Federal Court of Appeal | Cour d'appel fédérale

Date: 20231222

Docket: A-229-23

Citation: 2023 FCA 253

CORAM: **DE MONTIGNY C.J.**
LOCKE J.A.
GOYETTE J.A.

BETWEEN:

JANSSEN INC. and JANSSEN PHARMACEUTICA N.V.

Appellants

and

APOTEX INC.

Respondent

Heard at Toronto, Ontario, on December 7, 2023.

Judgment delivered at Ottawa, Ontario, on December 22, 2023.

PUBLIC REASONS FOR JUDGMENT BY: LOCKE J.A.

CONCURRED IN BY: DE MONTIGNY C.J.
GOYETTE J.A.

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PUBLIC REASONS FOR JUDGMENT

This is a public version of confidential reasons for judgment issued to the parties. The two are identical, there being no confidential information disclosed in the confidential reasons.

LOCKE J.A.

I. Background

[1] Janssen Inc. and Janssen Pharmaceutica N.V. (collectively, Janssen) appeal a decision of the Federal Court (2023 FC 912, *per* Justice Michael D. Manson), which dismissed Janssen's motion for summary judgment in four related patent infringement actions (Nos. T-1121-22, T-

1122-22, T-1248-22 and T-1249-22, the Underlying Actions) against Apotex Inc. pursuant to the *Patented Medicines (Notice of Compliance) Regulations*, S.O.R./93-133 (the *Regulations*). Janssen sought to have remedies claimed in the Underlying Actions granted on the basis that Apotex's defences were *res judicata*, an abuse of process and/or precluded by the doctrine of election. The Federal Court refused to grant summary judgment on any of these grounds, and allowed the Underlying Actions to proceed. A five-day trial in the Underlying Actions has been scheduled to commence on March 18, 2024.

[2] For the purposes of this appeal, only the question of abuse of process remains in issue. For the reasons set out below, I would allow the present appeal and grant Janssen's motion for summary judgment as the Federal Court should have done.

[3] The Underlying Actions concern Janssen's Canadian Patent No. 2,655,335 (the 335 Patent) for its 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, 150 mg/1.5 mL. Apotex seeks a notice of compliance (NOC) to permit it to market its generic version of INVEGA SUSTENNA. As part of the process for obtaining its NOC, and pursuant to section 5 of the *Regulations*, Apotex delivered notices of allegation (NOAs) to Janssen, which alleged that claims of the 335 Patent are invalid because they comprise unpatentable subject matter, namely methods of medical treatment. These NOAs do not otherwise allege that Apotex's generic version will avoid infringement of the 335 Patent. Janssen commenced the Underlying Actions pursuant to section 6 of the *Regulations*, and Apotex defended on the same basis as asserted in the NOAs.

[4] Janssen's motion for summary judgment, and its appeal before this Court, rely on the fact that the Underlying Actions were not the first patent infringement actions commenced pursuant to section 6 of the *Regulations* concerning the 335 Patent and Apotex's effort to introduce its generic version of INVEGA SUSTENNA to the market. In 2021, Janssen commenced another action against Apotex (No. T-124-21, the Prior Action) in response to an earlier NOA that it received from Apotex. The earlier NOA, and Apotex's defence to the Prior Action alleged that its generic version of INVEGA SUSTENNA would not infringe the 335 Patent because Apotex would not sell one of the essential elements of all of the claims thereof: the 75 mg dose. Apotex did not allege at that time that the 335 Patent was invalid. The Federal Court disposed of the Prior Action following a summary trial. It found that Apotex would infringe the 335 Patent by inducement if it entered the market with its generic version of INVEGA SUSTENNA. The Federal Court accordingly granted various injunctive remedies. That decision (2022 FC 107, 190 C.P.R. (4^{th}) 96) is under appeal before this Court in File No. A-36-22. That appeal has been heard, and a decision by this Court thereon is currently pending.

[5] In the present appeal, Janssen argues that the Federal Court should have found that Apotex's invalidity allegation in the Underlying Actions was an abuse of process because any such allegation could have, and should have, been raised in the context of the Prior Action. Janssen argues that Apotex should not be allowed to "litigate by instalments", and should have put its "best foot forward" in the Prior Action.

II. The Federal Court's Decision

[6] The Federal Court assessed Janssen's abuse of process argument in the context of the *Regulations*. It noted that subsection 5(1) thereof requires that "a generic drug manufacturer seeking an NOC must include in its submissions the required statements or allegations set out in subsection (2.1)" (see paragraph 71 of the Federal Court's reasons). Among these are allegations under paragraph 5(2.1)(*c*) that the patent is invalid (subparagraph 5(2.1)(*c*)(ii)), or that it "would not be infringed by the second person making, constructing, using or selling the drug" (subparagraph 5(2.1)(*c*)(iv)). The Federal Court found that nothing in the *Regulations* precludes more than one NOA in relation to the same patent, and in fact, a new NOA would be required upon the filing of a new submission.

[7] In this case, Apotex served four NOAs in relation to two submissions (abbreviated new drug submissions, or ANDSs). The first pair of NOAs was followed by a second pair because of arguments of procedural irregularities. Essentially, Apotex's ANDSs relate to prefilled syringes of 50 mg/0.5 mL, 100 mg/1.0 mL and 150 mg/1.5 mL (No. 233882, ANDS#1), and prefilled syringes of 25 mg/0.25 mL and 75 mg/0.75 mL (No. 239939, ANDS#2). ANDS#1 had been the object of the NOA of non-infringement that led to the Prior Action. With regard to ANDS#2, Apotex originally accepted that it would not enter the market until the expiration of the 335 Patent, as contemplated in paragraph 5(2.1)(*b*) of the *Regulations*, and so no previous action arose therefrom. Apotex served the NOAs that are the subject of the present appeal after the Federal Court's decision in the Prior Action.

[8] The Federal Court was of the view that it would have been an abuse of process for Apotex to have alleged a ground of invalidity of the 335 Patent in its original NOA, and then a different ground of invalidity in its subsequent NOAs. However, it concluded that Apotex's invalidity allegations following its original non-infringement allegations were permissible. It focused on the fact that paragraph 5(2.1)(*c*) of the *Regulations* provides for allegations of invalidity and of non-infringement in separate subparagraphs.

[9] The Federal Court concluded that the NOAs were not an abuse of process, and therefore the Underlying Actions and the resulting invalidity defences filed by Apotex were likewise not an abuse of process. Moreover, the Federal Court found that Janssen's arguments of abuse of process were not applicable to ANDS#2 because it had not been previously addressed by the Federal Court.

III. The Doctrine of Abuse of Process

[10] Judges have an inherent and residual discretion to prevent an abuse of the court's process: *Toronto (City) v. C.U.P.E., Local 79*, 2003 SCC 63, [2003] 3 S.C.R. 77 at para. 35 (*C.U.P.E.*). The doctrine of abuse of process engages "the inherent power of the Court to prevent the misuse of its procedure, in a way that would … bring the administration of justice into disrepute": *C.U.P.E.* at para. 37, citing *Canam Enterprises Inc. v. Coles* (2000), 194 D.L.R. (4th) 648, 51 O.R. (3d) 481 (C.A.) at para. 55. It is a flexible doctrine unencumbered by the specific requirements of concepts such as issue estoppel: *C.U.P.E.* at para. 37. Canadian courts have applied the doctrine of abuse of process to preclude relitigation in circumstances where the strict requirements of issue estoppel are not met, but where allowing the litigation to proceed would

nonetheless violate such principles as judicial economy, consistency, finality and the integrity of the administration of justice: *C.U.P.E.* at para. 37.

[11] The policy grounds supporting abuse of process by relitigation are:

A. That there be an end to litigation;

B. That no one should be twice vexed by the same cause;

C. To preserve the courts' and the litigants' resources;

D. To uphold the integrity of the legal system in order to avoid inconsistent results; and

E. To protect the principle of finality so crucial to the proper administration of justice (*C.U.P.E.* at para. 38).

[12] The focus of the doctrine of abuse of process is less on the interest of parties and more on the integrity of judicial decision making as a branch of the administration of justice: *C.U.P.E.* at para. 43.

[13] There are various circumstances in which relitigation does not result in an abuse of process. *Per C.U.P.E.*:

> 52 … [R]elitigation carries serious detrimental effects and should be avoided unless the circumstances dictate that relitigation is in fact necessary to enhance the credibility and the effectiveness of the adjudicative process as a whole. There may be instances where relitigation will enhance, rather than impeach, the

> integrity of the judicial system, for example: (1) when the first proceeding is tainted by fraud or dishonesty; (2) when fresh, new evidence, previously unavailable, conclusively impeaches the original results; or (3) when fairness dictates that the original result should not be binding in the new context…
>
> 53 The discretionary factors that apply to prevent the doctrine of issue estoppel from operating in an unjust or unfair way are equally available to prevent the doctrine of abuse of process from achieving a similar undesirable result. There are many circumstances in which the bar against relitigation, either through the doctrine of *res judicata* or that of abuse of process, would create unfairness. If, for instance, the stakes in the original proceeding were too minor to generate a full and robust response, while the subsequent stakes were considerable, fairness would dictate that the administration of justice would be better served by permitting the second proceeding to go forward than by insisting that finality should prevail. An inadequate incentive to defend, the discovery of new evidence in appropriate circumstances, or a tainted original process may all overcome the interest in maintaining the finality of the original decision. [citations omitted]

[14] As the Supreme Court of Canada held in *Danyluk v. Ainsworth Technologies Inc.*, 2001 SCC 44, [2001] 2 S.C.R. 460 at para. 18 (*Danyluk*), albeit in discussion of the doctrine of issue estoppel:

> The law rightly seeks a finality to litigation. To advance that objective, it requires litigants to put their best foot forward to establish the truth of their allegations when first called upon to do so. A litigant, to use the vernacular, is only entitled to one bite at the cherry. … A person should only be vexed once in the same cause. Duplicative litigation, potential inconsistent results, undue costs, and inconclusive proceedings are to be avoided.

[15] The obligation of litigants to put their best foot forward concerns not only questions or facts distinctly put in issue and directly determined, but extends to the material facts and the conclusions of law or of mixed fact and law that were necessarily (even if not explicitly) determined in the earlier proceedings: *Danyluk* at para. 24.

[16] The following additional guidance comes from the Supreme Court of Canada's decision in *Blencoe v. British Columbia (Human Rights Commission)*, 2000 SCC 44, [2000] 2 S.C.R. 307 at para. 120:

> In order to find an abuse of process, the court must be satisfied that, "the damage to the public interest in the fairness of the administrative process should the proceeding go ahead would exceed the harm to the public interest in the enforcement of the legislation if the proceedings were halted" (Brown and Evans, [*Judicial Review of Administrative Action in Canada.* Toronto: Canvasback, 1998], at p. 9-68). According to L'Heureux-Dubé J. in *Power*, [[1994] 1 S.C.R. 601], at p. 616, "abuse of process" has been characterized in the jurisprudence as a process tainted to such a degree that it amounts to one of the clearest of cases. In my opinion, this would apply equally to abuse of process in administrative proceedings. For there to be abuse of process, the proceedings must, in the words of L'Heureux-Dubé J., be "unfair to the point that they are contrary to the interests of justice" (p. 616). "Cases of this nature will be extremely rare" (*Power, supra*, at p. 616). In the administrative context, there may be abuse of process where conduct is equally oppressive.

[17] I turn now to jurisprudence in which the doctrine of abuse of process has been considered in the context of patent litigation.

[18] In *Sanofi-Aventis Canada Inc. v. Novopharm Limited*, 2007 FCA 163, 282 D.L.R. (4th) 476 at paras. 26, 35 (*Sanofi-Aventis*), and *Pfizer Canada Inc. v. Amgen Inc.*, 2019 FCA 249, 311 A.C.W.S. (3d) 823 at para. 57 (*Pfizer*), this Court has confirmed that the principles enunciated in *C.U.P.E.* must inform analysis with respect to abuse of process in the context of the *Regulations*.

[19] In *Apotex Inc. v. Merck & Co.*, [1999] F.C.J. No. 575, 167 F.T.R. 59 (F.C.T.D.) (*Merck*), Apotex brought an action to impeach the patent in suit after it had lost an earlier patent infringement action in which it had not raised the issue of invalidity of the patent. Apotex had

also lost a motion to vary the appeal judgment that declared the claims in issue valid. Merck moved to strike Apotex's statement of claim as an abuse of process. The Federal Court Trial Division granted the motion, on the basis that the validity of the patent implicitly underlay the finding of infringement in the previous action. At paragraph 25, the Court stated:

> … [I]t is apparent that the application of the doctrine of *res judicata* does not depend on whether the parties actually raised the issue or issues in previous proceedings, but rather whether the parties could have done so. Should a party choose to drop certain issues for reasons of tactics, strategies, or otherwise, the party seals its fate with regard to those decisions. Parties must bring forward their whole case, and will not be permitted to litigate by instalments in piecemeal fashion. It is a principle of law and also of policy that there be finality to court decisions: see also *Grandview v. Doering*, 1975 Can.LII 16 (SCC), [1976] 2 S.C.R. 621 at 634 and 636. Parties to litigation must be able to rely on the finality of final judgments so that they can adjust their affairs, if necessary, and conduct themselves accordingly.

[20] This Court in *Procter & Gamble Pharmaceuticals Canada Inc. v. Canada (Minister of Health)*, 2003 FCA 467, [2004] 2 F.C.R. 85 (*Procter & Gamble*), likewise extended the principle of finality to issues that could have been raised but were not, albeit in the context of issue estoppel. There, this Court found that an allegation pursuant to the *Regulations* that the patent in suit was not eligible to be listed on a patent list had been determined implicitly in a prior proceeding under the *Regulations* in which a prohibition order had been issued.

[21] In *AB Hassle v. Apotex Inc.*, 2005 FC 234, [2005] 4 F.C.R. 229, Apotex issued an NOA alleging non-infringement and invalidity of the patent in suit after a prior unsuccessful NOA alleging non-infringement only led to a prohibition order. At paragraph 81, the Federal Court concluded that Apotex's prior allegation of only non-infringement indicated that it had accepted the validity of the patent in suit, and that the issue of invalidity had effectively been decided. The

Federal Court found therefore that the later NOA was barred by issue estoppel, and that it also constituted an abuse of process.

[22] On appeal (*AB Hassle v. Apotex Inc.*, 2006 FCA 51, [2006] 4 F.C.R. 513 (*AB Hassle*)), this Court affirmed the Federal Court's abuse of process finding. At paragraph 24, this Court recognized that more than one NOA in respect of the same patent may be proper in certain circumstances, but it noted that the recipient of a second or subsequent such NOA could commence proceedings under the *Regulations*, and then argue that the NOA is an abuse of process. At paragraph 25, this Court provided the following non-exhaustive list of circumstances in which a second NOA may not be an abuse of process: if it is based on new facts, a newly discovered process, a change in the law, a situation that limits the scope or application of an existing prohibition order, or a new and definitive decision as to the validity or construction of the patent. This Court also recognized a residual discretion to decide an application even if it is determined to be an abuse of process. At paragraph 26, this Court found no error in the Federal Court's finding of abuse of process on the basis that Apotex could have raised its invalidity allegations in the previous proceedings. This Court also refused to interfere with the Federal Court's exercise of discretion.

[23] The principle from *AB Hassle* that segmentation of NOAs may be an abuse of process has since been reiterated by this Court in *Apotex Inc. v. Sanofi-Aventis*, 2014 FCA 68, [2015] 2 F.C.R. 828 at para. 76.

[24] Finally, this Court has commented that misconduct is not a required element to find abuse of process in Canada: *Sanofi-Aventis* at para. 43.

IV. Amendments to the *Regulations* in 2017

[25] Major amendments to the *Regulations* came into force in 2017. Of particular importance in the present appeal, the prior dual-track litigation approach was replaced. Formerly, the debate between the first person (typically, the owner or licensee of the patent in suit) and the second person (typically, the generic drug manufacturer) was whether the Minister of Health should be prohibited from issuing an NOC to the second person. This was decided based on whether the first person was successful in showing that the allegations in the second person's NOA were not justified. If so, a prohibition order would be issued. If not, the Minister of Health would remain free to issue an NOC to the second person. This prohibition proceeding was in the form of an application, and proceeded based on a paper record and without live witnesses. Regardless of the outcome of the prohibition proceeding, litigation under the *Patent Act*, R.S.C. 1985, c. P-4, (and outside the *Regulations*) could follow. If the prohibition order was refused, and the NOC issued to the second person, the first person could sue for patent infringement under section 55 of the *Patent Act*. On the other hand, if a prohibition order was issued, and the second person was kept off the market, it could commence an action under section 60 of the *Patent Act* seeking a declaration that the patent in issue is invalid and/or would not be infringed. Such actions under the *Patent Act* would be decided based on evidence gathered at trial with live witnesses in Court, and after discovery.

[26] Such dual-track litigation was allowed because the issues before the Court were technically different – the proceeding under the *Regulations* concerned not whether the patent in suit was valid or would be infringed, but whether certain allegations in that regard were justified. Another quirk of the *Regulations* prior to 2017 was that an unsuccessful first person might not have a practical right of appeal because an NOC might issue to the second person shortly after the Federal Court's decision, and before an appeal could be decided. An appeal on the question of prohibiting the Minister of Health from issuing the NOC would become moot upon issuance of the NOC.

[27] One key aim of the 2017 amendments to the *Regulations* was to eliminate the dual-track nature of litigation involving patents on medicines. Under the amendments, the second person still serves an NOA. However, the next step for the first person is now to commence an action rather than an application. As before, the commencement of the action prevents the Minister of Health from issuing an NOC to the second person for 24 months (subject to certain conditions), and the first person accepts the possibility of liability for damages to the second person if the action is ultimately dismissed. The important difference is that the action under the *Regulations* as they now stand decides the issues raised in the NOA (e.g. infringement, invalidity) once and for all just like an ordinary action under the *Patent Act*. The elimination of the dual-track litigation approach also provides an effective right of appeal for an unsuccessful first person. Even if the Federal Court rules in favour of the second person, and they obtain an NOC for their generic drug, the first person can pursue an appeal without concern that the matter has become moot.

V. The Parties' Arguments

[28] Janssen argues that, just as in *AB Hassle*, it was an abuse of process for Apotex to have served a prior NOA alleging only non-infringement of the 335 Patent and then, after losing on that basis, to have served further NOAs alleging invalidity of the 335 Patent. Janssen argues that the prior NOA, by failing to allege invalidity, necessarily accepted that the 335 Patent was valid, just as in *AB Hassle*. It argues that Apotex does not rely on any exception to the general rule that litigants must put their best foot forward.

[29] While Janssen acknowledges that the decisions in *AB Hassle* concern the *Regulations* as they stood before 2017, it argues that these decisions apply with even greater force under the current regime in which all issues are intended to be decided in a single proceeding.

[30] Janssen argues that the Federal Court erred in law by misframing the issue as being whether a second person is permitted to serve more than one NOA. In Janssen's view, an NOA is only the beginning of the adjudicative process, allowing the first person to commence an infringement action. The real issue is whether the subsequent NOA is an abuse of process because the issues raised in the second proceeding could have been raised in the first one.

[31] Janssen also argues that the Federal Court erred by failing to recognize the distinction between this case, in which Apotex could have but did not raise invalidity as an issue in the Prior Action, and parallel litigation between Pharmascience Inc. (PMS) and Janssen concerning the same patent, in which PMS did raise invalidity as an issue in the original proceeding. That

proceeding (T-1441-20) resulted in a summary trial regarding PMS's non-infringement allegation (2022 FC 62, 190 C.P.R. (4th) 1, which is the subject of an appeal in this Court, File No. A-69-22, which has been heard and remains under reserve), and proceeded to trial on the remaining invalidity issue (2022 FC 1218, 198 C.P.R. (4th) 329, which is the subject of another appeal in this Court, File No. A-205-22, which has also been heard and remains under reserve).

[32] Finally, Janssen argues that the Federal Court erred in finding its abuse of process arguments inapplicable to ANDS#2. Janssen argues that ANDS#2 is related to ANDS#1 in that they both concern different doses of its paliperidone palmitate product. Apotex's non-infringement argument in the Prior Action (concerning ANDS#1) was that it would not include the 75 mg dose, which is one of the doses contemplated in ANDS#2.

[33] For its part, Apotex notes that abuse of process is an extraordinary and discretionary remedy, and that its application in this case must be considered in the context of the *Regulations*. Apotex argues that the Federal Court's discretionary decision is particularly worthy of respect in this case because the same judge who decided the motions under appeal here also presided over separate trials involving Teva Canada Limited and PMS that dealt with the same drug and the same patent. Apotex argues that no judicial officer is better placed to assess whether abuse of process applies in the Underlying Actions.

[34] With regard to the context of the *Regulations*, Apotex notes that allegations of invalidity are treated differently from allegations of non-infringement. Apart from being listed in a separate subparagraph under paragraph 5(2.1)(*c*), the "statement of the legal and factual basis" that must

accompany an allegation "must be detailed in the case of an allegation that the patent … is invalid or void" (subparagraph 5(3)(*b*)(ii)). There is no similar requirement for detail for a non-infringement allegation.

[35] Apotex also relies on subsection 55.2(5) of the *Patent Act*, which provides as follows:

Inconsistency or conflict	**Divergences**
52.2(5) In the event of any inconsistency or conflict between **(a)** this section or any regulations made under this section, and **(b)** any Act of Parliament or any regulations made thereunder, this section or the regulations made under this section shall prevail to the extent of the inconsistency or conflict.	**55.2 (5)** Une disposition réglementaire prise sous le régime du présent article prévaut sur toute disposition législative ou réglementaire fédérale divergente.

[36] Apotex argues that the *Regulations* create a comprehensive regime in which the different treatment of allegations of invalidity and non-infringement is deliberate in view of the summary nature of proceedings thereunder, and is intended to prevail. In this context, Apotex argues that there is no abuse of process where a second person chooses to allege non-infringement only (hoping it will be successful on that issue), and then later alleges invalidity if the non-infringement allegation fails. Apotex argues that it did not stand to benefit from delaying its invalidity allegation because the effect would be to delay the time that this allegation would be addressed by the court.

[37] Apotex goes further and argues that proceedings under the *Regulations* would not proceed with the intended efficiency if a second person were allowed to introduce an invalidity issue in its defence that was not raised in its NOA. Apotex suggests that second persons would thereby be encouraged to withhold invalidity allegations in their NOAs. It also contends that requiring all allegations to be made in a single NOA would unnecessarily complicate litigation under the *Regulations*.

[38] Apotex also notes that the *Regulations* do not prohibit more than one NOA in respect of a particular drug and patent. It argues that such a prohibition could easily have been provided for if it had been intended, and there are good reasons not to complicate proceedings under the *Regulations* by requiring a second person to raise all possible allegations in a single NOA. Since the further NOAs in this case were not abusive, Apotex asserts, the Underlying Actions and Apotex's defences of invalidity therein were likewise not abusive.

[39] Apotex argues that *AB Hassle* is distinguishable from this case because the new invalidity allegations there were effectively a collateral attack on the court's prior conclusions on claim construction.

[40] Apotex further argues that Janssen's abuse of process argument, which is based on relitigation, cannot succeed because the appeal of the Federal Court's decision in the Prior Action remains pending, and is therefore not final.

[41] Finally, Apotex pushes back on Janssen's argument that the 2017 amendments to the *Regulations* were intended to have all allegations addressed in a single proceeding. Apotex argues that the aim was to avoid the inefficient dual-track litigation approach in which an issue could be argued and decided in a proceeding under the *Regulations* and then relitigated in a later proceeding outside the *Regulations*. Apotex argues that, here, it seeks to assert an argument that has not been considered by the court.

VI. Analysis

[42] The standard of review in this appeal on a discretionary issue is as contemplated in *Housen v. Nikolaisen*, 2002 SCC 33, [2002] 2 S.C.R. 235. Questions of law are reviewed on a standard of correctness, and questions of fact or of mixed fact and law from which no question of law is extricable are reviewed on a standard of palpable and overriding error. In this case, I conclude that the Federal Court erred in law in that it applied the incorrect legal test in determining that there was no abuse of process.

[43] Although the power to stay proceedings for abuse of process is a discretionary one, it must be exercised in accordance with settled jurisprudence, and failure to do so amounts to an error of law. In my view, the Federal Court erred in its consideration of Janssen's abuse of process argument by focusing on the distinction in the *Regulations* between non-infringement allegations and invalidity allegations, and the propriety of Apotex's service of multiple NOAs. Since the doctrine of abuse of process is about the inherent power of the Court to prevent the misuse of its procedure, the focus should instead have been on the proceedings before the Court – in this case, the Underlying Actions.

[44] In my view, the Regulatory Impact Analysis Statement (RIAS) that accompanied the 2017 amendments to the *Regulations* (Canada Gazette, Part II, Vol. 151, Extra No. 1) makes it clear that a principal aim was to avoid multiple proceedings concerning patents on medicines, regardless of whether those proceedings are within or outside the *Regulations*. The RIAS includes the following:

> Canada is … replacing summary prohibition applications with full actions resulting in final determinations of patent infringement and validity [page 32, see also pages 34 and 52 to similar effect]
>
> …
>
> The costly and inefficient practice of dual litigation is eliminated, leading to greater legal and market certainty [page 34]
>
> …
>
> More broadly, replacing the current summary proceedings with full actions will result in greater overall efficiency. As a result of this change, the Court will provide final determinations of patent infringement and validity [page 35]
>
> …
>
> Proceedings under the *Regulations* may now address any claim in a patent included on the patent register, not simply claims for the medicinal ingredient, the formulation, the dosage form, or the use of the medicinal ingredient … This eliminates the need for separate proceedings to address all claims in a single patent [page 37]
>
> …
>
> The NOA must provide the legal and factual basis for any allegation made in the submission or supplement. This will facilitate early consideration of issues likely to be raised in litigation. This requirement does not circumscribe or otherwise limit the issues and arguments that may be raised in a proceeding brought under the *Regulations*. The scope of proceedings will be defined by the pleadings in accordance with prevailing rules and practices. This will further align litigation under the *Regulations* with litigation under the [*Patent*] *Act* [page 40].

[45] Even though the specific measure in the 2017 amendments to the *Regulations* was to eliminate the proceeding that could lead to a prohibition order against the Minister of Health, the

aim of avoiding multiple proceedings was front and centre. A proceeding pursuant to section 6 of the *Regulations* as amended in 2017 would proceed as "an action for patent infringement, with procedural safeguards of examination for discovery and oral evidence as well as determinations on substantive patent validity and infringement" such that "an action commenced under section 6 of the Amended Regulations …, for all intents and purposes, is a proceeding identical to a section 55 action": see *Pfizer* at paras 8, 83.

[46] Further indication that an action under section 6 of the *Regulations* is to proceed and have an effect much like a normal patent infringement action is that a second person is not limited in its defence to what is alleged in the NOA. Subsection 6(3) of the *Regulations* provides that the second person may bring a counterclaim, and does not place a limit on the issues that may be raised therein. Moreover, as indicated at paragraph 44 above, the RIAS states at page 40 that the requirement in subparagraph 5(3)(*b*)(ii) of the *Regulations* that the NOA include a statement of the legal and factual basis of the allegation "does not circumscribe or otherwise limit the issues and arguments that may be raised in a proceeding brought under the *Regulations*." This Court has affirmed the permissibility of amendments to pleadings in an action under section 6 of the *Regulations* that introduce issues not raised in the underlying NOA: *Sunovion Pharmaceuticals Canada Inc. v. Taro Pharmaceuticals Inc.*, 2021 FCA 113, 183 C.P.R. (4th) 167, aff'g 2021 FC 37, 328 A.C.W.S. (3d) 149.

[47] In light of the foregoing jurisprudence, the Federal Court should have considered whether a defendant in a normal patent infringement action under section 55 of the *Patent Act* that defends itself on the basis of non-infringement (without challenging the validity of the patent in

suit) would, after losing on that defence, be allowed to commence a separate impeachment action concerning the same patent. In the absence of special circumstances (for example, of the kind noted in paragraphs 13 and 22 above), such a subsequent action would, in my view, typically constitute an abuse of process. I see no reason why this same reasoning should not apply in the case of separate actions under the *Regulations*.

[48] I would reject Apotex's argument that there are good reasons to permit sequential NOAs with each raising different allegations (see paragraph 38 above). The same reasoning might be applied in normal patent infringement actions, but such an approach in that context would be inconsistent with the jurisprudence.

[49] As noted at paragraph 22 above, this Court in *AB Hassle* (at paragraph 24) stated that, even if a second or subsequent NOA is permissible in certain circumstances, thus prompting the first person to commence proceedings under the *Regulations*, the first person may do so and then argue that the NOA is an abuse of process. This indicates that service of a proper NOA is not necessarily sufficient to avoid a finding that it, or the defence in the subsequent action, constitutes an abuse of process. In my view, this applies no less under the *Regulations* as amended in 2017.

[50] I would not distinguish *AB Hassle*, as Apotex urges, on the basis that it concerned claim construction issues that had already been addressed by the court. It is clear from paragraphs 21 and 22 of this Court's decision in that case that not all issues concerned claim construction, and

the principal question was whether the new allegations "could and should have" been raised in earlier proceedings.

[51] I would also not distinguish *Merck* and *Procter & Gamble* (discussed in paragraphs 19 and 20 above) as Apotex urges. In my view, both of these decisions are instructive in considering abuse of process in the present appeal, and the different circumstances are not grounds to distinguish them.

[52] I do not agree with Apotex's arguments (noted at paragraphs 36 and 37 above) that permitting second persons to introduce invalidity allegations that are not mentioned in their NOA would encourage them to withhold such allegations from the NOA, thus damaging the efficiency of the process and going contrary to the intention of the *Regulations*. I am not convinced that second persons would be encouraged to withhold allegations from their NOAs. The second person knows that the NOA is the document that the first person must consider when deciding whether to (i) commence an action under section 6 of the *Regulations* (and thereby accept the possibility of liability for damages to the second person if the action is unsuccessful), or (ii) avoid the possibility of such liability by doing nothing and allowing the second person to enter the market. A viable invalidity allegation would presumably urge a first person toward choosing the latter course of action. Therefore, the second person has a good reason to want to raise such an allegation in the NOA. Moreover, though the failure to include an invalidity allegation in an NOA would relieve the second person of the obligation to provide therein details of the allegation, it would also deny the second person the right to request from the first person the information as contemplated in subsection 5(3.1) of the *Regulations*, at least until discovery. This

could delay the production of documents like laboratory notebooks and research reports, as well as contact information for the inventor(s). Further, as acknowledged by Apotex, an invalidity allegation that was deliberately withheld from an NOA might be excluded from a subsequent action under section 6 of the *Regulations* as itself being an abuse of process for failing to follow the requirements of the *Regulations*.

[53] In my view, it was intended that the second person should raise all of its allegations in its NOA, and it should not to keep some in reserve in the event that it is not initially successful. Though this might lead to more complicated proceedings, it would meet the explicit goal of addressing all issues in a single action.

[54] It is also my view that subsection 55.2(5) of the *Patent Act*, contemplating inconsistencies or conflicts between the *Regulations* and any other Act of Parliament or regulations thereunder, is inapplicable here. I see no such inconsistency with the *Regulations* in the application of the doctrine of abuse of process in the circumstances of this case.

[55] I also do not agree with Apotex's argument that there can be no abuse of process in the present case because the appeal of the Federal Court's decision in the Prior Action remains pending. Firstly, the doctrine of abuse of process is flexible and not limited by the strict finality requirement that is applicable to the doctrine of issue estoppel: *C.U.P.E.* at para. 37. Moreover, the outstanding issue in the appeal concerning the Prior Action is unrelated to the invalidity issue at play in the Underlying Actions and in the present appeal. Patent validity is not in issue in the Prior Action.

[56] The concerning fact that remains in the present appeal is that Apotex decided to argue the invalidity of the 335 Patent only after being unsuccessful in the Prior Action, where it could have, but decided not to, raise the invalidity issue in its NOA or as part of its defence. This appears to be an attempt by Apotex to split its case and to litigate by instalments in a way that has been found to be an abuse of process. Even though Apotex did not raise invalidity as an issue in the Prior Action, it was implicitly considered. Subsection 43(2) of the *Patent Act* provides that a patent is presumed to be valid. Moreover, the imposition of injunctive remedies by the Federal Court in its decision in the Prior Action implies that it found the 335 Patent to be valid.

[57] With regard to ANDS#2, I agree with Janssen that the Federal Court erred in finding abuse of process inapplicable based on it being a distinct ANDS (relating to different dosage strengths) that had not been previously considered by the court. This was an overly rigid approach, which failed to recognize the flexibility of the doctrine of abuse of process. As Janssen argues, the 75 mg dose contemplated in ANDS#2 is the dose that was missing in ANDS#1 to provide a foundation for Apotex's unsuccessful allegation of non-infringement. Initially, Apotex accepted that an NOC would not issue in respect of ANDS#2 until the 335 Patent had expired. Just as with ANDS#1, Apotex could have, but did not, allege that the 335 Patent is invalid. Apotex's revised approach alleging invalidity in respect of ANDS#2 appears to be part of its back-up plan, along with ANDS#1, after failing in respect of its non-infringement allegation. It would be nonsense to prohibit Apotex from alleging invalidity of the 335 Patent for the purposes of ANDS#1 under the doctrine of abuse of process, but to permit the same allegation for the purposes of ANDS#2.

VII. Remedy

[58] Having concluded that the Federal Court erred in its consideration of abuse of process, I turn now to the question of remedy.

[59] Neither Janssen nor Apotex has requested that, in the event the present appeal is allowed, the motion be remitted to the Federal Court for reconsideration. I agree that such an approach would be inadvisable given the approaching trial date, and the amount of work that is surely being done even now in preparation therefor. Accordingly, I would consider Janssen's motion anew, and decide it here.

[60] In view of the circumstances discussed above, I am convinced that Apotex's defences in the Underlying Actions are sufficiently unfair that they are contrary to the interests of justice. Allowing the Underlying Actions to continue would go counter to the intent of the *Regulations* by permitting repeated litigation between the same parties concerning the same patent and the same ANDSs instead of having a single proceeding to finally decide the matter. This would impair the integrity of judicial decision-making, and bring the administration of justice into disrepute. I have heard no reason that would justify not applying the doctrine of abuse of process in this case. In my view, if Apotex had wished to allege the invalidity of the 335 Patent in the context of ANDS#1 or ANDS#2, it should have done like PMS did and raised it in the Prior Action.

[61] Janssen requests that the relief sought in its notice of appeal be granted. That relief is reproduced here for convenience:

1. Allow this appeal;

2. Reverse and/or set aside the Judgment and declare that the respondent's defences in each of Federal Court File Nos. T-1121-22, T-11-22, T-1248-22, and T-1249-22 are an abuse of process;

3. Grant the appellants' actions in each of Federal Court File Nos. T-1121-22, T-1122-22, T-1248-22, and T-1249-22;

4. Declare that the making, constructing, using or the making, constructing, using, or selling of APO-Paliperidone Palmitate, paliperidone palmitate extended release injectable suspension, supplied as prefilled syringes containing paliperidone as paliperidone palmitate in accordance with Abbreviated New Drug Submission ("**ANDS**") No. 233882, would infringe claims 1 to 63 of Canadian Patent No. 2,655,335 (the "**335 Patent**");

5. Declare that the making, constructing, using or the making, constructing, using, or selling of APO-Paliperidone Palmitate, paliperidone palmitate extended release injectable suspension, supplied as prefilled syringes containing paliperidone as paliperidone palmitate in accordance with ANDS No. 239939, would infringe claims 1 to 63 of the 335 Patent;

6. Grant an injunction until the expiry of the 335 Patent on December 17, 2028, restraining Apotex, as well as its subsidiary and affiliated companies, officers, directors, employees, agents, licensees, successors, assigns, and any others over whom Apotex exercises lawful authority, from:

    (a) Making, constructing, using, or selling APO-PALIPERIDONE INJECTION paliperidone palmitate prolonged-release injectable suspension in Canada in accordance with ANDS No. 233882 or ANDS No. 239939;

    (b) Offering for sale, marketing, or having APO-PALIPERIDONE INJECTION paliperidone palmitate pro-longed-release injectable suspension marketed in Canada in accordance with ANDS No. 233882 or ANDS No. 239939;

    (c) Importing, exporting, distributing, or having APO-PALIPERIDONE INJECTION paliperidone palmitate prolonged-release injectable suspension marketed [*sic*] in Canada in accordance with ANDS No. 233882 or ANDS No. 239939; and

    (d) Otherwise infringing or inducing infringement of the 335 Patent.

7. If needed, to the extent the actions in any of Court File Nos. T-1121-22, T-1122-22, T-1248-22, or T-1249-22 have been dismissed by the Federal Court before this Court hears and decides this appeal, grant an order setting aside or vacating such decision(s);

8. Award the appellants their costs of this appeal and of the underlying motions, with interest;

9. Order the return from the respondent to the appellants of any costs paid by the appellants to the respondent with respect to the underlying actions, with interest; and

10. Make such further and other order as this Honourable Court may deem just.

[62] Apotex notes that Janssen's statements of claim in the Underlying Actions do not seek a declaration that the invalidity argument raised in Apotex's NOAs and its defences constitute an abuse of process. Apotex argues that it is improper therefore for Janssen to seek such a declaration here.

[63] This argument lacks merit. Janssen's notice of motion before the Federal Court requested certain of the remedies sought in its statements of claim, and based itself in part on Apotex's abuse of process. I see no reason that Janssen's failure to raise abuse of process in its statements of claim should deny it the relief it seeks. Janssen's motion was procedural, not substantive.

[64] Apotex also argues that the injunctive relief Janssen seeks is too broad, covering activities that are outside the scope of the exclusive rights granted in respect of a patent as enumerated in section 42 of the *Patent Act*, and possibly encompassing activities permitted under section 55.2. Apotex refers specifically to the injunction against (i) offering for sale,

(ii) marketing, (iii) having marketed, (iv) importing, (v) exporting, (vi) distributing, or (vii) having distributed.

[65] Apotex has provided little by way of explanation as to how these activities are supposed to fall outside the scope of a patentee's exclusive rights. I note that an injunction of similar scope was granted by the Federal Court in its decision in respect of the Prior Action (2022 FC 107, 190 C.P.R. (4th) 96), and Apotex has not challenged the scope of that injunction in its appeal of that decision. That injunction is already in force. The only substantive difference that I can see between the scope of the injunction sought in the present appeal and that granted in the Prior Action is that the latter covers only ANDS #1, while the former would cover both ANDS#1 and ANDS#2.

[66] I also note that this Court affirmed injunctive remedies of the same scope as proposed in this appeal in a separate trial involving the 335 Patent and Janssen, against Teva: *Teva Canada Limited v. Janssen Inc.*, 2023 FCA 68, 2023 A.C.W.S. 3380, aff'g 2020 FC 593, 321 A.C.W.S. (3d) 539. Moreover, this Court has previously affirmed "distributing" and "offering for sale" as acts of infringement in *Nova Chemicals Corporation v. Dow Chemical Company*, 2014 FC 844, 129 C.P.R. (4th) 199 at para. 283, aff'd 2016 FCA 216, 142 C.P.R. (4th) 339.

[67] While section 42 of the *Patent Act* refers specifically to the patentee having "the exclusive right, privilege and liberty of making, constructing and using the invention and selling it to others to be used", it is well understood that this does not constitute a definition of

infringement. Rather, as stated in *Monsanto Canada Inc. v. Schmeiser*, 2004 SCC 34, [2004] 1 S.C.R. 902 at para. 34 (*Schmeiser*):

> The purpose of s. 42 is to define the exclusive rights granted to the patent holder. These rights are the rights to full enjoyment of the monopoly granted by the patent. Therefore, what is prohibited is "any act that interferes with the full enjoyment of the monopoly granted to the patentee": H. G. Fox, *The Canadian Law and Practice Relating to Letters Patent for Inventions* (4th ed. 1969), at p. 349; see also *Lishman v. Erom Roche Inc*. (1996), 68 C.P.R. (3d) 72 (F.C.T.D.), at p. 77.

[68] The majority in *Schmeiser* went on to discuss the breadth of what is contemplated by the exclusive right to use the invention. For example, it indicated that "[i]f there is a commercial benefit to be derived from the invention, it belongs to the patent holder": *Schmeiser* at para. 58. The same paragraph instructs that possession in commercial circumstances raises a rebuttable presumption of use.

[69] I am satisfied that the wording proposed by Janssen for the injunctive relief is appropriate. All of the activities that Apotex objects to including in the injunction are commercial in nature, and would presumably be done for a commercial benefit. The activities of distributing and having distributed are essentially sales and are thus clearly infringing. The other activities involve commercial use of the patented invention as contemplated in *Schmeiser*, and would therefore presumably also be infringing. The principle goal of the injunction is to prevent future infringement of the exclusive rights granted by the 335 Patent. In my view, the proposed injunction achieves this, and in clear terms.

[70] Moreover, I am not convinced that the proposed injunctive relief overlaps the exceptions to infringement contemplated in section 55.2 of the *Patent Act*.

VIII. Conclusion

[71] It follows from the foregoing that I would allow the present appeal and set aside the Federal Court's judgment on Janssen's motion for summary judgment. Issuing the judgment that the Federal Court should have issued, I would declare that Apotex's defences in the Underlying Actions are an abuse of process, and I would grant Janssen the appropriate relief sought in its notice of appeal, including declarations, injunctions, and costs before the Federal Court.

[72] In accordance with the agreement of the parties, I would order costs of the present appeal in the amount of $10,000, all-inclusive, to be paid by Apotex to Janssen.

"George R. Locke"
J.A.

"I agree
Yves de Montigny C.J."

"I agree
Nathalie Goyette J.A."

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

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