Federal Court  Cour fédérale

Date: 20230123

Docket: T-151-22

Citation: 2023 FC 63

Ottawa, Ontario, January 23, 2023

PRESENT: Associate Judge Mireille Tabib

BETWEEN:

TAKEDA CANADA INC.

Plaintiff

and

APOTEX INC.

Defendants/Patent Owner(s)

and

TAKEDA PHARMACEUTICAL COMPANY LIMITED and TAKEDA PHARMACEUTICALS USA, INC.

Defendants/Patent Owner(s)

AMENDED REASONS FOR ORDER AND ORDER

I. OVERVIEW

[1] The Plaintiff, Takeda, seeks an Order consolidating two actions commenced pursuant to section 6 of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 (the "Regulations"). Both actions involve the same parties, drug product and Abbreviated New Drug Submission. However, the first action, T-151-21 (the "First Action"), was instituted in February 2021 and is already scheduled to proceed to trial in September 2023. The second action, T-2262-22 (the "Second Action"), was commenced on October 5, 2022. It is common ground between the parties that this latter action cannot reasonably be ready to proceed to a trial in 2023. Thus, granting Takeda's motion necessarily entails abandoning the October 2023 trial dates in favour of a later consolidated trial in early 2024, over 24 months following the start of the First Action.

[2] Takeda's Notice of Motion also seeks the extension of the 24-month period contemplated in section 7 of the *Regulations*. Counsel for Takeda advised the Court at the hearing that its motion for a consolidation is, however, not contingent on that extension. In other words, Takeda would prefer a consolidated trial even if it was not accompanied by an extension of the 24-month stay. Finally, while Takeda's motion to consolidate is not contingent on the extension of the 24-month period, the reverse is not true. If the Court declines to consolidate, then there would be no basis to extend the 24-month period.

[3] Apotex vigorously opposes both the consolidation and the extension of the 24-month period

[4] For the reasons given below, the motion will be dismissed. As consolidation will not be ordered, it is unnecessary for me to consider the request for an extension of the 24-month period.

II. THE REGULATORY REGIME

[5] Bringing innovative medicinal drugs to market is extraordinarily expensive. In addition to the research and development investments needed to discover new drug therapies, obtaining an authorization to market a drug product in Canada (known as a Notice of Compliance ("NOC")) requires satisfying the Minister of Health that the drug is both safe and effective. The clinical trials that are typically conducted to demonstrate this take years to conduct and cost millions of dollars. Not surprisingly, innovative pharmaceutical companies seek to recoup these costs through the profits made by selling the products. Profitability is insured by patenting the inventions that went into making or using the drug product. A patent protects the drug from being copied and sold by others at a lesser price, undercutting the innovator's profits.

[6] While innovators play an essential role in creating and bringing new drugs to market, pharmaceutical companies dedicated to manufacturing and selling "generic" copies of these new drugs play an important role in fostering a competitive environment in which medicines necessary to treat Canadians are available at an affordable price. In order to facilitate the entry of generic products in Canada, the Minister of Health allows manufacturers to use to the safety and efficacy data generated by innovators, to help them prove that their proposed generic copy is equally safe and effective. In order to rely on an innovator's data, a generic manufacturer must simply establish that its product is bioequivalent to a drug already approved for sale in Canada

(the "Reference Product"). Submissions for approval of a generic drug based on an innovator's product are referred to as Abbreviated New Drug Submissions ("ANDS").

[7] The *Regulations* seek to strike a balance between the protection of patents that are essential to the business model of innovators and ensuring that cheaper generic drugs be available to the Canadian public as soon as possible. It sets up an elaborate regime whereby innovators can register patents against a new drug for which they have or are seeking approval. Once a patent is registered against that product, a generic can only use it as a Reference Product in an ANDS if it addresses the patent in one of the following ways:

- agreeing to wait until the patent's expiration before receiving its NOC; or,

- alleging that its proposed product does not infringe the patent listed or that the patent is invalid.

[8] Allegations to the effect that a listed patent will not be infringed or is invalid take the form of a Notice of Allegation ("NOA"), which the generic must serve on the innovator. On receipt of an NOA, the innovator may decide to allow the NOC to be issued in due course or to challenge the allegation. A challenge is made by filing an action in the Federal Court seeking a declaration that making, selling or using the proposed generic product in accordance with the ANDS would infringe the patent at issue in the NOA. The filing of such an action acts as an automatic interlocutory injunction against the issuance of the NOC while the patent is valid. An

NOC will only issue to the generic if the action is dismissed or withdrawn, or if more than 24 months have elapsed since the filing of the action and no judgement has been issued.

[9] In the event the innovator's action is dismissed, the *Regulations* entitle the generic to be compensated for losses it suffered as a result of the 24-month stay. It may claim, from the innovator, the profits it would have made from the time the NOC would have been issued, but for the stay, to the date the NOC actually issues following the dismissal of the action.

[10] The *Regulations* therefore establish a complex regime, meant to ensure that when manufacturers seek to market generic versions of drugs that are protected by patents, disputes as to the validity and infringement of the relevant patents are determined promptly. The *Regulations* proceed from the expectation that all participants in the process – innovators, generics and the Court – will act diligently to carry out the regulatory intent. To that end, they impose certain obligations on the parties and provide that failure of the parties to comply with these obligations can be sanctioned in a variety of ways including, where the defaulting party is the generic, by the extension of the 24-month stay.

III. THE FACTS

[11] The drug at issue in these matters is dexlansoprazole, which Takeda markets under the brand name Dexilant. Eight patents are listed against this medicine. Two of them expired in 2022 or earlier. Patent No 2,570,916 (the "916 Patent"), Patent No 2,702,356 and Patent No 2,671,369

expire much later, in 2025, 2028 and 2029 respectively. The three other patents, Patent No 2,499,574, Patent No 2,737,851 (the "851 Patent") and Patent No. 2,771,725 all expire on October 15, 2023.

[12] When Apotex filed its ANDS in late 2021, it chose not to challenge the validity of the five patents due to expire in 2023 or earlier, nor to allege that they would not be infringed. It advised the Minister that it was content to await their expiration before receiving its NOC. It did, however, deliver to Takeda NOAs relating to the remaining three patents. On January 27, 2022, Takeda instituted the First Action pursuant to section 6 of the Regulations, seeking a declaration that if Apo-dexlansoprazole was manufactured or sold in accordance with the ANDS, it would infringe two of those three patents. That First Action is currently scheduled to proceed to a two-week trial on October 16, 2023.

[13] On August 26, 2022, Apotex apparently changed its mind as to awaiting the expiration of the four patents due to expire in 2022 and 2023. To that effect, it served four NOAs on Takeda in respect of those four patents. On October 5, 2022, Takeda filed the Second Action, alleging that if Apotex were to manufacture and sell Apo-dexlansoprazole, it would infringe the claims of the 851 Patent, due to expire in October 2023. Takeda chose not to challenge Apotex's allegations in respect of the three other patents, and no more will be said about those in these reasons.

[14] Apotex readily admits that the NOAs sent in August 2022 reflected a change of heart, brought about by unexpected external circumstances. Those circumstances are set out in the

confidential versions of the parties'motion records and are not contested. It was obviously Apotex's intention to claim section 8 damages from Takeda from the time its ANDS became approvable, should it succeed in the First Action. However, given that it had not challenged the patents expiring in 2022 and 2023, the period for which it could claim damages would only have begun to run from October 15, 2023. The purpose of the NOAs served in August 2022 was therefore simply to increase the period for which it could potentially claim section 8 damages. Likewise, Takeda's decision to institute the Second Action is motivated solely by a desire to avoid that additional liability.

[15] Takeda initially argued on this motion that Apotex's delay in serving the NOA for the 851 Patent was a deliberate ploy to avoid having to explain the allegedly contradictory positions it has taken in respect of that patent and of the 916 Patent, litigated in the First Action. While Takeda still maintains that Apotex's position with respect to the 851 and 916 Patents are inherently contradictory, it all but now concedes that Apotex's change of heart in respect of the 851 Patent was not the result of a deliberate litigation strategy but a function of the unexpected external circumstances.

[16] Having considered the extensive evidence provided by Apotex, I am satisfied that both Apotex's initial decision to await patent expiry in respect of the 851 Patent and its decision to reverse course in 2022 were arrived at based on commercial considerations rather than litigation strategy.

IV. THE ISSUES

[17] Against this factual backdrop, Takeda submits that the First and Second Actions should be heard together. It argues that the contrary positions taken by Apotex on the 851 and 916 Patents must be resolved in a single trial, lest there be a risk of contradictory judgements. It also submits that there is considerable overlap between the issues in the two actions and that it would be wasteful and duplicative to try the matters separately.

[18] Takeda argues that consolidation will not prejudice Apotex. In any event, it argues that any prejudice to Apotex is of Apotex's own making and should not stand in the way of consolidation.

[19] Given that it is not possible to try a consolidated action before the expiration of the 24-month period applicable to the First Action, Takeda also asks that the Court extend the 24-month period by a period equivalent to the delay between start of the currently scheduled trial and the start of the consolidated trial. Takeda submits that, had Apotex sent its NOA regarding the 851 Patent at the same time as the others, all issues could and would have been determined together, at the October 2023 trial. Takeda argues that, whether intentional or not, Apotex's delay in sending an NOA for the 851 Patent will result in a delay in the determination of the First Action, given the alleged necessity of consolidation, and that the Court is thus justified in extending the 24-month period.

[20] Apotex, for its part, argues that there is no overlap between the actions, or, to the extent there is; it neither gives rise to a risk of contradictory judgements nor justifies the adjournment of the First Trial. It asserts that it would be prejudiced by the loss of the current trial dates, and that a consolidation should accordingly be refused. Apotex further submits that the *Regulations* do not impose on a generic an obligation as to when NOAs are to be served, and that it consequently has not breached any of its obligations under the *Regulations.* As such, it submits that the Court has no jurisdiction to extend the 24-month period.

[21] The issues for determination on this motion are therefore as follows:

(1) Should the First Action and the Second Action be consolidated?

(2) If consolidation is ordered, should the 24-month period be extended?

V. CONSOLIDATION

[22] Rule 105(a) governs the consolidation of proceedings. The purpose of consolidation is "the avoidance of a multiplicity of proceedings and the promotion of expeditious and inexpensive determination of those proceedings" (*Apotex Inc v Bayer Inc et al*, 2020 FCA 86 at para 45). In determining such motions, the Court may consider the following factors:

- the commonality of parties;
- common legal and factual issues;

- similar causes of action;

- parallel evidence; and

- the likelihood that the outcome of one case will resolve the other case (*Global Restaurant Operations of Ireland v Boston Pizza Royalties Ltd Partnership* 2005 FC 317).

[23] However, that same jurisprudence also recognizes that proceedings should not be consolidated if one of the parties would be prejudiced (see also *Eli Lilly and Co. v Apotex Inc.* (1994) 55 CPR (3d) 429). The burden rests on the moving party to persuade the Court that the responding party will not suffer appreciable prejudice or injustice or that continuing the actions separately would be an abuse of process or cause it prejudice. The moving party must prove a prejudice rather than a mere inconvenience (see *Sanofi Aventis Canada Inc et al v Apotex Inc* 2009 FC 1285, at para 11; *Apotex v Bayer*, above at paragraph 46). The overarching principle on a motion for consolidation should be, as stated in *John E. Canning Ltd v Tripap Inc* (1999) 167 FTR 93 at paragraph 26, “the general interest of justice, its proper administration and true interests of the parties.”

A. *Commonalities*

[24] 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. There are also some commonalities of fact: in the First Action, Apotex argues that the 916 Patent is invalid for

obviousness in view of information disclosed in the 851 Patent. In addition, Apotex in the First Action raises the Gillette defence, alleging that its product is made "in accordance with the directions of the 851 Patent" or "in a manner consistent with the teachings of the 851 Patent". In the Second Action, Apotex alleges that the 851 Patent is invalid for insufficient disclosure because its specification "does not set out clearly the various steps" in the process to make, compound or use the invention. The allegations in both actions therefore raise the common factual issues of how a person of skill in the art would read and understand the 851 Patent and its teachings.

[25] These commonalities are indeed significant and trying all issues involving the relevant teachings and the interpretation of the 851 Patent would create efficiencies and be desirable. That said, the area of overlap between the two actions is not so significant that hearing the actions separately would prove entirely wasteful or duplicative. The Second Action includes allegations of invalidity of the 851 Patent that are entirely separate and distinct from the allegations of infringement and invalidity of the 916 and other patents covered by the First Action. Indeed, Takeda acknowledged that it was precisely because of the absence of significant factual overlap between the two actions that the Second Action could not reasonably be briefed and heard in time for the scheduled start of the trial in the First Action.

[26] As discussed earlier, potential efficiencies do not, of themselves, justify consolidation in the absence of consent from Apotex. In order to succeed on its motion, Takeda must also establish either that pursuing the two actions separately would be prejudicial to it or that consolidation would not cause prejudice to Apotex.

B. *Prejudice to Takeda*

[27] Takeda alleges that pursuing the two actions to different trials would cause it prejudice in the following forms: first, that it forces it to defend two different actions, some eight months apart and with overlapping deadlines, and second, that the contradictory positions adopted by Apotex in the two actions may lead to inconsistent decisions.

[28] Takeda has not established that its resources would be unduly strained, resulting in prejudice, by having to pursue the two actions separately on overlapping schedules. Takeda is a sophisticated litigant, represented by capable and experienced counsel. There is no evidence that their resources would be insufficient to allow them to fully prepare and present their case in the circumstances as they exist. As discussed, there is minimal overlap of factual issues; there are no reasonable grounds to believe that key witnesses, be they of fact or expertise would prove unavailable or difficult to muster in either or both actions.

[29] As for Takeda's claim of prejudice arising from inconsistent pleadings and the risk of contradictory judgements, it is not persuasive. It is not inherently contradictory to say that the process followed by Apotex in making its product "accords with" the directions of the 851 Patent or is "consistent with" its teachings and to also say that the teachings of that patent are not, on their own, sufficiently clear or complete to meet the disclosure requirements of section 27(3)(a) of the *Patent Act*. While specific findings of fact may make the determination of the two arguments mutually exclusive, they are not necessarily so. In any event, because the two actions

are between the same parties, the findings of fact in the First Action will be binding on both parties in the Second Action under the principles of issue estoppel, eliminating the likelihood of contradictory judgements.

[30] I am, accordingly, not satisfied that maintaining a separation between the two actions is prejudicial to Takeda.

C. *Prejudice to Apotex*

[31] Consolidation necessarily involves the adjournment of the trial set to begin in October 2023, and a delay in the determination of the issues raised in the First Action. The earliest a consolidated trial could be heard, according to the schedule proposed by Takeda, is March 2024, a delay of five months. Takeda argues that pushing back the determination of the First Action will not be prejudicial to Apotex, either because it will not be delayed in entering the market or because, if delayed, it will not lose market share or a first-mover advantage, as there are currently no other potential generic entrant in the market for this drug.

[32] The first scenario urged by Takeda assumes that the Court will not extend the 24-month period, that Apotex will thus obtain its NOC upon the expiration of the stay, on January 27, 2024, and immediately enter the market. However, Takeda’s argument discounts the possibility that the Court would rule on the First Action prior to January 27, 2024, giving Apotex an even earlier entry. It also ignores the fact that in entering the market ahead of the trial and of the

determination of the issues raised in the First Action, Apotex would be entering this market "at risk". Should the Court subsequently determine that either of the two patents covered by the First Action are valid and infringed by Apotex's product, it would then face the prospect of being liable to Takeda for infringement. I am satisfied that this risk, which includes exposure to the cost of litigation and a potential liability to Takeda beyond the profits realized by the sale of Apotex's product, is inherently prejudicial to Apotex.

[33] Takeda's second argument, that delaying Apotex's eventual entry onto the market until the determination of a consolidated action would not be prejudicial because Apotex would remain first to market, recognizes the significant advantage enjoyed by the first generic entrant on the market. It therefore implicitly acknowledges that the loss of this advantage constitutes a material prejudice to Apotex. The problem with Takeda's argument is that the assumption that Apotex would remain first to market despite a five-month delay is entirely speculative. The fact that no other generic has yet served an NOA on Takeda in respect of dexlansoprazole in no way establishes that no other generic competitor will manifest itself in the interim. It is entirely possible for a proposed generic to have filed an ANDS and to be approvable without having yet served an NOA. There is, further, no guarantee that Takeda would choose to challenge an NOA from another generic. I should add that I am not persuaded by Takeda's argument that Apotex would necessarily be able to recoup all losses from a delayed entry through a section 8 action. While it may certainly claim those losses, there is significant uncertainty as to whether this claim would ultimately succeed, especially if Apotex were to receive its NOC but choose not to enter "at risk". Takeda has certainly not conceded that Apotex would be entitled to all its losses in that eventuality.

[34] 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" or delay its potential entry by five months, with the attending risk of losing first-mover advantage. Both of these scenarios are prejudicial to Apotex.

[35] Takeda has failed to establish, as was its burden on this motion, that delaying the determination of the issues raised in the First Action to a second, consolidated, trial in March 2024 would not cause prejudice to Apotex.

D. *Arguments based on Apotex's conduct*

[36] Takeda argues that any prejudice to Apotex is entirely of Apotex's own making. It submits that there was no reason for Apotex not to serve all of its NOAs at the same time, ensuring that all issues relating to all patents listed against the Reference Product be heard and determined at the same time and within 24 months. Apotex, knowing that it was indeed possible that it would become approvable earlier than October 2023, nevertheless chose to hold back serving some of its NOAs, while reserving to itself the right to unilaterally change its mind. Takeda argues that Apotex knew that this would result in duplicative and piecemeal litigation, to Takeda's and the Court's prejudice, and contrary to the legislative intent of the *Regulations*.

[37] The argument that Apotex failed to act in accordance with the purpose and intent of the *Regulations* is a recurrent theme in Takeda's submissions. It underlies its request to extend the

24-month period, but it also features prominently on the issue of consolidation, as a basis to justify the adjournment of the existing trial, to support consolidation and to ignore or discount any prejudice that might be caused to Apotex from the consolidation and adjournment. It is essentially analogous to an argument that consolidation in this case is appropriate because allowing the two actions to proceed separately would condone an abuse of process. Avoiding an abuse of process has sometimes been cited as potential grounds for a consolidation order (*Mon-Oil Ltd v R*, 1989 [1989] F.C.J. No. 227, 26 C.P.R. (3d) 379, 27 F.T.R. 50, at para 4, citing *Fruit of the Loom Inc v Chateau Lingerie Mfg Co Ltd* (1984) 79 C.P.R. (2d) 274 at page 278).

[38] Takeda's argument is not tenable as a true abuse of process argument. An abuse of process is characterized by the misuse of the judicial process for ulterior motives. However, Apotex's choices surrounding the timing of the service of its NOAs were not guided by the desire to obtain an illegitimate advantage. I am satisfied that they were guided solely by commercial considerations.

[39] Given my conclusion that Takeda would not be prejudiced by separate trials and that Apotex did not deliberately withhold sending the NOA concerning the 851 Patent in order to gain an improper advantage, Takeda's argument urging me to nevertheless disregard the prejudice that would be caused to Apotex from consolidation necessarily presupposes that Apotex acted improperly in failing to serve the NOA relating to the 851 Patent earlier. Takeda's position is premised on the notion that the *Regulations* either require a generic to serve all of its NOA simultaneously or, at the very least, 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. Such

an interpretation is not supported either by the provisions of the *Regulations* or by the jurisprudence.

[40] Section 6.09 of the *Regulations* expressly mandates that "[e]very […] second person […] shall act diligently in carrying out their obligations under these Regulations […]". Tellingly, however, Takeda does not refer to any provision of the *Regulations* that requires a second person to send all relevant NOAs at the same time. The only provision that expressly addresses the timing of service of an NOA is section 5(3)(a), which states that a second person who makes an allegation against a listed patent as part of its ANDS submission must serve and NOA "on or after" the date of filing of the ANDS.

[41] The Federal Court of Appeal has consistently held that a second person has no obligation regarding the timing of the delivery of an NOA, and that it is free to deliver as many NOAs as there are patents listed on the Register, even if that leads to a separate proceeding for each patent (*AB Hassle v Canada (Minister of National Health & Welfare)*, [2000] FCJ No. 855 (CA) at para 19; *Parke-Davis Division, Warner-Lambert Canada Inc v Canada (Minister of Health)*, 2002 FCA 454 at para 67, leave to appeal refused [2003] SCCA No 66 (SCC); *AB Hassle v Apotex Inc*, 2006 FCA 51 at para 2; *Eli Lilly Canada Inc v Teva Canada Limited*, 2018 FCA 53 at para 75, leave to appeal refused [2018] 3 SCR vi). While these decisions predate the significant amendments made to the *Regulations* in 2018, the nature of the amendments do not compel a re-evaluation of those authorities. On the contrary, given the consistent jurisprudential interpretation of a second person's rights and obligations with respect to the delivery of NOAs,

one would have expected that any legislative intent to depart from the jurisprudential interpretation would have been clearly signalled.

[42] I am accordingly not satisfied that the *Regulations* impose a positive obligation on a second person to serve all NOAs listed against a Reference Product at the same time or within such time as will ensure that all resulting litigation be determined within 24 months. This is not to say that decisions generics might take in respect of the timing of NOAs can never be questioned or lead to some sort of procedural sanctions. However, given that Apotex has not directly breached an obligation under the *Regulations*, and that its conduct was not dictated by improper motives, I find no reason to depart from established jurisprudence to the effect that the Court will not impose consolidation where doing so would cause prejudice to a party.

VI. Other matters

[43] As mentioned earlier, Takeda's request for an extension of the 24-month period is contingent on consolidation being ordered. Given my determination that it is not appropriate to order consolidation, I need not address that part of the motion.

[44] Takeda's Notice of Motion sought, as an alternative relief, that the Second Action be stayed pending the final outcome of the First Action. Apotex does not strongly oppose that measure, given that the 851 Patent will expire on October 15, 2023, and does not stand in the way of the issuance of its NOC. Indeed, Apotex acknowledges that the determination of the

Second Action only becomes relevant if it is successful on the First Action and thus become entitled to claim section 8 damages. Apotex however urged the Court to dismiss the alternative relief, at least until such time as the parties can discuss and make full submissions as to the duration of the stay, particularly given its incidence on an eventual section 8 action.

[45] At the Court's suggestion, both parties agreed that portion of the motion should simply be adjourned.

VII. Costs

[46] Apotex submitted at the hearing that, if it were successful on the motion, an award of costs in its favour in the amount of $3000 would be appropriate. I find that amount reasonable, particularly given that Takeda proposed that costs be fixed at $5000.

ORDER

THIS COURT ORDERS that:

1. That part of the motion, seeking, in the alternative, an Order staying the action in T-2034-22 pending the final outcome of the proceedings in T-151-22 is adjourned.

2. The motion is otherwise dismissed, with costs payable to the Defendant in the amount of $3000.

3. The parties shall, by February 15, 2023, file further written submissions with respect to the request for an alternative relief. The parties shall include in their written submissions their mutual date of availability for a hearing of that part of the motion.

"Mireille Tabib"
Associate Judge

FEDERAL COURT

SOLICITORS OF RECORD

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