Federal Court  Cour fédérale

Date: 20230628

Dockets: T-1121-22
T-1122-22
T-1248-22
T-1249-22

Citation: 2023 FC 912

Ottawa, Ontario, June 28, 2023

PRESENT: The Honourable Mr. Justice Manson

BETWEEN:

JANSSEN INC. AND
JANSSEN PHARMACEUTICA N.V.

Plaintiffs

and

APOTEX INC.

Defendant

PUBLIC JUDGMENT AND REASONS

(Confidential Judgment and Reasons issued June 28, 2023)

I. Introduction

[1] The Plaintiffs, Janssen Inc. and Janssen Pharmaceutica N.V. (collectively "Janssen"), move for summary judgment in Court files T-1121-22, T-1122-22, T-1248-22 and T-1249-22,

four related patent infringement actions (collectively the "Within Actions") brought under subsection 6(1) of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 (the "*Regulations*"). In each action, Janssen argues that the Defendant, Apotex Inc. ("Apotex"), will infringe Canadian Patent No. 2,655,335 (the "335 Patent"). Apotex defends the actions on the sole basis that the 335 Patent is invalid on the ground of unpatentable subject matter, as a method of medical treatment.

[2] On this motion for summary judgment, Janssen argues that Apotex's patent invalidity defence is *res judicata* and constitutes an abuse of process, based on the litigation history of the 335 Patent.

II. Background

A. *The 335 Patent*

[3] The 335 Patent is listed on the Patent Register pursuant to the *Regulations* in respect of Janssen's paliperidone palmitate suspension, marketed as INVEGA SUSTENNA, in prefilled syringes of 50 mg/0.5 mL, 75 mg/0.75 mL, 100 mg/1.0 mL and 150 mg/1.5 mL Janssen Pharmaceutica N.V. is the registered owner of the 335 Patent.

[4] INVEGA SUSTENNA is indicated for the treatment of schizophrenia and related disorders. The 335 Patent is titled, "Prolonged-Release Injectable Suspensions of Paliperidone Palmitate and Dosage Forms and Delivery Systems Incorporating Same".

[5] Claims 1, 17, and 33 of the 335 Patent describe the dosing regimen for non-renally impaired patients in need of treatment for schizophrenia or related disorders:

A. A first loading dose of 150 milligrams equivalent ("mg-eq") of paliperidone palmitate administered into the deltoid muscle on day 1 of treatment;

B. A second loading dose of 100 mg-eq of paliperidone palmitate administered into the deltoid on day 8 ± 2 days; and

C. Maintenance doses of 75 mg-eq of paliperidone palmitate administered into the deltoid or gluteal muscle monthly ± 7 days after the second loading dose.

[6] Claims 2, 18 and 34 describe the dosing regime for renally impaired patients and follows the same dosing schedule, dosing windows and injection sites as for non-renally impaired patients, except with loading doses of 100 mg-eq and 75 mg-eq, and maintenance doses of 50 mg-eq.

[7] Apotex seeks to market in Canada a generic version of INVEGA SUSTENNA (the "APO Product"). Abbreviated New Drug Submission ("ANDS") No. 233882 ("ANDS #1") relates to prefilled syringes [redacted] the APO Product. ANDS No. 239939 ("ANDS #2") relates to prefilled syringes [redacted]

B. *Litigation History of the 335 Patent*

[8] The 335 Patent has previously been the subject of three relevant actions commenced by Janssen.

[9] In February 2018, Janssen commenced an action in Court file T-353-18 against Teva Canada Limited ("Teva") in respect of the 335 Patent and Teva's generic version of INVEGA SUSTENNA (the "Teva Action"). Janssen alleged infringement of claims 1 to 48 of the 335 Patent. At trial, Teva withdrew its plea of unpatentable subject matter and defended the action only on the grounds of obviousness and non-infringement. On May 5, 2020, this Court held that the asserted claims 1 to 48 were valid and not obvious and Teva would infringe claims 1 to 16 and 33 to 48 (*Janssen Inc v Teva Canada Ltd*, 2020 FC 593). Teva appealed on the issues of direct infringement and validity and Janssen cross-appealed on the issue of inducing infringement. In a decision dated March 23, 2023, the Court of Appeal dismissed Teva's appeal and allowed Janssen's cross-appeal (see *Teva Canada Limited v Janssen Inc*, 2023 FCA 68).

[10] In November 2020, Janssen commenced an action in Court file T-1441-20 against Pharmascience Inc. ("PMS") in respect of the 335 Patent and PMS's generic version of INVEGA SUSTENNA (the "PMS Action"). On motion for summary trial on January 19, 2022, this Court held that PMS would infringe the claims of the 335 Patent (*Janssen Inc v Pharmascience Inc*, 2022 FC 62 [*PMS-paliperidone 1*]; appeal to the Federal Court of Appeal ongoing). By Judgment dated August 23, 2022, the Court decided the remaining issues in the PMS Action, finding that PMS had failed to prove its obviousness and method of medical treatment

allegations with respect to the 335 Patent (*Janssen Inc v Pharmascience Inc*, 2022 FC 1218 [*PMS-paliperidone 2*]; appeal to the Federal Court of Appeal ongoing).

[11] The parties also previously litigated the issue of whether Apotex would infringe the 335 Patent. Apotex delivered to Janssen a Notice of Allegation ("NOA") in respect of ANDS #1 dated December 4, 2020 ("NOA #1"). In NOA #1, Apotex alleged it would not infringe the 335 Patent by marketing the APO Product [redacted]. Apotex did not make invalidity allegations in respect of the 335 Patent in NOA#1.

[12] On January 18, 2021, in response to NOA #1, Janssen commenced an action in Court file T-124-21 (the "First Apotex Action"). In the Statement of Claim for T-124-21, Janssen relied on the presumption of patent validity in subsection 43(2) of the *Patent Act*, RSC, 1985, c P-4 (the "*Patent Act*"). Apotex delivered its Statement of Defence dated February 17, 2021. Apotex's Statement of Defence alleged non-infringement but did not challenge the validity of the 335 Patent.

[13] On May 4, 2021, Apotex commenced a motion for summary trial. The substantive issue before the Court was whether Apotex would infringe the 335 Patent, despite not seeking approval for [redacted] its generic paliperidone palmitate product. In support of its non-infringement allegation, Apotex submitted an affidavit including copies of the Form Vs submitted to Health Canada in ANDS #1 and ANDS #2. In the allegations section of Form V for ANDS #1, Apotex indicated that it was alleging patent non-infringement but did not indicate that it was alleging patent invalidity. In Form V for ANDS #2, Apotex accepted that a Notice of

Compliance ("NOC") would not issue until the 335 Patent expires and did not make non-infringement or invalidity allegations.

[14] On January 31, 2022, the Court held that Apotex would infringe the 335 Patent despite not seeking approval for [redacted] and issued a declaration of infringement and injunction in respect of Apotex's proposed product in ANDS #1 (see *Janssen Inc v Apotex Inc*, 2022 FC 107 [*APO-paliperidone 2022*]). At trial, Apotex maintained that it would wait to sell [redacted] until the 335 Patent expires, and if it did not it would be required to serve a distinct NOA in respect of ANDS #2.

[15] Following the decision in *APO-paliperidone 2022*, Apotex sought to amend its Statement of Defence in T-124-21 to include an allegation of invalidity on the basis of unpatentable subject matter as a method of medical treatment. Apotex subsequently withdrew its request to amend its pleading. Instead, Apotex amended its Form Vs for ANDS # 1 and ANDS #2 to include allegations of invalidity.

[16] Apotex has appealed the January 31, 2022 Judgment from the First Apotex Action to the Federal Court of Appeal and that appeal is ongoing.

C. *The Within Actions*

[17] Apotex delivered to Janssen two NOAs dated April 20, 2022, one in respect of ANDS #1 and the other in respect of ANDS #2. Upon Janssen's insistence that these two NOAs were improper, Apotex delivered a second NOA in respect of each ANDS on May 5, 2022. In each

NOA, Apotex alleges that the claims of the 335 Patent are invalid because they comprise unpatentable subject matter, namely, methods of medical treatment. Apotex does not allege non-infringement.

[18] Janssen subsequently commenced the actions in Court files T-1122-22 and T-1248-22 in response to the two NOAs relating to ANDS #1 (the "ANDS #1 Actions") and the actions in Court files T-1121-22 and T-1249-22 in response to the two NOAs relating to ANDS#2 (the "ANDS #2 Actions"). The actions in T-1121-22 and T-1122-22 were commenced on June 2, 2022 and the actions in T-1248-22 and T-1249-22 on June 16, 2022.

[19] Both parties agree that non-infringement is not at issue in the Within Actions.

[20] Apotex filed its Statements of Defence for the Within Actions on July 27, 2022. By Order dated November 23, 2022, the trial for the Within Actions was fixed to start on March 18, 2024. The parties have completed first round examinations for discovery.

III. Issues

A. Is Janssen's motion for summary judgment out of time?

B. Is the matter appropriate for summary judgment?

C. Is there a genuine issue for trial in any of the Within Actions?

(1) Does the doctrine of *res judicata* preclude Apotex from defending the Within Actions?

(2) Does the doctrine of abuse of process preclude Apotex from defending the Within Actions?

(3) Does the doctrine of election preclude Apotex from defending the ANDS #2 Actions?

IV. Analysis

A. *Is Janssen's motion for summary judgment out of time?*

[21] Motions for summary judgment are governed by Rules 213-215 of the *Federal Courts Rules*, SOR/98-106 (the "*Rules*"). Rule 213(1) provides that a party may move for summary judgment after the filing of a Statement of Defence but prior to the time and place for trial being fixed:

213 (1) A party may bring a motion for summary judgment or summary trial on all or some of the issues raised in the pleadings at any time after the defendant has filed a defence but before the time and place for trial have been fixed.	**213 (1)** Une partie peut présenter une requête en jugement sommaire ou en procès sommaire à l'égard de toutes ou d'une partie des questions que soulèvent les actes de procédure. Le cas échéant, elle la présente après le dépôt de la défense du défendeur et avant que les

heure, date et lieu de
l'instruction soient fixés.

[22] In this case, Apotex filed its Statements of Defence in respect of T-1121-22 and T-1122-22 on July 12, 2022 and its Statements of Defence in respect of T-1248-22 and T-1249-22 on July 27, 2022. The Order fixing the time and place was issued on November 23, 2022.

[23] The record indicates that Janssen has considered pursuing summary judgment since the beginning phases of the Within Actions:

A. In a letter dated June 10, 2022, Janssen advised the Court that it "may bring motions for summary judgment".

B. In a letter dated July 20, 2022, Janssen stated to the Court that the motions referred to in the letter dated June 10, 2022 were still "being contemplated" and that it was not "in a position to confirm if or when they intend to bring any of those motions until at least pleadings have been closed".

C. After the close of pleadings, in a letter to the Court dated August 11, 2022, Janssen wrote that it "intend[ed] to bring summary judgment motions in all four actions".

D. Following up in a letter dated September 14, 2022, Janssen confirmed to the Court that it still intended to bring motions for summary judgment. Janssen also advised that it would be seeking to amend the Protective and Confidentiality Order in the

First Apotex Action to allow it to use confidential materials from that action in the Within Actions in support of its motions for summary judgment.

[24] However, Janssen did not move for summary judgment until filing its Notice of Motion on March 24, 2023.

[25] As a result, Apotex argues that Janssen is barred from moving for summary judgment.

[26] Apotex contends that Janssen could have brought its motion for summary judgment at any time in the four month period between the filing of the Statements of Defence (July 27, 2022) and the Order fixing time and place (November 22, 2022) but simply chose not to do so. Instead, Janssen delivered its Notice of Motion on March 24, 2023, four months after the time and place for trial had been fixed. Since the summary judgment motion does not address the merits of Apotex's invalidity defence, Apotex contends that it has been put on a "dual track" by simultaneously proceeding through discovery and motions relating to the merits of the Within Actions and defending this motion.

[27] Apotex further argues that no "special circumstances" exist under Rule 55 of the *Rules* that would allow the Court to vary or dispense with the timeliness requirement of Rule 213(1).

[28] Janssen disagrees, arguing that under the particular facts of this proceeding its motion should be permitted to proceed. Janssen points out that Apotex was well aware that Janssen would pursue summary judgment since the early phases of litigation and that Janssen agreed only

to fix a date for trial "without prejudice" to its right to bring such a motion. Moreover, Janssen observes that in actions brought under the *Regulations*, parties are encouraged to set a trial date early in the case management process so that actions can be resolved efficiently within a two-year period.

[29] I disagree with Apotex. As a procedural matter, under Rules 56 and 58, the timeliness issue is not properly before the Court. Rule 56 specifies that non-compliance with the *Rules* does not render a proceeding void; rather it is an "irregularity" which is to be addressed in Rules 58 to 60.

56 Non-compliance with any of these Rules does not render a proceeding, a step in a proceeding or an order void, but instead constitutes an irregularity, which may be addressed under rules 58 to 60.	**56** L'inobservation d'une disposition des présentes règles n'entache pas de nullité l'instance, une mesure prise dans l'instance ou l'ordonnance en cause. Elle constitue une irrégularité régie par les règles 58 à 60.

[30] Rule 58 specifies that it is the party challenging the other's compliance with the *Rules* that must bring a motion "as soon as practicable":

58 (1) A party may by motion challenge any step taken by another party for non-compliance with these Rules.	**58 (1)** Une partie peut, par requête, contester toute mesure prise par une autre partie en invoquant l'inobservation d'une disposition des présentes règles.
(2) A motion under subsection (1) shall be brought as soon as practicable after the moving	**(2)** La partie doit présenter sa requête aux termes du paragraphe (1) le plus tôt

party obtains knowledge of the irregularity.	possible après avoir pris connaissance de l'irrégularité.

[31] Here, Janssen's motion was brought outside of the period specified in Rule 213(1). This constitutes an irregularity under Rule 56 and does not render Janssen's motion void or allow Apotex to defend the merits of the summary judgment motion based on Janssen's non-compliance. Rather, it was for Apotex to bring a motion under Rule 58 to challenge Janssen's non-compliance with the *Rules* as soon as it was practicable and it did not do so.

[32] Furthermore, Rule 59 specifies that the Court can cure irregularities only "on a motion under Rule 58". Interpreted in light of Rule 47(2), which provides that whenever the *Rules* specify that powers of the Court are to be exercised on motion, they may only be exercised on motion, it is clear that it is not for the Court to, of its own volition, invalidate proceedings or steps in proceedings based on procedural irregularities under the *Rules*.

[33] In any event, given the history of proceedings and the relevant litigation background referred to above, I would have found that special circumstances exist in this case under Rule 55 to allow Janssen to proceed with this motion.

B. *Is there a genuine issue for trial in any of the Within Actions?*

[34] Pursuant to Rule 215(1) of the *Rules*, if the Court "is satisfied that there is no genuine issue for trial with respect to a claim or defence, it shall grant summary judgment accordingly".

Under Rule 215(2)(b), if the only genuine issue is a question of law, the Court may determine the question of law and dispose of the summary judgment motion accordingly.

[35] As with applying any of the *Rules*, the Court must apply the principles for summary judgment motions consistently with Rule 3, in order to secure the just, most expeditious and least expensive outcome of every proceeding.

[36] There will be no genuine issue for trial when the Court is able to make necessary findings of fact, apply the law to those facts, and achieve a fair and just determination on the merits of the claims (*Hryniak v Mauldin*, 2014 SCC 7 at para 49).

[37] Janssen moves for summary judgment based on the litigation history of the 335 Patent. Namely, Janssen argues that Apotex's invalidity defence to the Within Actions is *res judicata* and an abuse of process.

[38] I am satisfied that these issues are appropriate for determination on summary judgment. There is no dispute between the parties with respect to the 335 Patent's litigation history, including the character of the allegations made by Apotex in the First Apotex Action or in the Within Actions, or the relevant timings of when each of the allegations were made. The sole dispute between the parties is with respect to the questions of law and the application of law to settled facts relating to the re-litigation issues raised by Janssen.

[39] As such, it would be in keeping with the objectives set out in Rule 3, to dispose of these issues by summary judgment. It would be just, expeditious and potentially less expensive to deal with these matters on this motion, rather than to delay the matters to trial, when the Court will be in no better position to assess the relevant undisputed facts and apply the law.

(1) Does the doctrine of *res judicata* preclude Apotex from defending the Within Actions?

[40] The doctrine of *res judicata* is founded on the idea that a dispute, once judged to finality, is not subject to re-litigation (*Danyluk v Ainsworth Technologies Inc*, 2001 SCC 44 at para 18 [*Danyluk*]).

[41] There are two branches of *res judicata*, cause of action estoppel and issue estoppel. Cause of action estoppel precludes one from bringing an action against another when that same cause of action has been determined by a court of competent jurisdiction in an earlier case; issue estoppel occurs when some point or fact raised has already been decided (*Angle v MNR*, [1975] 2 SCR 248 at 254 [*Angle*]).

(a) *Cause of Action Estoppel*

[42] The test for cause of action estoppel is as follows:

A. There was a final decision of a court of competent jurisdiction;

B. The parties to the subsequent litigation are the same parties or in privy with the parties from the prior action;

C. The cause of action in the prior action must not be separate and distinct; and

D. The basis of the cause of action in the subsequent action was or could have been argued in the prior action with the exercise of reasonable diligence.

(*Grandview v Doering*, [1976] 2 SCR 621 at 636-37 [*Grandview*])

[43] Janssen argues that the test for cause of action estoppel is met for both the ANDS #1 Actions and the ANDS #2 Actions. Janssen makes the following arguments with respect to the ANDS #1 Actions and each prong of the *Grandview* test:

A. The decision of this Court in respect to the merits of the First Apotex Action is final and the fact that an appeal to the Federal Court of Appeal is ongoing does not obviate finality.

B. The parties to the Within Actions are the same as those in the First Apotex Action.

C. The causes of action are not separate and distinct since Janssen is seeking the same relief in the form of a declaration of infringement in the Within Actions as was granted by the Court in the First Apotex Action. Moreover, the First Apotex Action was brought in respect of ANDS #1, the very same dosage strengths of ||| Apotex's paliperidone palmitate injection product.

D. Through the exercise of reasonable diligence, Apotex could have alleged invalidity in the First Apotex Action. The construction of the claims of the 335 Patent was not challenged in the First Apotex Action as the claims were constructed by the Court in the Teva Action and invalidity on the basis of unpatentable subject matter as a method of medical treatment was raised in the PMS Action. Accordingly, Apotex had all the necessary facts to make its allegation of invalidity during the First Apotex Action.

[44] Janssen also asserts that these arguments apply with equal force with respect to the ANDS #2 Actions. Despite the fact that ANDS #2 concerns [redacted] the APO Product than ANDS #1, Janssen submits that distinction is irrelevant to the issue of whether the 335 Patent is valid.

[45] Apotex contests that Janssen has met the test for cause of action estoppel, arguing the following with respect to the *Grandview* test:

A. The decision in the First Apotex Action is not final as appeal to the Federal Court of Appeal is ongoing. The fact that Janssen asserted the presumption of patent validity in subsection 43(2) of the *Patent Act* in the First Apotex Action is irrelevant as this presumption merely creates an evidential burden and not a legal presumption.

B. Apotex does not contest that the parties in the First Apotex Action are the same as the parties in the Within Actions.

C. The causes of action are separate and distinct. *Res judicata* must be considered in the context of the "extraordinary nature" of the *Regulations* and the procedures they set out. Under subsection 5(2.1) of the *Regulations* and jurisprudence under the previous version of the *Regulations*, an allegation of non-infringement is distinct from an allegation of invalidity. Furthermore, under the *Regulations* the "second person" determines the cause of action and issues in dispute. Apotex was entitled to advance two separate causes of action.

D. Apotex did not need to raise its invalidity defence in the First Apotex Action. The question is not whether Apotex *could* have raised this defence in the First Apotex Action the question is whether it *should* have.

[46] Furthermore, Apotex insists that Janssen's *res judicata* arguments, even if accepted, are wholly inapplicable to the ANDS #2 Actions. The causes of action and issues at play in the First Apotex Action concerned only [redacted] the APO Product. No declaration of infringement has issued in respect [redacted] ANDS #2.

[47] I find that the Within Actions do not meet the *Grandview* test for cause of action estoppel. I am not satisfied that there is currently a final decision.

[48] There is conflicting case law on whether a decision is final when there is a pending appeal. The authorities that are binding on this Court tend to favour the position a decision is not final until the appeal process has been completed. In *obiter*, when considering the abuse of

process doctrine, the Supreme Court of Canada has stated "A decision is final and binding on the parties only when all available reviews have been exhausted or abandoned" (*Toronto (City) v CUPE, Local 79*, 2003 SCC 63 at para 46 [*CUPE*]).

[49] The Federal Court of Appeal has adopted the Supreme Court's words in *CUPE* in the context of *res judicata*/issue estoppel:

> … what finality for issue estoppel purposes entails. A decision is final and binding on the parties "when all available reviews have been exhausted or abandoned"
>
> (*Eli Lilly Canada Inc v Teva Canada Limited*, 2018 FCA 53 at para 83)

[50] Justice Stratas echoed this view in *Canada v MacDonald*, 2021 FCA 6:

> If an appeal is brought, the appeal court can interfere with the order or judgment. Thus, an order or judgment under appeal is not final for the purposes of the doctrine of *res judicata*. But an aspect of finality remains: the court that issued the order or judgment cannot reconsider, suspend, set aside or vary it.
>
> (at para 15)

[51] There is no dispute that the appeal of the judgment of this Court in *APO-paliperidone 2022* is pending in Federal Court of Appeal file A-36-22. Given the rulings with respect to finality of the Supreme Court of Canada and Federal Court of Appeal, I find that there is no final decision and the first prong of the *Grandview* test is not met.

(b) *Issue Estoppel*

[52] The test for issue estoppel is as follows:

A. The same question has been decided;

B. The judicial decision that decided the question is final; and

C. The parties to the judicial decision or their privies were the same persons as the parties.

(*Danyluk* at para 25)

[53] Elements (1) and (2) are identical to those in the test for cause of action estoppel. Thus, the finding that the Court's decision in *APO-paliperidone 2022* is not final applies with equal force here.

[54] What distinguishes issue estoppel from cause of action estoppel is the requirement that the same question be already decided as opposed to the same cause of action.

[55] Janssen argues that the relevant question in the First Apotex Action was whether Apotex would infringe a valid claim of the 335 Patent with its paliperidone palmitate injection product in accordance with Apotex's ANDS#1 and that question has been squarely answered in the First Apotex Action.

[56] Apotex disagrees with Janssen's characterization of the relevant question. Apotex argues that the question in the First Apotex Action was infringement and in the Within Actions it is invalidity.

[57] I agree with Apotex. The relevant question is whether the 335 Patent is valid and that question was not decided in the First Apotex Action.

[58] While courts in Canada have adopted broader views of the nature of the question relevant to issue estoppel, the Supreme Court of Canada has repeatedly applied the "traditional view" of issue estoppel. That is, the same question must have been actually raised and decided in the prior proceeding. In *Grandview*, Justice Ritchie stated the following:

> It is obvious here that the question of whether or not the water entered the aquifer and thus saturated the respondent's soil was not determined in the 1969 action because it was not raised and it would therefore not be strictly accurate to classify the present case as one of issue estoppel
>
> [Emphasis Added]
>
> (*Grandview* at 638)

[59] In *Angle*, Justice Dickson stated that "It will not suffice if the question arose collaterally or incidentally in the earlier proceedings or is one which must be inferred by argument from the judgment" (at 255).

[60] In *R v Van Rassel*, [1990] 1 SCR 225, Justice McLachlin stated that issue estoppel applies "only in circumstances where it is clear from the facts that the question has already been decided" (at 238).

[61] Most recently, Justice Binnie endorsed this view in *Danyluk* stating that "Issue estoppel extends to the material facts and the conclusions of law or of mixed fact and law ("the questions") that were necessarily (even if not explicitly) determined in the earlier proceedings" (at para 24).

[62] The question raised about whether the 335 Patent is invalid as a method of medical treatment in the Within Actions was not determined in the First Apotex Action, nor was it determined by implication. Janssen may have raised the presumption of patent validity under subsection 43(2) of the *Patent Act* in its pleadings; however, Apotex did not make any allegations with respect to the 335 Patent's validity. The Court expressly observed that invalidity was not in issue in its reasons, stating "…patent validity is not an issue because Apotex does not allege invalidity" (*APO-paliperidone 2022* at para 105).

[63] Moreover, Janssen's submission that there was an implicit finding as to the issue of invalidity of the 335 Patent is particularly without merit given the litigation in the PMS Action. In the PMS Action, issues of non-infringement were dealt with on summary trial prior to proceeding to trial for determination of the invalidity issues. When the Court held that there would be infringement at summary trial, it did not "implicitly" decide the issue of validity as

well; rather the Court held that the validity issues remained and were to proceed to trial, which they did (see *PMS-paliperidone 1; PMS-paliperidone 2*).

[64] Issue estoppel is also inapplicable to the ANDS#2 Actions, as [redacted] its generic product that Apotex seeks approval for in ANDS#2 were not at issue in the First Apotex Action. Even under Janssen's view, the issue in the First Apotex Action did not relate to [redacted] the ANDS #2 Actions and was "whether Apotex will infringe a valid claim of the 335 Patent with its paliperidone palmitate injection product in accordance with Apotex's ANDS#1".

(2) Does the doctrine of abuse of process preclude Apotex from defending the Within Actions?

[65] The doctrine of abuse of process has applied to bar needless litigation that may not meet the technicalities of issue estoppel or cause of action estoppel (*CUPE* at para 42).

[66] For much the same reasons as with its argument respecting cause of action and issue estoppel, Janssen argues that Apotex "testing a non-infringement allegation before alleging invalidity" constitutes an abuse of process. Janssen argues that allowing these actions to continue would lead to the absurd result that generic drug manufacturers could deliver one NOA making just one allegation, fully litigate that issue, only to then deliver another NOA with a fresh allegation in respect of the same patent and drug. Janssen highlights that the Regulatory Impact Analysis Statement (the "RIAS") that accompanied the 2017 amendments to the *Regulations*

states that "[the amendments eliminate] the need for separate proceedings to address all claims in a single patent" (published in Canada Gazette, Part II, Vol 151, Extra on September 7, 2017).

[67] Apotex argues that abuse of process is an extraordinary remedy that need be applied sparingly in the context of re-litigation. Moreover, Apotex insists that abuse of process must be considered in light of the *Regulations*, which clearly distinguish between invalidity and non-infringement. Moreover, had the Governor-in-Council contemplated a requirement to deliver NOAs in respect of both infringement and invalidity at the same time, it could have included that restriction specifically in the legislation.

[68] I agree with the parties that abuse of process must be considered in light of the comprehensive regime Parliament has set out in the *Regulations*. It is the *Regulations* that generate the right of action and set out the process by which such actions are to be commenced. Ultimately, the question must be whether what Apotex has done by bringing the ANDS #1 Actions and the ANDS #2 Actions is abusive of that process.

[69] I find that it is not. The *Regulations*, when viewed contextually and purposively, do not preclude successive dual NOAs in respect of the same patent, one alleging non-infringement and another alleging invalidity.

[70] Nowhere in the text of the *Regulations* does it state that a "second person" (essentially the term for a generic drug manufacturer under the *Regulations*) can serve only one NOA in respect of each patent. On the contrary, the *Regulations* require that an NOA is served on a

patentee each time an allegation is made leading to, in some cases, successive NOAs and successive litigation.

[71] Subsection 5(1) of the *Regulations* provides that a generic drug manufacturer seeking a NOC must include in its submissions the required statements or allegations set out in subsection 5(2.1). Paragraph 5(2.1)(c) categorizes the various finite allegations that a generic may make:

5(2.1)(c) an allegation that	**5(2.1) c)** soit toute allégation portant que :
(i) the statement made by the first person under paragraph 4(4)(d) is false,	**(i)** la déclaration faite par la première personne en application de l'alinéa 4(4)d) est fausse,
(ii) that patent or certificate of supplementary protection is invalid or void,	**(ii)** le brevet ou le certificat de protection supplémentaire est invalide ou nul,
(iii) that patent or certificate of supplementary protection is ineligible for inclusion on the register,	**(iii)** le brevet ou le certificat de protection supplémentaire est inadmissible à l'inscription au registre,
(iv) that patent or certificate of supplementary protection would not be infringed by the second person making, constructing, using or selling the drug for which the submission or the supplement is filed,	**(iv)** en fabriquant, construisant, exploitant ou vendant la drogue pour laquelle la présentation ou le supplément est déposé, la seconde personne ne contreferait pas le brevet ou le certificat de protection supplémentaire,
(v) that patent or certificate of supplementary protection has expired, or	**(v)** le brevet ou le certificat de protection supplémentaire est expiré,
(vi) in the case of a certificate of supplementary protection, that certificate of	**(vi)** dans le cas d'un certificat de protection supplémentaire,

supplementary protection cannot take effect.	celui-ci ne peut pas prendre effet.

[72] Subparagraphs 5(2.1)(c)(ii) and (iv) clearly distinguish allegations of invalidity from allegations of non-infringement. There is, however, no such distinction between individual grounds of invalidity. If a generic drug manufacturer were attempting to serve a second NOA in order to pursue different grounds of invalidity it did not pursue in previous litigation that would almost certainly be abusive of the process set out under the *Regulations*.

[73] That is not what Apotex has done. Apotex alleged only non-infringement in its Form V prior to the First Apotex Action and subsequently amended that Form V to include an allegation of invalidity. There is no dispute that as an administrative matter, Form Vs may be amended.

[74] Once a paragraph 5(2.1)(c) allegation is levelled, a generic drug manufacturer has no choice but to serve another NOA, with the prescribed requirements. Paragraph 5(3)(a) uses imperative language, stating a generic drug manufacturer "shall" serve a "first person" (essentially the term for a drug innovator under the *Regulations*) with a NOA; the generic has no choice but to comply. The innovator then must then commence, within 45 days, an action for a declaration of infringement under subsection 6(1) of the *Regulations*.

[75] Furthermore, the references in the RIAS to avoiding "separate proceedings" must be understood in light of the state of play under the old *Regulations*. The duplicative litigation that the amendments to the *Regulations* sought to avoid was not litigation stemming from successive distinct NOAs in respect of the same patent. Rather, the new *Regulations* were implemented to

avoid the dual track litigation that occurred under the old *Regulations* where limited issues of patent validity or infringement were addressed summarily via applications for prohibition orders under the *Regulations*, and then re-litigated as actions for infringement under the *Patent Act*. The new *Regulations* address this by providing a right to commence a full action under subsection 6(1) and foreclosing *Patent Act* infringement actions through section 6.01 (see also *Sunovion Pharmaceuticals Canada Inc v Taro Pharmaceuticals Inc*, 2021 FC 37 at paras 11-25).

[76] Once Apotex amended its Form V, it was required to serve another NOA, giving Janssen 45 days to initiate a subsection 6(1) action, which it then did. This is the very process compelled by the new *Regulations* and Parliament's design within. While abuse of process is a flexible doctrine, it is to be applied sparingly in the clearest and most obvious of cases (*R v Mahalingan*, 2008 SCC 63 at para 42, citing from *Blencoe v British Columbia (Human Rights Commission)*, 2000 SCC 44 at para 120). This is not such a case; there is no abuse of process.

[77] I also agree with Apotex that Janssen's abuse of process and other re-litigation arguments are inapplicable to the ANDS #2 Actions. The ANDS #2 Actions are wholly distinct actions arising from different NOAs, raising distinct allegations served in respect of a different ANDS submitted and in respect of [redacted] the APO Product that has not been previously considered by the Court. Janssen's argument relating to the doctrine of election is the only one relevant to the ANDS #2 Actions.

(3) Does the doctrine of election preclude Apotex from defending the ANDS #2 Actions?

[78] With respect to the ANDS #2 Actions, Janssen raises the doctrine of election. The doctrine of election is founded on the principle that a party cannot exercise a right that conflicts with another if they have consciously and unequivocally exercised the latter (*Teva Canada Limited v Wyeth LLC*, 2012 FCA 141 at para 29).

[79] Janssen argues that Apotex, in an attempt to escape liability for infringement in the First Apotex Action, consciously elected to base its allegation of non-infringement on the fact that it would wait to receive a NOC for [redacted] until after the 335 Patent expires. According to Janssen, Apotex's attempts to move away from its decision not to pursue an NOC [redacted] in the ANDS #2 Actions should be barred by operation of the doctrine of election.

[80] Apotex argues that Janssen is improperly attempting to shoehorn this doctrine of election argument into its abuse of process argument, although the two are distinct doctrines. According to Apotex, Janssen is doing so because it has not properly pleaded doctrine of election in its Statements of Claim for the ANDS #2 Actions. Apotex further submits that there is no contradiction as "[i]f Apotex succeeds in the within actions, and the Court finds the 335 Patent to be invalid, it will have effectively expired".

[81] I disagree that if there is a finding that the 335 Patent is invalid it will have "effectively expired". Before amending its Form V for ANDS #2, Apotex alleged that it would wait until the expiry of the 335 Patent before seeking to market [redacted] product, a wholly distinct allegation from invalidity. If the two allegations are one and the same as Apotex claims, there

would have been no need for it to amend its Form V in respect of ANDS #2 after the First Apotex Action.

[82] However, upon review of relevant portions of the summary trial transcripts of the First Apotex Action, it is clear that Apotex made no conscious and unequivocal representation to the Court that it would wait for the expiry of the 335 Patent before seeking approval for [redacted]. Apotex clearly left open the door that it may seek to amend its Form V in respect of ANDS #2 and serve Janssen with an NOA when it did so. When arguing about the appropriateness of summary trial, counsel for Apotex stated, "… if [the ANDS #2 Form V] changes, if my client ever decides to make an allegation, my client is required under the [*Regulations*] to serve an allegation to give rise to a proceeding…"

[83] The doctrine of election is inapplicable.

V. Conclusion

[84] The motion is dismissed.

[85] Apotex did not make submissions on costs other than requesting costs. In its Notice of Motion, Janssen requested costs of this motion on a solicitor-client basis, or alternatively these costs set at 25% of Janssen's actual fees and 100% of its disbursements. In order to reflect the two positions and award the successful party, I award costs of this motion to Apotex at 25% of actual fees and 100% of disbursements.

JUDGMENT in T-1121-22, T-1122-22, T-1248-22, T-1249-22

THIS COURT'S JUDGMENT is that:

1. The motion is dismissed.

2. Costs to Apotex at 25% of actual fees and 100% of its disbursements associated with this motion.

"Michael D. Manson"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

DOCKETS:	T-1121-22, T-1122-22, T-1248-22, T-1249-22
STYLE OF CAUSE:	JANSSEN INC. AND JANSSEN PHARMACEUTICA N.V. v APOTEX INC.
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