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To Consolidate or Not to Consolidate – This is the Federal Court's Question

In a recent decision, *Takeda Canada Inc v Apotex Inc*, the Federal Court dismissed the Plaintiff, Takeda's, motion for consolidation of two actions against Apotex relating to Takeda's dexlansoprazole (DEXILANT) under section 6 of the *Patented Medicines (Notice of Compliance) Regulations* (the "*PM(NOC) Regulations*").

Background

Eight patents are listed against Takeda's DEXILANT, two of which expired in 2022 or earlier, three expire in 2025, 2028, and 2029, and the remaining three all expire on October 15, 2023.

When Apotex filed its Abbreviated New Drug Submission ("ANDS") in late 2021, it advised the Minister of Health it was content to await the expiration of the five patents due to expire in 2022 and 2023 before receiving its Notice of Compliance ("NOC"). It did, however, deliver to Takeda Notices of Allegations ("NOAs") relating to the remaining three patents. In response, Takeda commenced the First Action on January 27, 2022.

On August 26, 2022, Apotex apparently changed its mind on waiting until the expiration of four of the patents and served four NOAs on Takeda. In response, Takeda commenced the Second Action on October 5, 2022.

Apotex readily admitted the second set of NOAs reflected a change of heart brought about by "unexpected external circumstances". Those confidential circumstances were not contested. Takeda initially argued that Apotex's delay in serving the NOA was a deliberate litigation strategy to avoid having to explain the contradictory positions it had taken in respect of the two Actions. Takeda later conceded that Apotex's change of heart was a function of unexpected external circumstances.

The trial of the First Action is scheduled for October 2023. Takeda's motion sought a consolidated trial of the First and Second Actions in March 2024, as well as an extension of the 24-month stay in the First Action from January 27, 2024, until a determination of the proposed consolidated trial.

Discussion

Rule 105(a) of the *Federal Courts Rules* addresses consolidation of proceedings. The purpose of consolidation is to avoid a multiplicity of proceedings and the promotion of expeditious and inexpensive determination of those proceedings. In determining these motions, the Court may consider the commonality of the parties, issues, facts, causes of action, and evidence as well as the likelihood that an outcome of one case will resolve the other case and potential prejudice.

Key Findings

Commonalities

The Court accepted the two actions have clear commonalities; they involve the same parties, represented by the same counsel; they involve the same Apotex product and the same ANDS. Further there were some commonalities of fact: the two actions raise common factual issues in respect of one of the patents-in-issue, the 851 Patent and its teachings. There was no commonality on certain facts in the Second Action. The Court held the Second Action includes entirely separate and distinct allegations of invalidity of the 851 Patent as compared to the allegations of infringement and invalidity of three patents asserted in the First Action. Associate Judge Tabib found that while trying all issues relating to the 851 Patent would create efficiencies, “the area of overlap between the two actions is not so significant that hearing the actions separately would prove entirely wasteful or duplicative”.

Prejudice to Takeda

Prejudice is another important factor considered in the context of a motion for consolidation. To this end, Takeda asserted that pursuing two actions to different trials would cause it prejudice by (1) forcing it to defend two different actions eight months apart with overlapping deadlines, and (2) the contradictory positions adopted by Apotex may lead to inconsistent decisions.

The Court was not persuaded by either argument, finding Takeda had not established its resources and would be unduly strained by having to pursue the two actions separately on overlapping schedules, and further, issue estoppel would eliminate the likelihood of contradictory judgments.

Prejudice to Apotex

Takeda addressed the potential prejudice to Apotex under two alternative scenarios – consolidation without or with an extension of the 24-month stay.

Takeda asserted that delaying the determination of the First Action will not be prejudicial to Apotex under either scenario because (1) if there is no extension of the stay, then it will not be delayed in entering the market (assuming Apotex will obtain its NOC on the expiration of the stay on January 27, 2024) or, (2) even if the stay is extended and Apotex is delayed in entering the market, it will not lose market share or a first-mover advantage, as there are no other potential generic entrants in the market for this drug at this time.

The Court disagreed with Takeda concluding both scenarios were prejudicial to Apotex. The Court found delaying the determination of the issues raised in the First Action to accommodate a consolidated trial would either force Apotex to assume the risk of entering the market "at risk", which includes exposure to the cost of litigation and a potential liability to Takeda, or delay its potential entry by five months, with the attending risk of losing first-mover advantage, a significant advantage enjoyed by the first generic entrant on the market.

Apotex's Conduct

Takeda further asserted that if there was any prejudice to Apotex it was entirely of its own making. There was no reason for Apotex not to serve all of its NOAs at the same time, ensuring all issues relating to all patents listed against Dexilant be heard within the 24-month stay. In doing so, Takeda alleged that Apotex failed to act in accordance with the purpose and intent of the *PM(NOC) Regulations*, an argument the Court found analogous to an argument of abuse of process.

The Court rejected this argument, finding this situation did not amount to an abuse of process because Apotex's choices surrounding timing of service of its NOAs were not guided by a desire to obtain an improper advantage, but solely by commercial considerations.

The Court further emphasized that Takeda's position, premised on the notion that the *PM(NOC) Regulations* either require a generic to serve all its NOAs simultaneously, or at the very least, to take all reasonable steps to ensure all disputes pertaining to patents listed on the Register to be determined within the 24-month period, is not supported by either the *PM(NOC) Regulations* or jurisprudence.

Key Takeaways

There are a few key takeaways. According to this decision a party seeking approval for a generic drug (defined in the *PM(NOC) Regulations* as a "Second Person") is not required to serve all its NOAs listed against a drug approved for sale in Canada simultaneously. Nor does the Second Person need to

take all reasonable steps to ensure that all disputes pertaining to patents listed on the Register be determined within the same 24-month period.

This is not to say decisions Second Persons may make in respect of timing of NOAs can never be questioned. The holding in this case is premised on the Court's finding that the timing of Apotex's NOAs was "brought about by unexpected external circumstances" and "guided solely by commercial considerations". Unfortunately, the details of those circumstances are confidential, obscuring precisely what circumstances the Court found justified the delay in delivering the second set of NOAs. In a subsequent case, if a Court were to find that litigation strategy played some role in respect of timing of NOAs, then it might lead to a different result. Perhaps we may also see relief in section 8 proceedings (under section 8(6)) or other costs consequences (e.g., section s. 6.12(2)) used to balance this concern. However, in the absence of a breach of an obligation under the *PM(NOC) Regulations* or conduct that was found to be dictated by improper motives, merely staggering the delivery of NOAs alone does not appear to be sufficient foundation for consolidation under the *PM(NOC) Regulations*.

A final takeaway is we are seeing a recent trend for the Court to resist consolidation of actions under the *PM(NOC) Regulations*. We previously discussed *Apotex Inc v Janssen Inc* here, a recent decision where the Federal Court considered a consolidation motion under section 8 of the *PM(NOC) Regulations*. As is the case here, in *Apotex Inc v Janssen Inc* the Court was not persuaded to order consolidation. Nonetheless we expect to continue to see motions for consolidation as the factors to be considered depend on the facts and prejudice in each case.