Federal Court Cour fédérale

Date: 20220131

Docket: T-124-21

Citation: 2022 FC 107

Ottawa, Ontario, January 31, 2022

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 January 31, 2022)

I. Introduction

[1] This is a motion brought by the Defendant, Apotex Inc. [Apotex], for a summary trial.

II. Background

[2] The proceeding underlying this motion is a patent infringement action brought by the Plaintiffs, Janssen Inc. and Janssen Pharmaceutica N.V. [collectively, Janssen] pursuant to subsection 6(1) of the *Patent Medicine (Notice of Compliance) Regulations*, SOR/93-133 [the "*Regulations*"] in regards to Canadian Patent No. 2,655,335 [the "335 Patent"].

[3] Janssen Inc. is a "first person" in accordance with the *Regulations*. Janssen Pharmaceutica N.V. is the registered owner of the 335 Patent and is a party to this action pursuant to subsection 6(2) of the *Regulations*.

A. *The 335 Patent*

[4] The 335 Patent is titled, "Prolonged-Release Injectable Suspensions of Paliperidone Palmitate and Dosage Forms and Delivery Systems Incorporating Same."

[5] The 335 Patent issued from an application filed in Canada on December 17, 2008, claiming priority from United States Patent Application No. 61/014,918 filed on December 19, 2007. The 335 Patent was published on June 19, 2009 and issued on September 6, 2016. The 335 Patent has not expired.

[6] The 335 Patent contains 63 claims – all of which are asserted in this action. Claims 1, 2, 17, 18, 33, 34, 49, and 50 are independent claims.

[7] The 335 Patent relates to dosing regimens for long-acting injectable paliperidone palmitate formulations for the treatment of schizophrenia and related disorders. The 335 Patent teaches a dosing regimen that ensures an optimum plasma concentration-time profile for treating patients with paliperidone. The inventors targeted a plasma concentration exposure range of 7.5 ng/mL to 40 ng/mL of paliperidone after injection to ensure efficacy and minimize adverse side effects.

[8] To achieve therapeutic blood plasma concentrations rapidly, the 335 Patent teaches a "loading dose" regimen, wherein a specific dose is administered on Day 1 and a different specific dose is administered on Day 8, both in the deltoid muscle. The "loading dose" regimen is followed by a "maintenance dose" regimen of monthly doses of paliperidone palmitate administered thereafter, in either the deltoid or the gluteal muscle.

[9] The dosing regimen incorporates "dosing windows" of ± 2 days for the second loading dose, and ± 7 days for the monthly maintenance doses.

[10] The claims of the 335 Patent break down into four sets:

i. Claims 1 to 16 relate to prefilled syringes adapted for administration according to the claimed dosing regimens;

ii. Claims 17 to 32 relate to a use of a "dosage form" according to the claimed dosing regimens;

iii. Claims 33 to 48 relate to use of paliperidone as paliperidone palmitate in the manufacture/preparation of a “medicament” adapted for administration according to the claimed dosing regimen; and

iv. Claims 49 to 63 relate to a “dosage form” adapted for administration according to the claimed dosage regimens.

[11] The claimed dosing regimen for non-renally impaired psychiatric patients in need of treatment for schizophrenia (or related disorders) is defined in claims 1, 17, and 33:

i. A first loading dose of 150 milligrams equivalent [mg-eq.] of paliperidone palmitate administered into the deltoid muscle on Day 1 of treatment;

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

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

[12] The claimed dosing regimen for renally impaired patients, as defined in claims 2, 18, and 34, follows the same dosing schedule, dosing windows, and injection sites as set out above for non-renally impaired patients. Except with loading doses of 100 mg-eq. and 75 mg-eq., and maintenance doses of 50 mg-eq.

B. *INVEGA SUSTENNA®*

[13] The 335 Patent is listed on the Patent Register maintained by the Minister of Health pursuant to the *Regulations* in respect of Janssen's paliperidone palmitate suspension, marketed under the brand name INVEGA SUSTENNA®, in dosage strengths of 50 mg-eq., 75 mg-eq., 100 mg-eq., and 150 mg-eq.

[14] The product monograph for INVEGA SUSTENNA® sets out dosing regimens falling within the claims of the 335 Patent.

C. *Previous Litigation regarding the 335 Patent*

[15] The Plaintiffs have previously asserted claims 1 to 48 of the 335 Patent against Teva Canada Limited [Teva] in Court File No. T-353-18 [*Janssen Inc. v. Teva Canada Limited*, 2020 FC 593 [*Teva Paliperidone*]].

[16] In *Teva Paliperidone*, I held, *inter alia*, that:

- An essential element of claim 1 is a continuous maintenance dose of 75 mg-eq. of paliperidone injected into the deltoid or the gluteal muscle monthly ± 7 days after the second loading dose of 100 mg-eq., with the first loading dose being 150 mg-eq. [*Teva Paliperidone* at paragraph 145].

- The essential elements of claim 2 are the same as claim 1, except that the patient in need of treatment must have renal impairment, and the claimed dose amounts

> are about 100 mg-eq. (first loading dose), 75 mg-eq. (second loading dose), and 50 mg-eq. (maintenance dose) [*Teva Paliperidone* at paragraph 146].

[17] In that decision, I concluded that Teva would directly infringe claims 1 to 16 and 33 to 48, but not claims 17 to 32, of the 335 Patent if it comes to market with its paliperidone palmitate product in accordance with its Abbreviated New Drug Submission [ANDS] [*Teva Paliperidone* at paragraph 35].

[18] Based on the evidence before me in *Teva Paliperidone*, I also held that Teva would not induce infringement of any of claims 1 to 48 of the 335 Patent because "the Teva [product monograph] recommends that the prescribing physician select the maintenance dose for patients with renal impairment based on individual patient characteristics" [*Teva Paliperidone* at paragraphs 35, 282, and 290].

[19] The appeal of *Teva* Paliperidone is currently pending.

D. *Apotex's Abbreviated New Drug Submission*

[20] Apotex filed its ANDS No. 233882 on [redacted] The ANDS seeks approval to market and sell in Canada [redacted] doses of its *proposed* APO-PALIPERIDONE INJECTION product [the "APO Product"], a generic version of Janssen's INVEGA SUSTENNA® product.

[21] ANDS No. 233882 does not seek approval for [redacted] of paliperidone palmitate.

E. *The Present Action*

[22] On December 4, 2020, Apotex served Janssen with a Notice of Allegation in respect of the 335 Patent and ANDS No. 233882 [the "NOA"].

[23] The NOA alleged that the APO Product, that is the subject of ANDS No. 233882, would not infringe the 335 Patent. Apotex did not allege that the 335 Patent is invalid.

[24] In response to the NOA, the Plaintiffs commenced the underlying action against the Defendant pursuant to subsection 6(1) of the *Regulations* on January 18, 2021. The Plaintiffs are seeking:

i. A declaration that the making, constructing, using, or selling of the APO Product by Apotex in accordance with ANDS No. 233882 would infringe claims 1 to 63 of the 335 Patent, directly and/or indirectly;

ii. A permanent injunction restraining Apotex (as well as its subsidiaries and affiliates) from:

a. Making, constructing, using, or selling the APO Product in Canada;

b. Offering for sale, marketing, or having the APO Product marketed in Canada;

c. Importing, exporting, distributing, or having the APO Product distributed in Canada; and

d. Otherwise infringing or inducing others to infringe the 335 Patent.

iii. If Apotex makes, constructs, uses, or sells the APO Product before the expiry of the 335 Patent, damages or an accounting of Apotex's profits, as the Plaintiffs may elect, resulting from Apotex's infringing activities in respect of the 335 Patent;

iv. The Plaintiffs' costs of this action; and

v. Any other relief that this Honourable Court deems just.

[25] By Order dated February 10, 2021, the time and place for the trial of this action was set for September 26, 2022 in Toronto for ten days.

[26] On February 17, 2021, Apotex delivered a Statement of Defence denying the allegations of infringement and relying on the allegations in its NOA. Apotex advised the Plaintiffs of its intent to bring a motion for summary trial on February 19, 2021.

[27] The Plaintiffs delivered a Reply dated March 1, 2021.

III. Issues

[28] The issues to be decided on this motion are:

(1) Has Apotex established that this matter is appropriate to be decided by way of summary trial?

(2) If yes, should Janssen's infringement action be dismissed because Apotex is not seeking approval for [redacted] of the APO Product, or, conversely, should Janssen's infringement action be allowed because the product monograph for the APO Product will induce infringement of the 335 Patent?

IV. Analysis

A. *Has Apotex established that this matter is appropriate to be decided by way of summary trial?*

[29] Motions for summary trial are directed in accordance with the *Federal Courts Rules*, SOR/98-106 [the "*Rules*"] 213 and 216.

[30] *Rule* 213 permits a party to bring a motion for 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.

[31] Summary trial need not be reserved for cases where the summary trial will result in determination of every issue. The Court has discretion to look at one or more issues and

determine whether it is appropriate to deal with those issues by way of summary trial [*Rule* 213(1); *Teva Canada Limited v. Wyeth and Pfizer Canada Inc.*, 2011 FC 1169 (rev'd on other grounds 2012 FCA 141) [*Teva Canada*] at paragraph 32].

[32] Pursuant to *Rule* 216(6), if the Court is satisfied that there is sufficient evidence for adjudication, regardless of the amounts involved, the complexities of the issues, and the existence of conflicting evidence, the Court may grant judgment, unless it would be unjust to do so.

[33] Furthermore, *Rule* 3 provides that the *Rules* shall be interpreted and applied so that every proceeding is determined on its merits in the just, most expeditious, and least expensive way.

[34] Ultimately, "the Court must be satisfied that the prerequisites in the Rules for summary judgment or summary trial, understood in light of Rule 3, are met and that it is able to grant summary judgment, fairly and justly, on the evidence adduced and the law" [*Viiv Healthcare Company v. Gilead Sciences Canada, Inc.*, 2021 FCA 122 at paragraph 42].

[35] In addition to those conditions set out in *Rule* 216(6) above, there are a number of other factors to be considered on a motion for summary trial. These include, *inter alia*, the complexity and urgency of the matter; any prejudice likely to arise by delay; the cost of taking the case forward to a conventional trial in relation to the amount involved; whether credibility is a crucial factor and the deponents of the conflicting affidavits have been cross-examined; whether the summary trial involves a substantial risk of wasting time and effort, and producing unnecessary

complexity; and any other matters which may arise for consideration [*Wenzel Downhole Tools Ltd. v. National-Oilwell Canada Ltd.*, 2010 FC 966 at paragraphs 36-37].

(1) The Parties' Positions

[36] Apotex, as the party moving for summary trial, bears the burden of demonstrating that summary trial is appropriate [*Teva Canada* at paragraph 35].

[37] Apotex submits that all of the factors militating in favour of granting judgment following a summary trial are present in this matter:

i. The issues are well defined and will permit the resolution of the case in its entirety. In fact, there is only one issue to be decided: whether Apotex will induce infringement of the claims of the 335 Patent despite not [redacted] – there are no issues of claim construction, validity, or direct infringement;

ii. There are sufficient facts and evidence to permit adjudication. In fact, there are no further facts that will come out if the Parties proceed to trial;

iii. The evidence is not controversial;

iv. There will be no issues in assessing credibility in this case because the witnesses will testify *viva voce*; and

v. The questions of law are straightforward and mirror those already addressed in *Teva Paliperidone*.

[38] Further, Apotex submits that a summary trial will be the just, most expeditious, and least expensive determination on the merits.

[39] In addition, Apotex submits that, even though this motion was brought after a time and place for trial was fixed counter to *Rule* 213, this Court should recognize that it acted as expeditiously as possible in bringing this motion.

[40] It is customary in actions brought pursuant to the *Regulations* that the time and place for trial be fixed early on. In this instance, a trial was fixed a week before Apotex had filed its Statement of Defence. Within days of filing its Defence, Apotex advised Janssen of its intention to bring this motion and sought a case management conference.

[41] As such, Apotex suggests that this is a special circumstance and this Court should, pursuant to *Rule* 55, dispense with compliance to the timing set out in *Rule* 213 and allow this motion for summary trial.

[42] Janssen's position is that this matter is not appropriate for summary trial for the following reasons:

i. There has not yet been full discovery;

ii. There is conflicting expert evidence; and

iii. The appeal of *Teva Paliperidone* remains pending and its outcome may answer questions of law in respect of the test for inducing infringement.

[43] The only issue for determination on this application is whether, by not seeking approval for [redacted] in their ANDS and product monograph, the Defendant cannot and does not infringe any of the claims in the 355 Patent.

[44] Pursuant to *Rule* 216(6), I am satisfied that there are sufficient facts and evidence for the adjudication of the issue put forward by the Parties and it is an appropriate proceeding for summary trial. I also find that pursuant to *Rule* 55, the Court should proceed with this motion notwithstanding the timing issue with respect to *Rule* 213.

[45] Any disputes concerning expert and witness credibility can be addressed through the *viva voce* testimony provided in this matter. With respect to full discovery, it was Janssen who proposed the current timetable, which has discovery scheduled following the hearing of this motion. In addition, Janssen has not provided an indication of what information it requires at discovery that would be pertinent to this motion. That is, Janssen has not indicated what information it perceives to be missing and how this information could influence whether Apotex's product monograph will induce infringement.

[46] It should also be noted that the evidence engaged before the Court in this matter is not the same as the evidence before the Court in the *Teva Paliperidone* matter.

B. *Should Janssen's infringement action be dismissed because Apotex is not seeking approval for* [redacted] *of the APO Product, or, conversely, should Janssen's infringement action be allowed because the product monograph for the APO Product will induce infringement of the 335 Patent?*

(1) Burden and Onus of Proof

[47] The preliminary issue of which party bears the burden of proof on the merits, once a matter is before the Court for determination by summary trial and the Court has determined the matter is appropriate for a summary trial, was raised in this proceeding.

[48] Apotex submits that the burden in this motion reflects that of the underlying action – Janssen bears the normal civil burden of proof with respect to their allegation of infringement, namely, to establish Apotex's infringement of the 335 Patent on a balance of probabilities.

[49] In contrast, Janssen submits that Apotex bears the burden of proof of establishing non-infringement. Apotex is the moving party on this motion and is the party asserting the issue of non-infringement of the 335 Patent.

[50] As set out in *Janssen v. Pharmascience*, 2022 FC 62 at paragraphs 46 to 62, the burden for the determination of the merits of a summary trial reflects that of the underlying trial.

[51] Therefore, while on a motion for summary trial the burden is on the moving party to demonstrate that a summary trial is appropriate, once the onus of the merits of the matter, in terms of either infringement or validity, are before the Court for determination, the burden and onus of proof of the underlying action applies.

[52] Accordingly, the plaintiff asserting a claim of infringement in the underlying action bears the burden of proof on a balance of probabilities to prove that claim at the motion for a summary trial. Similarly, if the defendant asserts an affirmative validity defence in the underlying action,

they bear the burden of proof on a balance of probabilities to prove that defence at the motion for summary trial.

[53] Moreover, the parties in a motion or summary judgment or summary trial are required to put their best foot forward, regardless of where the onus lies [*Kobold Corporation et al. v NCS Multistage Inc.*, 2021, FC 1437 [*Kobold*] at paragraph 148].

[54] As stated above, Apotex argues that the sole issue in this motion is whether Janssen's infringement action should be dismissed because Apotex is not seeking approval for [redacted] and, thus, will not induce infringement of the 335 Patent. Janssen has the burden of proving infringement on a balance of probabilities.

[55] With Janssen's acknowledgment that direct infringement is not at issue in this matter because Apotex is not seeking approval of [redacted] the issue is narrowed to whether, on a balance of probabilities, Janssen can satisfy the Court on a balance of probabilities that Apotex will induce infringement of the 335 Patent.

[56] At the hearing, the Parties further agreed that really the sole issue for the Court to determine is the second prong of the *Corlac* test for inducing infringement: whether the inducer influenced the third party to the point that the infringing act would not have occurred without the influence.

[57] Notwithstanding the question of onus with respect to Apotex's assertion of non-infringement, the result reached below would not be different even if I were to find that the onus is on Apotex to prove infringement.

(2) The Experts and Fact Witnesses

(a) *Apotex's Experts*

(i) Dr. Oloruntoba Oluboka

[58] Dr. Oluboka is a Clinical Associate Professor in the Department of Psychiatry at the University of Calgary and a practicing clinical psychiatrist in the Calgary area. His primary area of speciality is in the treatment of refractory mood and psychotic disorders, including schizophrenia.

[59] Dr. Oluboka obtained his Bachelor's degree in Surgery and Medicine and completed his residency in psychiatry at the University of Ilorin in Nigeria. He completed a Research Fellowship in mood disorders at Western University and an additional psychiatry residency at Dalhousie University.

[60] In addition to teaching on various topics in regards to schizophrenia and related disorders, Dr. Oluboka has an active clinical psychiatry practice. He treats and oversees patients with schizophrenia and related disorders, and often prescribes INVEGA SUSTENNA® as a pharmacotherapy treatment. Dr. Oluboka is also actively involved in research and education on the use of long-acting antipsychotic therapy for schizophrenia and bipolar mood disorder.

[61] Dr. Oluboka was qualified as an expert in psychiatry with particular expertise in the diagnosis, treatment, and management of mood and psychotic disorders, including schizophrenia, schizoaffective disorder, and treatment-resistant schizophrenia, and the nature and clinical use of antipsychotic drugs, including INVEGA SUSTENNA®, for the treatment of mood and psychotic disorder, and treatment-resistant schizophrenia.

[62] On cross-examination, Dr. Oluboka stated that, while product monographs are included in the relevant literature that is reviewed by treating psychiatrists, physicians do not review the product monographs of generic drugs. This is because the generic product monographs are "carbon copies" of the product monographs for the brand name drug, which physicians are already familiar with through their many years of prescribing the brand name drug before the generic drug comes to the market.

[63] When pressed by counsel for Janssen, Dr. Oluboka agreed that some physicians might refer to generic product monographs. However, he maintained that most physicians would "more often than not" use and refer to the brand name product monographs.

[64] Dr. Oluboka also agreed that he does prescribe the claimed dosing regimen – 150 mg-eq. and 100 mg-eq. loading doses with a 75 mg-eq. maintenance dose – to some patients, as do other psychiatrists. In addition, he agreed that a [redacted] Dr. Oluboka stated that the choice of maintenance dose is based, in part, on the efficacy

and tolerability experienced after the two loading doses. A patient's individual characteristics are also used in the determination of the maintenance dose.

[65] Scientific papers were put before Dr. Oluboka in order to highlight the mean dose of paliperidone palmitate in the maintenance phase. One study found that the mean dose of paliperidone palmitate in the maintenance phase was 82.6 mg. Dr. Oluboka would not agree that 82.6 mg was closer to the 75 mg dose available than it was to 100 mg until repeatedly pressed by counsel for Janssen. His reluctance to agree to what was readily apparent goes to his credibility and weight to be attributed to his evidence.

(ii) Dr. Maria Zhang

[66] Dr. Zhang is a Clinician Educator and Advanced Practice Clinical Leader (Pharmacy) at the University of Toronto and the Centre for Addition and Mental Health in Toronto [CAMH].

[67] Dr. Zhang obtained her Bachelor of Pharmacy and Doctor of Pharmacy degrees from the University of Toronto.

[68] In her role at CAMH, Dr. Zhang supports and advances clinical pharmacy services for mental health patients by functioning as a resource for the pharmacists and pharmacy technicians. She also oversees educational programs delivered by the Pharmacy Department.

[69] In her role at the University of Toronto, Dr. Zhang coordinates and lectures pharmacy students of varying levels, with a focus on psychiatric disorders.

[70] Dr. Zhang was qualified as an expert in pharmacy practice and medication management, including the physician-pharmacist relationship, prescribing and drug dispensing practice, and the use of product monographs, particularly with respect to the treatment of major psychotic disorders, such as schizophrenia and schizoaffective disorder.

[71] Dr. Zhang was a credible witness. She provided evidence that the product monographs for INVEGA SUSTENNA® and the APO Product are largely identical. She also stated that, while pharmacists refer to product monographs when a product is new on the market, there is a "very low" chance that product monographs will be referred to once they are familiar with it, such as by the time the generic product is introduced.

[72] Dr. Zhang also noted that the prescribing physician will prescribe "paliperidone palmitate" and it is the pharmacists who will choose whether the brand name or generic product will be used to fulfill the prescription. She also stated that INVEGA SUSTENNA® and the APO Product would be treated as interchangeable.

[73] On cross-examination, Dr. Zhang agreed that the product monograph for the APO Product refers to [redacted]

[74] Based on the evidence before the Court, the relevant third parties who may be sufficiently influenced by the product monograph for the APO Product to implement the claimed dosing regimen, thereby directly infringing the 335 Patent, are prescribers (such as a physician or nurse

practitioner) and/or patients. Therefore, limited weight is attributed to Dr. Zhang's evidence as a pharmacist expert.

(b) *Apotex's Fact Witnesses*

(i) Mr. Nicholas Boorman

[75] Mr. Boorman is the Vice-President of Marketing and Commercial Operations for Apotex. His evidence addressed Apotex's marketing plans for its APO Product.

[76] Mr. Boorman stated that Apotex would not market or promote the APO Product in any way to physicians or patients in Canada. However, the APO Product will be a part of its patient support program (ApoAssist) and a general communication alerting pharmacists in Canada to the launch of a new product will be delivered.

[77] On cross-examination, Mr. Boorman agreed that the product monograph for the APO Product would also be posted on the Health Canada website accessible to both physicians and patients. Furthermore, if approved, pharmacists will be provided a notice of dosage strengths available, the prices of the available products, and a contact number for pharmacists to reach an Apotex Order Desk to inquire about purchasing the products. This notice also refers to the INVEGA SUSTENNA® product as the brand name equivalent and the Apotex Order Desk is able to provide the INVEGA SUSTENNA® product monograph if requested.

(ii) Mr. Duane Terrill

[78] Mr. Terrill is the Director of Regulatory Affairs Canada and Caribbean for Apotex. His evidence outlined his knowledge of the filing of ANDS No. 233882 in regards to the APO Product.

[79] Mr. Terrill also provided information on [redacted] Mr. Terrill noted that [redacted]

(c) *Janssen's Experts*

(i) Dr. Ofer Agid

[80] Dr. Agid is a Medical Doctor with specialized training in the field of psychiatry. Dr. Agid also holds several clinical, teaching, and research positions at CAMH and the University of Toronto.

[81] Dr. Agid obtained his medical degree and completed his psychiatry residency in Israel.

[82] Dr. Agid's psychiatry practice focusses on the diagnosis, treatment, and management of psychotic disorders, including schizophrenia and related disorders, and other complex mental disorders. He is actively involved in schizophrenia research, a large aspect of which focusses on the pharmacology of antipsychotics.

[83] Dr. Agid was qualified as an expert in the diagnosis, treatment, and management of psychotic disorders (including schizophrenia, schizoaffective disorder, schizophreniform disorder, and treatment-resistant schizophrenia) and the nature and clinical use of antipsychotic drugs, including INVEGA SUSTENNA®, for the treatment of psychotic disorders (including schizophrenia, schizoaffective disorder, schizophreniform disorder, and treatment-resistant schizophrenia).

[84] Dr. Agid stated that product monographs were an important source of information for physicians for the optimization of treatment of patients. He also stated that some physicians will consult both the brand name and generic product monographs based on their availability in the hospital formulary at that time.

[85] Dr. Agid further provided that, while physicians generally use skill, judgment, and experience when making clinical decisions for patients, they also use the product monographs. Dr. Agid disagreed with Apotex's expert Dr. Oluboka that physicians would rely on individual characteristics, such as age, sex, weight, severity of illness, or overall physical health – other than renal impairment as set out in the product monograph.

[86] During cross-examination, counsel for Janssen objected to the use of Dr. Agid's previous statements in *Teva Paliperidone*. I find that Dr. Agid's previous statements were used for the purpose agreed upon by the Parties ahead of trial – that is, to impeach the credibility of Dr. Agid.

[87] Counsel for Janssen further argued that the Defendant's use of prior statements in the cross-examination of Dr. Agid went against the rule set out in *Browne v. Dunn*, (1893) 6 R 67 (HL). The rule in *Browne v. Dunn*, in essence, requires that a party intending to bring evidence to impeach or contradict the testimony of a witness must present the witness with that evidence and give them an opportunity to explain or answer while on the witness stand. I find that the Defendant did correctly follow this rule. Dr. Agid was provided, and referred to, his previous expert statements filed in *Teva Paliperidone*, as well as the transcript of his testimony provided in *Teva Paliperidone*, in order to allow him to justify his evidence in this case.

[88] During cross-examination, Dr. Agid suffered from several credibility issues:

i. When Dr. Agid was referred to his previous expert reports provided for *Teva Paliperidone*, he insisted that he could not recall his opinion even after being referred to specific paragraphs.

ii. In contrast to his examination-in-chief, Dr. Agid agreed that when prescribing medication to patients with schizophrenia, physicians will base their prescribing decision on individual characteristics, as well as knowledge acquired from their medical training and continued education, treatment experiences, and medical literature and product monographs.

iii. Dr. Agid denied considering race in his prescribing practices. However, he was aware that patients of Asian ethnicity typically require lower doses of anti-psychotic medication and agreed that he considers this in his prescribing practices.

iv. Dr. Agid had no recollection of several peer-reviewed articles on the subject of paliperidone palmitate dosing that he was asked about (and recalled) during *Teva Paliperidone*, even after the Defendant provided him with both the article and a transcript of his pervious testimony in *Teva Paliperidone*.

(ii) Dr. Pierre Chue

[89] Dr. Chue is a Medical Doctor with specialized training in the field of psychiatry. He holds several clinical, research, and teaching positions with Alberta Health Services and the University of Alberta.

[90] Dr. Chue obtained his Bachelor of Medicine and Surgery from the Welsh National School of Medicine.

[91] Dr. Chue's practice focuses on the treatment of adult patients with mental illness, including schizophrenia and schizoaffective disorder.

[92] As a result of his education, practical experience, and involvement in physician education, Dr. Chue claims expertise in the disorders of schizophrenia and schizoaffective disorder, including how these disorders are treated and managed by physicians. He commonly prescribes INVEGA SUSTENNA® and has been a member of advisory boards for INVEGA SUSTENNA®. He has an understanding of how paliperidone palmitate is prescribed by other Canadian clinicians.

[93] Dr. Chue was qualified as an expert in the diagnosis and treatment of schizophrenia and schizoaffective disorder. This expertise includes the clinical use of injectable depot medications, such as paliperidone palmitate, *i.e.* INVEGA SUSTENNA®.

[94] Dr. Chue testified that product monographs contain evidence-based information approved by Health Canada, which provides information in terms of how to safely and effectively administer medication, and they represent the baseline that clinicians follow in practice. Further, Dr. Chue stated that the review of product monographs is considered to be best clinical practice, and that many clinicians review product monographs to inform their prescribing practices, including, in some cases, the generic product monographs.

[95] Further, Dr. Chue provided that some physicians will be influenced to prescribe the claimed dosing regimen by the product monograph for the APO Product.

[96] On cross-examination, Dr. Chue agreed that treating physicians will base their prescribing decisions on their professional skill and judgment, training, experience, and individual patient characteristics – with the product monograph included in a physician's skill and judgment, and experience. He further qualified that the choice of maintenance dose is also based on a patient's response to the loading dose regimen.

[97] Dr. Chue further testified that, though maintenance doses and dosing windows may be adjusted, he would first reach a baseline using the claimed dosing regimen set out in the product

monograph. He also agreed that his prescribing practice for paliperidone palmitate would not change if the APO Product were to be approved and enter into the market.

[98] Dr. Chue was a credible witness. Notwithstanding the evidence provided by Dr. Agid, Dr. Chue's evidence corroborated his earlier expert statement that some physicians would be influenced by the product monograph for the APO Product to prescribe the claimed dosing regimen.

(iii) Mr. Richard Jones

[99] Mr. Jones is a Pharmacist and currently the Regional Director of Pharmacy Services at Island Health – the health authority for Vancouver Island, which provides publicly funded health care services through a network of more than 100 hospitals, clinics, health units, and long-term care locations.

[100] Mr. Jones is responsible for the safe and effective clinical and technical pharmacy operations of hospitals and health care centres under the purview of Island Health, including nine hospital pharmacies and two outpatient community pharmacies. This includes managerial oversight of over 370 pharmacists and associated pharmacy staff, such as pharmacy technicians and assistants.

[101] Mr. Jones was qualified as an expert in drug formulary management, including the process and considerations involved in listing a drug product on a hospital drug formulary, and

pharmacy practice and medication management in a hospital setting, including prescribing methods, drug dispensing practices, and pharmacy clinical practice processes.

[102] Mr. Jones testified that a generic product monograph will be reviewed before a generic drug product is added to a hospital formulary. In addition, he stated that if the APO Product is added to formularies, it will be interchangeable with INVEGA SUSTENNA® – with the APO Product [redacted]

[103] On cross-examination, Mr. Jones testified that his current role is administrative and that he has not filled a prescription in approximately two decades. Mr. Jones stated that pharmacists might refer to product monographs, especially when they are verifying a prescription. Mr. Jones agreed that it is the physician that makes the prescribing decisions, including which maintenance dose within the range from 50 mg-eq. to 150 mg-eq. to prescribe for a patient.

[104] As stated above, based on the evidence before the Court, the relevant third parties who may be sufficiently influenced by the product monograph for the APO Product to implement the claimed dosing regimen, thereby directly infringing the 335 Patent, are prescribers (such as a physician or nurse practitioner) and/or patients. Therefore, limited weight is attributed to Mr. Jones' evidence as a pharmacist expert.

(3) Claims Construction

[105] Apotex asserts that claim construction is not an issue in this matter because claims 1 to 48 have already been construed in *Teva Paliperidone*. Further, patent validity is not an issue because Apotex does not allege invalidity.

[106] Nevertheless, all 63 claims of the 335 Patent are alive in this motion and the applicable principles of claim construction have been summarized by the Federal Court of Appeal in *Tearlab Corporation v. I-Med Pharma Inc.*, 2019 FCA 179 at paragraphs 30 to 34:

> [30] The general principles of claim construction are now well established and were set out by the Supreme Court in three cases (*Whirlpool* at paras. 49-55; *Free World Trust v. Électro Santé Inc*., 2000 SCC 66, [2000] 2 S.C.R. 1024 at paras. 31-67 [*Free World Trust*]; *Consolboard Inc. v. MacMillan Bloedel (Sask.) Ltd*., 1981 CanLII 15 (SCC), [1981] 1 S.C.R. 504 at p. 520 [*Consolboard*]). These principles can be summarized as follows.
>
> [31] The *Patent Act* promotes adherence to the language of the claims, which in turn promotes fairness and predictability (*Free World Trust* at paras. 31(a), (b) and 41). The words of the claims must, however, be read in an informed and purposive way (at para. 31(c)), with a mind willing to understand (at para. 44). On a purposive construction, it will be apparent that some elements of the claimed invention are essential while others are non-essential (at para. 31(e)). The interpretative task of the court, in claim construction, is to separate and distinguish between the essential and the non-essential elements, and to give the legal protection to which the holder of a valid patent is entitled only to the essential elements (at para. 15).
>
> [32] To identify these elements, the claim language must be read through the eyes of a POSITA, in light of the latter's common general knowledge (*Free World Trust* at paras. 44-45; see also *Frac Shack* at para. 60; *Whirlpool* at para. 53). As noted in *Free World Trust*:
>
> > [51] …The words chosen by the inventor will be read in the sense the inventor is presumed to have intended, and in a way that is sympathetic to accomplishment of the inventor's purpose expressed or implicit in the text of the claims. However, if the inventor has misspoken or otherwise created an

> unnecessary or troublesome limitation in the claims, it is a self-inflicted wound. The public is entitled to rely on the words used *provided* the words used are interpreted fairly and knowledgeably. [Emphasis in the original.]
>
> [33] Claim construction requires that the disclosure and the claims be looked at as a whole "to ascertain the nature of the invention and methods of its performance, … being neither benevolent nor harsh, but rather seeking a construction which is reasonable and fair to both patentee and public" (*Consolboard* at p. 520; see also *Teva Canada Ltd. v. Pfizer Canada Inc.*, 2012 SCC 60, [2012] 3 S.C.R. 625 at para. 50). Consideration can thus be given to the patent specifications to understand what was meant by the words in the claims. One must be wary, however, not to use these so as "to enlarge or contract the scope of the claim as written and … understood" (*Whirlpool* at para. 52; see also *Free World Trust* at para. 32). The Supreme Court recently emphasized that the focus of the validity analysis will be on the claims; specifications will be relevant where there is ambiguity in the claims (*AstraZeneca Canada Inc. v. Apotex Inc.*, 2017 SCC 36, [2017] 1 S.C.R. 943 at para. 31; see also *Ciba* at paras. 74-75).
>
> [34] Finally, it is important to stress that claim construction must be the same for the purpose of validity and for the purpose of infringement (*Whirlpool* at para. 49(b)).

[107] The relevant date for construing the claims is the publication date: June 19, 2009.

(4) Infringement

[108] To establish that the APO Product will directly infringe the 335 Patent, Janssen must prove, on a balance of probabilities, that the APO Product will embody all of the essential elements of one or more of the claims of the 335 Patent: "There is no infringement if an essential element is different or omitted" [*Free World Trust v. Électro Santé Inc.*, 2000 SCC 66 at paragraph 31(f)].

[109] Apotex submits that its APO Product cannot directly infringe the 335 Patent because its ANDS is not seeking approval of [redacted] – an essential element of the 335 Patent as determined in *Teva Paliperidone*. In addition, Apotex submits that its product monograph does not teach the dosing regimen claimed in the 335 Patent.

[110] Janssen does not argue against the above positon of Apotex with respect to direct infringement. Instead, Janssen's position is that Apotex will be inducing direct infringement of the 335 Patent.

[111] The *Patent Act* affords the patentee with the "exclusive right, privilege and liberty of making, constructing and using the invention and selling it to others to be used" [*Patent Act*, RSC, 1985, c P-4, section 42]. Any interference with these exclusive rights or privileges, whether direct or indirect, constitutes an infringement of the patent. As stated by the Supreme Court, the test for infringement is "did the defendant's activity deprive the inventor in whole or in part, directly or indirectly, of full enjoyment of the monopoly conferred by law?" [*Monsanto Canada Inc. v. Schmeiser*, 2004 SCC 34 at paragraph 35].

[112] Aside from direct infringement, a defendant may be liable for indirect infringement where, by their actions, they induce or procure another party to infringe the patent (*i.e.* inducement).

[113] There is a three "prong" test for inducement: (1) direct infringement by a third party; (2) the inducer influenced the third party to the point that the infringing act would not have occurred

without the influence; and (3) the defendant knew that its influence would bring about the infringing act [*Corlac Inc. v. Weatherford Canada Ltd*., 2011 FCA 228 [*Corlac*]].

[114] As stated previously, at the hearing, the Parties further agreed that the key issue for the Court to determine is the second prong of the *Corlac* test for inducing infringement.

[115] In addition, as set out above, Janssen, as the party that raised the allegation of infringement and bears the burden of proving infringement on a balance of probabilities in the underlying action, also bears the burden of proof of establishing infringement as raised in this summary trial motion. Though Janssen bears the burden of proving infringement, there is no question that Apotex must also put its best foot forward on this motion in respect of the issue of alleged non-infringement [*0871768 B.C. Ltd. v. Aestival (The)*, 2014 FC 1047 at paragraph 62; *Kobold* at paragraph 148].

(a) *Prong 1: Direct Infringement*

[116] The first prong of the inducement test requires that the "act of infringement must have been completed by the direct infringer" [*Corlac* at paragraph 162]. No direct contact is required between the inducer and the direct infringer [*Hospira Health Care Corporation v. Kennedy Trust for Rheumatology Research*, 2020 FCA 30 [*Hospira FCA*] at paragraph 26]. There is also no requirement that the alleged inducer supply all components or elements of the claimed invention [*The Copeland-Chatterson Company v. Hatton*, 1906 CarswellNat 10, 10 Ex CR 224 (Ex Ct); *MacLennan v. Produits Gilbert Inc*., 2008 FCA 35 [*MacLennan*]; *Hospira Healthcare Corporation v. Kennedy Trust for Rheumatology*, 2018 FC 259 [*Hospira FC*]; *Janssen Inc. v.*

Apotex Inc., 2019 FC 1355]. This is a question of liability, not quantification [*Hospira FCA* at paragraph 45].

[117] Apotex submits that no patients will receive doses of the APO Product corresponding to the claimed dosing regimens, because Apotex will not sell [redacted] which is an essential element of all of the claimed dosing regimens.

[118] Janssen submits that there can be inducement where the inducer sells only one component of a patented combination.

[119] Janssen claims that the APO Product is clearly meant to be used (and will be used) in combination with [redacted] in the same dosing and administration regimens claimed in the 335 Patent, and when that occurs there will be direct infringement. Whether or not Apotex will supply [redacted] is immaterial.

[120] According to Janssen's experts Drs. Agid and Chue, the APO Product will be prescribed to treat those disorders in the claimed dosing regimen, whereby [redacted]

[121] For patients with renal impairment, [redacted]

[122] The Parties' pharmacist experts, Mr. Jones and Dr. Zhang, both testified that INVEGA SUSTENNA® and the APO Product will be designated as interchangeable and that both products will be listed on hospital formularies, [redacted] Their evidence also supports that of the other Janssen experts that, in practice, the APO Product and INVEGA SUSTENNA® will [redacted]

[123] Based on the evidence, I am satisfied that Janssen has established direct infringement will occur by prescribing physicians. When considered in totality, the expert evidence demonstrates that prescribers (as a third party) will implement the dosing regimen claimed in the 335 Patent, notwithstanding that Apotex [redacted]

[124] There appears to be several instances in the APO Product product monograph that will influence a physician to prescribe [redacted] as part of the claimed dosing regimen leading to direct infringement of the 335 Patent: (i) in the recommended maintenance dose ranges in which [redacted]; and (ii) in tables outlining instructions for switching patients from oral paliperidone to an injectable product, like the APO Product or

INVEGA SUSTENNA®. In addition, there is no dispute that [redacted] for renally-impaired patients.

(b) *Prong 2: Inducement*

[125] As stated above, the Parties agree that the key issue for the Court to determine is the second prong of the *Corlac* test for inducing infringement.

[126] As articulated in *Corlac,* the second prong of the inducement test requires that "the acts of infringement must be influenced by the acts of the alleged inducer to the point that, without the influence, direct infringement would not take place" [*Corlac* at paragraph 162].

[127] The "but for" influence required in the second prong of the *Corlac* test sets a high bar – higher than "encouragement to infringe," a "subtle reference" to the infringing use, or "attempting to induce others to infringe" [*Teva Paliperidone* at paragraph 262-264; *Janssen Inc. v. Apotex Inc.*, 2021 FC 7 at paragraph 242].

[128] As stated above, there is no requirement for the presence of direct contact between the inducer and the direct infringer. Direct infringement may occur (and often does) through indirect means. It is well established that product monographs play a "key role" in indicating the intention of generic pharmaceuticals and the likelihood of infringement [*AB Hassle v. Canada (Minister of Health)*, 2002 FCA 421 [*AB Hassle FCA*] at paragraph 55].

[129] Apotex submits that, similar to the facts present in *Teva Paliperidone*, the Apotex product monograph [redacted] However, the Apotex product monograph also [redacted]. Apotex proposes that the similarity between the facts in this matter and *Teva Paliperidone*, should lead the Court to come to a similar conclusion: that any act of direct infringement would be a result of physician skill and judgment applied to specific patient characteristics, rather than any influence exercised by the product monograph for the APO Product.

[130] Furthermore, Apotex submits that the Plaintiffs ought to be precluded by the doctrine of abuse of process from tendering any evidence or advancing any arguments contrary to the factual findings made in *Teva Paliperidone*. I disagree.

[131] My decision in *Teva Paliperidone* was based on the review of the Teva product monograph. There is a different product monograph in this case – the Apotex product monograph – and, therefore, different factual circumstances. The factual findings in *Teva Paliperidone* cannot be relied on as findings of fact in this case. Each case must be decided on its own, separate evidentiary record. The doctrine of abuse of process is not applicable in this case.

[132] The crux of Apotex's argument related to this second prong is that the experts all agree that the ultimate dosing decision is based on physician skill and judgment, not the language in the product monograph. Further, physicians have been steeped in the claimed dosing regimen throughout their training, clinical experience, and use of the INVEGA SUSTENNA® product.

As such, the introduction of the product monograph for the APO Product will not influence or change their prescribing practices and will not amount to the level of influence necessary to meet the second prong of the *Corlac* test.

[133] In response, Janssen argues that the case law clearly establishes that instructions from the alleged infringer as to the use of their product, such as a product monograph in the case of pharmaceuticals, can be the source of the influence even where the instructions are not followed [*AB Hassle FCA* at paragraph 55; *AB Hassle v. Genpharm Inc*., 2003 FC 1443 [*AB Hassle FC*]; *Genpharm Inc. v. AB Hassle*, 2004 FCA 413; *Hospira FC*; *Abbott Laboratories Limited v. Canada (National Health & Welfare)*, 2006 FC 1411[*Abbott*]].

[134] Furthermore, inducement can be established based on the language and information in a generic drug product monograph, including on inferences reasonably drawn [*AB Hassle FC* at paragraph 155, aff'd *AB Hassle FCA*; *Abbott* at paragraph 40, aff'd 2007 FCA 251].

[135] In fact, express instructions to use a product in an infringing manner are not required for the second prong of the test [*Windsurfing International Inc. v. Trilantic Corp* (1985), 8 CPR (3d) 241 (FCA) at paragraphs 264, 265-266; *AB Hassle FC* at paragraph 155, aff'd *AB Hassle FCA*; *Abbott*, aff'd 2007 FCA 251].

[136] Further, Janssen agrees that it is trite that physicians use skill and judgment in prescribing drugs to their patients. However, the infringing use need not be the only instructed use to support

inducement and it is irrelevant to the inducement test whether skill and judgment is implicated in the decision to use a pharmaceutical for an infringing use [*Hospira FCA* at paragraphs 27 to 29].

[137] Janssen claims that Apotex's product monograph, which will be used by healthcare professionals, contains [redacted]

[138] As outlined previously, each expert agrees that patients may receive the claimed dosage regimen as a result of referring to the Apotex product monograph. All four experts acknowledged on cross-examination that while the product monograph for the APO Product does not explicitly recommend [redacted]

[139] As stated above, on cross-examination, Dr. Oluboka agreed that some physicians might refer to generic product monographs. Dr. Oluboka also agreed that he does prescribe the claimed dosing regimen – 150 mg-eq. and 100 mg-eq. loading doses with a 75 mg-eq. maintenance dose – to some patients, as do other psychiatrists. In addition, he agreed that [redacted]

[140] On cross-examination, Apotex's expert Dr. Zhang agreed that the product monograph for the APO Product [redacted] She also provided evidence that, while uncommon, a maintenance dose of 75 mg-eq. is prescribed.

[141] Each of Janssen's experts recognized that Apotex does not intend to [redacted] In their opinions, based on the Apotex product monograph, when physicians prescribe paliperidone palmitate for use in regimens that [redacted]

[142] Janssen also states that Apotex's argument that there can be no inducement, as the ultimate dosing decision is based on physician skill and judgment, is incorrect. In *MacLennan*, the Court found inducement where the direct infringers made and practiced the claimed combination on the basis of their own skill. Janssen argues that if the standard for the second prong of the inducement test precluded the use of skill and judgment, it would be an impossible standard to meet and that product monographs for proposed generic medicines would never be capable of inducing infringement.

[143] Based on the expert evidence as a whole, I find that Apotex's product monograph includes recommendations to prescribers for use of the claimed dosage regimen.

[144] For non-renally impaired patients, the APO Product product monograph recommends [redacted]

[145] For those patients with renal impairment, the APO Product product monograph recommends [redacted]

[146] For those patients switching from a 6 mg paliperidone palmitate tablet to the APO Product, the product monograph recommends [redacted]

[147] Notwithstanding the exercise of skill and judgment by prescribing physicians in selecting the dosing regimen for patients, the evidence before the Court in this case establishes that acts of infringement will be influenced by the acts of the alleged inducer, Apotex, to the point that, without the influence, direct infringement will not take place. Apotex's product monograph will influence prescribers and patients to implement the claimed dosage regimen, thereby directly infringing the 335 Patent.

[148] I am satisfied, on the evidence before the Court that Janssen has proven, on a balance of probabilities, that at least some prescribers of the impugned APO Product will be sufficiently influenced by the Apotex product monograph to induce infringement by those prescribing physicians.

(c) *Prong 3: Knowledge of Influence*

[149] The third prong of the inducement test requires that the inducer had knowledge of its influence (*i.e.* knowledge of its actions). Knowledge that the direct infringer's activity will be an infringement is not required. Knowledge can be inferred from the inducer having made and distributed the source of the influence (*e.g.* instructions, manuals, product monographs) [*Western Oilfield Equipment Rentals Ltd. v. M-I LLC,* 2019 FC 1606 at paragraph 133].

[150] The Federal Court of Appeal held that it was "not difficult" to meet the third prong of the test where the inducer created and distributed the product monograph which was the source of the influence [*Hospira FCA* at paragraph 44].

[151] Apotex argues that it would not knowingly influence physicians, pharmacists, or patients to prescribe, dispense, or use the claimed dosing regimens. Apotex could not knowingly exercise influence to prescribe, dispense, or use [redacted]

[152] Apotex's fact witness Mr. Boorman testified that Apotex does not typically market its products to physicians (or patients), and will not market the Apotex products to physicians (or

patients). Mr. Boorman's evidence is that Apotex conducts limited marketing and promotion to pharmacists, consisting only of providing the pharmacist with basic information about a newly launched generic drug, such as the name of the drug, dosage strength, and pricing and ordering information. Apotex does not provide any clinical information concerning its drugs to pharmacists, including dosing regimens, nor does it proactively provide its product monograph to pharmacists.

[153] Apotex's expert, Dr. Oluboka, also testified that generic pharmaceutical companies do not market to physicians, who are ultimately responsible for the prescribing decision. Thus, Apotex will not knowingly influence them.

[154] Dr. Zhang also testified that generic pharmaceutical companies do not market their products to pharmacists from a clinical perspective.

[155] Drs. Oluboka and Zhang both opined that Apotex's product monograph would not influence the prescribing or dispensing of the APO Products.

[156] In addition, Apotex claims that, based on the findings in *Teva Paliperidone* (*i.e.* that physicians and pharmacists are not influenced by generic product monographs when they are familiar with the brand product), it could not reasonably expect that its actions and materials will influence any acts of direct infringement. This is especially the case when the Court held that the prescribing of a particular dosing regimen is a matter of physician skill and judgment. In other words, it would be unjust to find that Apotex knows that its product monograph (or any other

actions or materials) will influence acts of direct infringement when the Court has held that, in the context of this particular drug and this particular patent, such influence is, effectively, not possible.

[157] The evidence of Janssen's experts, Drs. Agid and Chue and Mr. Jones, shows that the third prong of the inducement test is met. As stated previously, each of the experts provided evidence of how the Apotex product monograph will influence the use of the APO Product, which will [redacted]

[158] Whether or not Apotex specifically markets its product to physicians is irrelevant, given that the Apotex product monograph will be available to all physicians on the Health Canada website. This fact alone demonstrates that Apotex will knowingly exert its influence, particularly as Janssen's experts affirm that some clinicians do indeed review generic product monographs.

[159] Apotex's assertion that it "cannot reasonably be expected" to have knowledge of its influence in light of the opinions of its experts is flawed. First, the knowledge aspect of the third prong of the inducement test includes what Apotex knows but also what it ought to know. Second, the fact that one physician's opinion might be that physicians are not influenced by the product monograph does not exculpate Apotex. Further, even if this was a valid argument, it now falls flat on its face: Apotex can now "reasonably be expected" to have the required knowledge given that Janssen's experts have stated that some physicians will be influenced by the Apotex product monograph to infringe the claims of the 335 Patent. This is sufficient to satisfy the third prong of the test.

[160] I find that the third prong of the *Corlac* test is met. Apotex is aware that its product monograph for the APO Product contains guidance on implementing the claimed dosage regimen, [redacted] Apotex has knowledge of its influence.

V. Conclusion

[161] This is an appropriate case for determination by summary trial. Janssen has shown on a balance of probabilities that Apotex's product monograph for the APO Product will induce infringement of Janssen's 335 Patent. Costs are awarded to Janssen.

[162] Having sent a draft of these Reasons & Judgment to the Parties in accordance with the Protective and Confidentiality and Order, issued on March 22, 2021, I received submissions from the Parties regarding whether injunctive relief should be included in the Judgment.

[163] The Defendant objects to the Plaintiffs' request for addition of injunctive relief to the Judgment. They argue that the Plaintiffs have provided no justification for this addition and that injunctive relief is redundant, given the declaration of infringement already present in the Judgment. In addition, the Defendant highlights that, at no time during closing argument, did the Plaintiffs request an injunction, nor have these Reasons addressed the propriety of an injunction.

[164] The Plaintiffs' argue the following in support of their request for injunctive relief:

i. Injunctive relief was requested in the Plaintiffs' Statement of Claim;

ii. Injunctive relief is available pursuant to subsection 6(4) of the Regulations and is an available remedy under section 57 of the Patent Act, RSC, 1985, c P-4; and

iii. Successful plaintiffs in patent actions are typically awarded an injunction.

[165] Given the finding of infringement and the relief sought in the Statement of Claim, I hereby add the injunctive relief sought by the Plaintiffs to the Judgment.

JUDGMENT in T-124-21

THIS COURT'S JUDGMENT is that:

1. The motion is dismissed.

2. The making, constructing, using, or selling of APO-PALIPERIDONE INJECTION, paliperidone palmitate prolonged-release injectable suspension, by Apotex Inc. ["Apotex"] 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"].

3. An injunction is granted 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:

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

    ii. 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; and

iii. Importing, exporting, distributing, or having APO-PALIPERIDONE INJECTION paliperidone palmitate prolonged-release injectable suspension marketed in Canada in accordance with ANDS No, 233882.

4. Costs to the Plaintiffs to be assessed in accordance with Column III of Tariff B.

"Michael D. Manson"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

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APPEARANCES:

PETER WILCOX MARIAN WOLANSKI MEGAN POCALYUKO JULIETTE SAKRAN	FOR THE PLAINTIFFS
ANDREW BRODKIN DANIEL CAPPE DINO CLARIZIO	FOR THE DEFENDANT

SOLICITORS OF RECORD:

BELMORE NEIDRAUER LLP TORONTO, ONTARIO	FOR THE PLAINTIFFS
GOODMANS LLP TORONTO, ONTARIO	FOR THE DEFENDANT