going second, because they will be able to adjust to the outcome of the Teva and Apotex proceedings. This may mean that their trials do not proceed at all, or, if they do continue, it may be anticipated that the issues will in some way be narrowed or better focused. They have no absolute right to participate in the earlier trials, and will not be prejudiced by not having that opportunity. The risks of different rulings are reduced because the same judge is currently assigned to hear all of these matters.

[26] On the other hand, there is considerable force to the argument that both Taro and Sandoz have, in fact, caught up to the trial preparations of Teva and Apotex, and so there is no necessary delay inherent in adding them as defendants in the trial of common issues at this stage. There are obvious savings of time and expense to Bayer and to the Court by avoiding two or possibly three trials on issues which are common to all of the proceedings, and the matters are only separated by a matter of months. If they are not added as defendants, it is an inevitable consequence of the schedule that the trial preparation steps for all of these matters will advance in a similar time frame, given the exigencies of the schedule and the need to complete them all within the respective 24-month periods.

[27] A further consideration is that Teva has filed both a defence and a counterclaim (I note that Sandoz has done the same). This is relevant because of the nature of the remedies that may result if Teva is successful in their counterclaim, in which they allege that the three other

relevant patents held by Bayer are invalid. If Teva is successful at trial on this question, then it appears that upon the expiry of the 561 Patent all of the four defendants will be in a position to go to market with their versions of rivaroxaban. Teva's claim of a "first mover advantage" may therefore effectively disappear if it is successful in its counterclaim.

[28] It is also necessary to weigh the interests of Bayer, which is involved as plaintiff in all of the proceedings. If Taro and Sandoz are not added as defendants, Bayer argues it will be prejudiced by having to deal with the duplication and potential overlap in trial preparations for separate hearings on similar legal and factual questions, occurring in roughly the same time frame. The reality is that Bayer has decided that it is in its interests to launch four separate actions in regard to its patents relating to rivaroxaban (*N.B.*: at the time of writing this decision, Bayer has launched a total of seven actions, including a second claim against Teva, and new actions against Dr. Reddy's Laboratories Ltd. et al (T-1187-19) and Accord Healthcare Inc. (T-1221-19)). That is its right, and there are no doubt commercial and practical considerations that motivated it to do so. Under the *Regulations*, Bayer gains the advantage of a 24-month stay by launching these proceedings, but it may also bear the financial consequences if its claims on the merits do not succeed. This is all part of the overall balance of interests struck by Parliament in the *Regulations*.

[29] In the matters before the Court, Bayer may feel it had few options to defend its patents other than by launching these actions. And, I repeat, that is its right. However, having launched four separate actions, Bayer can hardly claim undue prejudice because it will now have to manage several separate proceedings during the same time frame. That is a natural consequence of its actions, and is a natural consequence of the regime set out in the *Regulations*.

[30] It is true that Bayer may take the same benefit as Taro and Sandoz in relation to the subsequent trials. That is to say, based on the possible outcome of the trials in Teva and Apotex, Bayer may either avoid a future trial or trials with Taro and Sandoz, or take the benefit of a possible narrowing of the issues at the subsequent trials. However, if Taro and Sandoz are not added as defendants it is also possible that Bayer will bear the burden of two or three trials of the same issues.

[31] The principles set out in Rule 3 dictate that the burden to Bayer and to the Court of dealing with these four actions should not be needlessly increased, where there is a feasible alternative. There is a significant interest in avoiding the risk of inconsistent decisions, in particular where the schedule that is currently set can be adhered to by all of the defendants, even if doing so imposes an added burden on Taro and Sandoz.

[32] Having carefully considered the submissions of the parties, I have concluded that it is in the interests of justice to add Taro and Sandoz as defendants in the hearing of common issues currently set for Teva and Apotex. I find there are two primary considerations that weigh in favour of adding Taro and Sandoz as defendants at this stage of the proceeding.

[33] First, although adding new defendants will no doubt add a degree of complexity and require some greater efforts to coordinate as between counsel, it is evident that Taro and Sandoz are now ready to proceed in accordance with the schedule previously established for Teva and Apotex. I note that whatever extra burden is imposed, it will be shared by all of the parties, and I have confidence that the experienced counsel representing all of the parties in these matters can collaborate to ensure that the matters proceed in accordance with this schedule. It may be that

Taro and Sandoz may incur extra burdens or expenses by having to meet this schedule, but they have agreed to do so.

[34] Second, I find it is in the interests of justice to hear the evidence and submissions of all of the parties prior to making the determinations on claims construction and invalidity. The claims are virtually identical; the only significant difference evident from the pleadings is that Taro challenges only one of the three patents that are put in issue by the other defendants. It is in the interests of the parties and the Court to avoid the risk of different rulings in these matters, and the most efficient and effective means of achieving that is to join Taro and Sandoz as defendants in the trial of common issues. Moreover, it is in the interests of justice that the Court has the benefit of the evidence and submissions of all of the parties to these matters before making a ruling that will have an impact on each of them.

[35] Adding two defendants to the trial of the common issues will likely add some time to that trial. This will inevitably be less time than would be needed for a completely separate trial of these issues. Furthermore, the parties will be expected to coordinate their efforts in order to avoid duplicative evidence or submissions.

[36] I find that an important consideration is the tight timelines set by the *Regulations*, and the efforts that Teva and Apotex have expended, together with Bayer, to advance their preparations for trial. At the end of the day, all of the parties and the Court are required to work within a very short 24-month time frame in order to get these matters ready for hearing, and then to complete the trial, and to write and issue the decision. That is an inherent part of the current arrangement set out in the *Regulations*. This means that Taro and Sandoz must now adapt their trial preparations to the schedule set for Teva and Apotex.

[37] A second consequence of this schedule is that that the trial of the common issues for Teva and Apotex will be followed by separate hearings on the issue of infringement for each of them. These must be completed within the 24-month period, and so it is likely that the separate hearings on infringement for Taro and Sandoz will not be scheduled until after the trials on all issues are completed for Teva and Apotex. This sequence may mean that there will be a gap of several months between the proceedings. I note as well that the infringement issues may not proceed at all against Taro and Sandoz, depending on the outcome of the first two matters. This will not prejudice any parties, however, since it has been agreed among all of the parties that the hearings on the issue of infringement will be held separately for each defendant.

V. Conclusion

[38] For these reasons, I find that in the particular circumstances of this case, it is in the interests of justice to add Taro and Sandoz as defendants to the hearing of common issues currently set for Teva and Apotex.

[39] The trial preparations for all of the defendants will proceed as currently scheduled.

ORDER in T-1960-18, T-2093-18, T-435-19 and T-806-19

THIS COURT ORDERS that:

1. The trial of common issues in *Bayer Inc et al v Taro Pharmaceuticals Inc* (T-435-19) and *Bayer Inc et al v Sandoz Canada Inc* (T-806-19) shall be heard together with the trial of common issues previously set for *Bayer Inc et al v Teva Canada Limited* (T-1960-18) and *Bayer Inc et al v Apotex Inc* (T-2093-18).

2. The trial preparations shall continue in accordance with the schedule currently set for the Teva and Apotex matters.

"William F. Pentney"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

DOCKETS:	T-1960-18, T-2093-18, T-435-19, T-806-19
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ORDER AND REASONS:	PENTNEY J.
DATED:	AUGUST 1, 2019

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