

Federal Court



Cour fédérale

Date: 20191112

Docket: T-1187-19

Citation: 2019 FC 1408

Ottawa, Ontario, November 12, 2019

PRESENT: Case Management Judge Mireille Tabib

BETWEEN:

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

Plaintiffs

and

**DR. REDDY'S LABORATORIES LTD.,
DR. REDDY'S LABORATORIES LIMITED and
DR. REDDY'S LABORATORIES, INC.**

Defendants

ORDER AND REASONS

[1] The present action is, chronologically, the fifth action to have been commenced by Bayer pursuant to subsection 6(1) of the *Patented Medicines (Notice of Compliance) Regulations* SOR/93-133 in relation to the drug rivaroxaban and the three patents listed against it. By this motion, Dr. Reddy's Laboratories seeks an order directing that the portions of the trial dealing with invalidity issues that are common with the first four actions be allowed to proceed in September 2020, at the same time as the trials scheduled in the four preceding actions.

[2] For the reasons that follow, Dr. Reddy's motion will be dismissed.

I. PROCEDURAL HISTORY AND CONTEXT

[3] The undersigned is designated as case management judge for all of the actions taken by Bayer in respect of rivaroxaban, and Justice William Pentney has been designated as the trial judge for all of them.

[4] The first two actions were instituted by Bayer against Teva and Apotex on November 9, 2018 and December 7, 2018 respectively. By order dated February 14, 2019, reported at *Bayer Inc v Teva Canada Ltd*, 2019 FC 191 (*Bayer No 1*), and over the objections of Bayer, I ordered that the trials of the common invalidity issues raised by these two actions proceed together, with the remaining portions of the trials on infringement continuing separately afterwards.

[5] Subsequently to that order, on March 8, 2019 and May 17, 2019, Bayer instituted the third and fourth actions against Taro and Sandoz respectively. A hearing to determine whether Taro and Sandoz could "join in" the common trials of invalidity issues was held on June 24, 2019 before Justice Pentney. By order dated August 1, 2019, and this time, over the objections of Teva and Apotex but with the support of Bayer, the trials of the common invalidity issues in those two cases were also ordered to proceed at the same time as the Teva and Apotex trials (*Bayer v Taro et al*, 2019 FC 1039 (*Bayer No 2*)). The hearing of the common issues is scheduled to begin in early September 2020. The infringement portions of the actions against Teva and Apotex will proceed in late September and early October 2020, and it is expected that the trials of the remaining issues for the Taro and Sandoz actions will be held in early 2021.

[6] Dr. Reddy's Notice of Allegation in respect of rivaroxaban was served on June 7, 2019 and the present action was commenced on July 22, 2019.

[7] The parties in the first four actions have been cooperating to conduct joint discoveries of the inventors and of Bayer's representatives in respect of the common issues, and these oral discoveries are largely completed. There remain only refusals motions and potential re-attendance to be completed. Dr. Reddy has declared itself ready to accept the transcript of the discoveries of Bayer's representatives and of the inventors and the answers to undertakings already provided, and to comply with such schedule as will be necessary for it to be ready to proceed to a trial on the invalidity issues in September 2020.

[8] Bayer, Teva and Apotex all vigorously oppose Dr. Reddy's motion. Taro and Sandoz have not taken a position.

II. ANALYSIS

[9] In essence, Dr. Reddy reiterates in support of its motion all of the arguments that were made by Bayer, Taro and Sandoz before Justice Pentney in *Bayer No 2*, argues that this case is on all fours with *Bayer No 2* and that it should follow the same determination. Apotex and Teva also repeat the arguments they made before Justice Pentney, noting that leave to appeal the order in *Bayer No 2* has been granted and that these arguments should be given due consideration here. The parties' arguments are thoroughly set out in *Bayer No 2* and need not be repeated here.

[10] As Justice Pentney mentioned in his decision, the determination to be made on this motion is discretionary and requires consideration of two main factors: the requirement to determine matters under the *Regulations* within a 24-month time frame and the overall balance of interests as between innovators, generics and the wider public interest. Justice Pentney discussed and considered the parties' competing interests and found that on balance, the interest of justice favoured adding Taro and Sandoz's cases to the common hearing of invalidity issues of Teva and Apotex's.

[11] Notwithstanding the pending appeal and recognizing that different judges may exercise their discretion to reach a different result on identical facts, I would, all things being equal, have reached the same conclusion as Justice Pentney. However, all things are not equal in the circumstances as they present themselves on this motion.

[12] First, Bayer does not support the addition of Dr. Reddy's case to the common hearing. It argues, as do Teva and Apotex, that the addition of one more party in the circumstances will make the proceeding so unwieldy that it will jeopardize the parties' ability to meet the 24-month period in the earlier actions. I agree that adding yet another set of lawyers to an already crowded proceeding adds a layer of complexity and unwieldiness that tips the efficiency balance against the addition of another party in the circumstances of this case. Even with the best of intentions, remaining steps would be more difficult to schedule and coordinate, and the schedule is already tight. More importantly, perhaps, the days scheduled for the common trial are barely sufficient to accommodate the active participation of four defendants, and there are simply no additional days of common availability of the existing participants to lengthen the common trial. If Dr. Reddy is

to add anything of value to the pre-trial steps and to the hearing, then more time would necessarily be needed to accommodate that contribution. Conversely, if Dr. Reddy's presence does not add to the trial time or pre-trial steps because it does not plan on contributing something distinct and useful to the proceedings, then what would be the point of adding it to the common hearing?

[13] Second, it is reasonably feasible to hold a full trial on all issues in Dr. Reddy's action, if necessary, within the 24-month period mandated by the *Regulations* without unduly taxing the resources of the Court and of Bayer. There is a difference of over six months between the institution of the first two actions and Dr. Reddy's action. A significant part of the 24-month period that applies to the determination of Dr. Reddy's action therefore falls outside the period within which the first two actions must be determined. There is, further, nearly 2 months between the expiration of the last 24-month delay (applicable to Sandoz) and the expiration of the period for Dr. Reddy's action. The efficiencies and savings of time made from joining Taro and Sandoz to the common hearing will also lighten the burden on Bayer and on the Court of preparing and conducting the remaining portions of the Taro and Sandoz trials, in early 2021. Even without the participation of Dr. Reddy, the judgements that will likely be rendered in 2020 in the Teva and Apotex matters will provide a very good indication of the evidence likely to be led at the trial of this action, and of the findings of fact and law that are likely to be made as a result. One would hope that this will help to narrow the issues for trial in Dr. Reddy's action. Even if it does not, it will be possible to hold a full two-week trial on all issues, before the same judge, and still meet the requirements of the *Regulations*.

[14] Permitting Dr. Reddy to proceed to trial on common issues at the same time as the other four defendants would certainly make efficient use of Court resources and avoid duplication. However, I find that those efficiencies and savings cannot, in the circumstances of this case, be realized without imperilling the Court's ability to hear and determine the Teva and Apotex actions within the period mandated by the *Regulations* and putting unreasonable strain on Bayer's resources.

[15] That finding, combined with the fact that holding a full trial for Dr. Reddy before the same Judge in the spring of 2021 is a reasonable alternative, outweighs all other considerations raised by Dr. Reddy and is determinative of the motion.

III. COSTS

[16] Dr. Reddy submits that Bayer should be ordered to pay the costs of this motion to all parties, regardless of the outcome, as the just cost consequence of its decision to exercise its right to institute all of the actions pursuant to the *Regulations*. I see no reason why Bayer's exercise of its rights under the *Regulations* should, in and of itself, expose it to liability for costs of motions its opponents might bring – and lose – in these actions.

[17] Dr. Reddy's submissions on costs also mention "that the sensible approach would certainly be for Bayer to accept that the outcome of the trial of the common invalidity issues will be binding on Bayer in Dr. Reddy's action" implying that such an offer was made by Dr. Reddy to settle this motion and was refused by Bayer. There is no evidence before me that this might be the case, or that the offer – as it should – included the reciprocal acceptance of the outcome by

Dr. Reddy; indeed, it would not be appropriate for settlement offers to be brought to the Court's attention before it has determined the motion.

[18] Bayer has not requested its costs on this motion. Costs, if awarded, would therefore normally be awarded against the unsuccessful party, Dr. Reddy, and in favour of Teva and Apotex, the only two other successful parties that have requested their costs.

[19] I note, however, that Bayer's responding motion record was served and filed a week before Teva and Apotex's, and that it put forward all of the arguments on which I have relied to dismiss the motion. Apotex and Teva's records added little to the debate; their opposition to the motion and the principal grounds therefor were already well understood from *Bayer No 2*. Their positions could have been put forward in a very summary and joint manner. In the circumstances, I decline to make an award of costs.

ORDER

THIS COURT ORDERS that:

1. Dr. Reddy's motion is dismissed, without costs.

"Mireille Tabib"

Case Management Judge

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET: T-1187-19

STYLE OF CAUSE: BAYER INC. AND OTHER V. DR. REDDY'S
LABORATORIES LTD AND OTHERS

PLACE OF HEARING: CONSIDERED IN WRITING WITHOUT PERSONAL
APPEARANCE

ORDER AND REASONS: TABIB P.

DATED: NOVEMBER 12, 2019

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