Federal Court



Cour fédérale

Date: 20181016

Dockets: T-1163-18

T-1416-18

Citation: 2018 FC 1034

Ottawa, Ontario, October 16, 2018

PRESENT: Madam Prothonotary Mireille Tabib

Docket: T-1163-18

BETWEEN:

BIOGEN CANADA INC., BIOGEN INTERNATIONAL GMBH AND ACORDA THERAPEUTICS, INC.

Plaintiffs

and

TARO PHARMACEUTICALS INC.

Defendant

Docket: T-1416-18

AND BETWEEN:

BIOGEN CANADA INC., BIOGEN INTERNATIONAL GMBH AND ACORDA THERAPEUTICS, INC.

Plaintiffs

and

APOTEX INC.

Defendant

ORDER AND REASONS

- [1] The actions in respect of which the present order is issued were instituted pursuant to s. 6 of the *Patented Medicine (Notice of Compliance) Regulations* (SOR/93-133) (the *Regulations*).
- [2] Both actions were taken in response to Notices of Allegations sent by Taro Pharmaceuticals Inc., in T-1163-18 and by Apotex Inc., in T-1416-18. In their respective Notices of Allegations, these generics allege that the fampidrine product each of them wishes to sell in Canada, and which they have compared with Biogen's fampidrine product (sold under the name Fampyra), will not infringe Canadian Patent 2,562,277 (the '277 Patent) and that the '277 Patent is invalid.
- [3] The Taro action was commenced on June 15, 2018; the Apotex action was commenced on July 24, 2018. In their respective statements of defence to the actions, both Taro and Apotex assert the invalidity of the '277 Patent, and raise many of the same grounds of invalidity. Where there are differences in the grounds of invalidity pleaded, those differences are about to disappear: Apotex has announced its intention to amend its statement of defence to add to its defence the invalidity allegations made by Taro, with Biogen's consent. Biogen has indicated that it would provide its consent should Taro wish to amend its own statement of defence to add grounds of invalidity raised in Apotex's defence.
- [4] Following a first case management conference held in early July 2018, the Court fixed a schedule for the principal stages of the proceedings in the Taro action, and set down the trial of that action for 10 days beginning on March 2, 2020.

- [5] At the first case management conference in the Apotex action, held in early September 2018, Biogen and Apotex proposed a schedule for the principal stages of their action that would also see them ready for a two week trial as early as March 2, 2020.
- [6] The question that arises is whether the trial of the two actions should proceed concurrently, at least on the invalidity issues.
- In pharmaceutical patent litigation, it has been the practice of the Court to assign, where reasonably possible, the same judge to hear matters involving the same patent and same medicine. The science and technology involved in such litigation is so complex that it requires considerable time and effort for a judge to acquire a working knowledge of the basic non-contentious scientific concepts that are required to determine the factual questions at issue. It is simply sound use of judicial resources for the Court to put that hard earned knowledge to work on subsequent cases that require it. A judge who is intimately familiar with the evidence adduced in one case will also have a keener sense of where the differences in the evidence adduced in a different case might justify a different result, without offending the principles of judicial comity and predictability.
- [8] Following this practice, the Court would thus normally assign the same Judge to both the Taro and Apotex trials.
- [9] Given that the invalidity issues in both actions are essentially the same, that counsel for Biogen are the same, that the same inventors will be called to testify to the same factual issues, that the two actions will be heard in the same period of time and that the judge should be the

same, efficient use of the Court and the parties' time all but demands that the invalidity issues in both actions be tried together.

- [10] Both Biogen and Apotex readily consent to this measure. Taro does not.
- [11] Taro's objections are not based on any perceived substantive or procedural prejudice it might suffer from a common trial, but on the perception that doing so will result in concurrent judgments, resulting for Taro in a loss of the commercial advantage of being first to market with a generic fampidrine product.
- [12] I find, however, that in the circumstances of this case, ordering the common invalidity issues to proceed to trial concurrently would not have the effect of depriving Taro of any commercial or strategic rights conferred on it by the *Regulations*.
- [13] Being the first to send out a Notice of Allegations in respect of a particular medicine does not entitle a generic to be the first to obtain a judgment in an action taken pursuant to the Regulations, or guarantee it that result.
- [14] Although the Regulations contemplate a 24 month period for such actions to proceed to trial and to judgment, each litigation is unique and proceeds at its own pace. Certain actions will have fewer issues in dispute and certain pairs of counsel will find common ground more easily or will have more common dates of availability for discoveries, pre-trial motions or trial. As a result, an action initiated several weeks later could conceivably come to trial before an action that was instituted earlier. An innovator might reach a settlement with a generic whose notice of allegation postdated another generic's. Even where trials are scheduled to take place separately and in the order in which the actions were instituted, there is no guarantee that a judgment will

issue in the same order. The Court might assign different judges, who work at different speeds. Even where the same judge hears both actions in succession, that judge may find it more convenient to wait, or may not have time to issue judgment in the first action before both are heard. Finally, despite some common issues, one trial may raise more difficult issues than the other and may accordingly take more time to determine.

- [15] Bearing these factors in mind, Apotex could end up coming to market or having its judgment before Taro, even if the trials were scheduled to proceed separately.
- [16] On the other hand, a common trial on the common invalidity issues would not necessarily result in Apotex having its judgment at the same time as Taro.
- [17] Indeed, an order that the trials proceed concurrently on invalidity issues will not bifurcate the issues of the Apotex trial, but merely schedule the trial of the common invalidity issues to start, in the Apotex trial, at the same time as Taro's. Apotex's trial, as concerns all other issues, will then be adjourned to continue in April 2020, while Taro's trial will continue to its scheduled conclusion on March 13, 2020. Thus, the trial judge would be in a position, should she choose or be able, to issue a judgment in the Taro trial before completing the Apotex trial. Given that the evidence on invalidity will have been common, Apotex and Biogen might know the likely outcome of the Apotex trial on invalidity when the Taro judgment is issued, but that judgment will not be effective or binding, in and of itself, in respect of the Apotex action.
- [18] In conclusion, I am satisfied that an order scheduling the Apotex trial, in respect of any common invalidity issue, to begin on March 2, 2020 and take place concurrently with the trial of the Taro action on these common issues, constitutes the most efficient use of the Court and the

parties' time and resources, would achieve the just, most efficient and least expensive determination of the issues in both actions, and would not likely result in prejudice to Taro's substantive or procedural rights, including any rights it may have pursuant to the Regulations.

ORDER

THIS COURT ORDERS that:

- 1. The trial in Court file T-1416-18 will take place in Toronto, beginning at 9:30 a.m. on March 2, 2020, and, in respect of all common invalidity issues, will be heard concurrently with the trial in T-1163-18.
- 2. The trial in Court file T-1416-18 will be adjourned, following the common invalidity issues, and will resume in Toronto, beginning at 9:30 a.m. on April 20, 2020, for duration not exceeding one week.

"Mireille Tabib"
Prothonotary

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET: T-1163-18

STYLE OF CAUSE: BIOGEN CANADA INC., BIOGEN INTERNATIONAL

GMBH, AND ACORDA THERAPEUTICS, INC. v

TARO PHARMACEUTICALS INC.

AND DOCKET: T-1416-18

STYLE OF CAUSE: BIOGEN CANADA INC., BIOGEN INTERNATIONAL

GMBH, AND ACORDA THERAPEUTICS, INC. v

APOTEX INC.

ORDER AND REASONS: TABIB P.

DATED: OCTOBER 16, 2018

APPEARANCES:

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