Federal Court Cour fédérale

**Date: 20220119**

**Docket: T-1441-20**

**Citation: 2022 FC 62**

**Ottawa, Ontario, January 19, 2022**

**PRESENT: The Honourable Mr. Justice Manson**

**BETWEEN:**

**JANSSEN INC. and JANSSEN PHARMACEUTICA N.V.**

**Plaintiffs**

**and**

**PHARMASCIENCE INC.**

**Defendant**

**PUBLIC JUDGMENT AND REASONS**

**(Confidential Judgment and Reasons issued January 19, 2022)**

## I. Introduction

[1] This is a motion brought by the Defendant, Pharmascience Inc. [Pharmascience or PMS], for summary trial or, alternatively, for a dismissal of the underlying action pursuant to section 6.08 of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 [the *"Regulations"*].

## 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] asserting infringement of Canadian Patent No. 2,655,335 [the "335 Patent"] by the Defendant.

[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 laid open on June 19, 2009, issued on September 6, 2016, and has not expired.

[6] The 335 Patent contains 63 claims – each of which is 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 of 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] In order to rapidly achieve therapeutic blood plasma concentrations, 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 comprised of doses of paliperidone palmitate administered monthly 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 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 second 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, but 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/0.5 mL (*i.e.* 50 mg-eq.), 75 mg/0.75 mL, 100 mg/1 mL, and 150 mg/1.5 mL.

[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. *Pharmascience's Previous Abbreviated New Drug Submission*

[20] On February 28, 2020, Pharmascience served a Notice of Allegation and Detailed Statement in respect of its ANDS No. 236094 in regards to the 335 Patent and seeking approval for pms-PALIPERIDONE PALMITATE in strengths of 50 mg/0.5 mL, 75 mg/0.75 mL, 100 mg/1 mL, and 150 mg/1.5 mL.

[21] In response, Janssen commenced an infringement action under subsection 6(1) of the *Regulations* on April 8, 2020 in Court File No. T-455-20. On October 2, 2020, the action in respect to ANDS No. 236094 was discontinued on consent.

E. *Pharmascience's Current Abbreviated New Drug Submission*

[22] Pharmascience's current ANDS No. 244641 was filed on [redacted] and seeks approval to market and sell in Canada [redacted] doses of its *proposed* pms-PALIPERIDONE PALMITATE product [the "PMS Product"], a generic version of Janssen's INVEGA SUSTENNA® product.

[23] Pharmascience's current ANDS No. 244641 does not seek approval for [redacted] of paliperidone palmitate.

F. *The Present Action*

[24] On October 16, 2020, Pharmascience served a Notice of Allegation and Detailed Statement [the "Notice"] in respect of the 335 Patent and its current ANDS No. 244641.

[25] The Notice alleges that the 335 Patent is invalid or void and would not be infringed by the making, constructing, using, or selling of the PMS Product by Pharmascience. Janssen denies these allegations.

[26] In response to the Notice, the Plaintiffs commenced the underlying action against the Defendant pursuant to subsection 6(1) of the *Regulations* on November 27, 2020. The Plaintiffs are seeking:

a. A declaration that the making, constructing, using, or selling of pms-PALIPERIDONE PALMITATE by Pharmascience in accordance with ANDS

No. 244641 would infringe claims 1 to 63 of the 335 Patent, directly and/or indirectly;

b. A permanent injunction restraining Pharmascience (as well as its subsidiaries and affiliates) from:

   i. Making, constructing, using, or selling the PMS Product in Canada;

   ii. Offering for sale, marketing, or having the PMS Product marketed in Canada;

   iii. Importing, exporting, distributing, or having the PMS Product distributed in Canada; and

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

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

d. The Plaintiffs' costs of this action; and

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

## III. Issues

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

(1) Has Pharmascience 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 Pharmascience is not seeking approval for ▌▌ prefilled syringes of the PMS Product?

## IV. Analysis

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

[28] Motions for summary trial are governed under the *Federal Courts Rules*, SOR/98-106 [the *"Rules"*] 213 and 216.

[29] *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.

[30] 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].

[31] 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.

[32] 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.

[33] 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 [*Viiv*] at paragraph 42].

[34] 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

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

[36] Pharmascience submits that this matter should be determined by way of summary trial because the PMS Product is missing an essential element of every claim of the 335 Patent [redacted] – and, thus, will not infringe or induce infringement. This argument relies on *Teva Paliperidone*, which, as stated above, is currently before the Federal Court of Appeal.

[37] Janssen submits that summary trial is not appropriate in this case for three reasons. Firstly, Janssen claims that it would be inappropriate to decide this summary trial motion while the appeal of *Teva Paliperidone* remains pending, as the outcome may answer questions of law in respect of the test for inducing infringement.

[38] In response, Pharmascience argues that the pending appeal in *Teva Paliperidone* should not prevent the hearing of this proceeding on its own evidence. Pharmascience states that both Parties maintain the right to appeal the finding in this proceeding. Further, the Supreme Court of Canada has found that a court order stands unless it is set aside on appeal [*Toronto (City) v. C.U.P.E. (Local 79)*, 2003 SCC 63 at paragraph 33].

[39] Secondly, Janssen asserts that there are issues of conflicting expert evidence and credibility. Pharmascience has put forward one expert, Dr. Alina Iosif. Janssen questions Dr. Iosif's qualifications. They also question her credibility. During her cross-examination, Dr. Iosif agreed that [redacted]. Dr. Iosif had not addressed this table in her affidavit. Given that Pharmascience has elected to proceed on a paper record, Janssen claims that the credibility and conflicting expert evidence favour the dismissal of this motion for summary trial.

[40] As stated above, *Rule* 216(6) provides that this Court may grant summary judgment, regardless of the existence of conflicting evidence, if there is sufficient evidence for adjudication. Cross-examinations of each expert and fact witness on their affidavit evidence have been conducted and the transcripts have been provided to this Court. This Court has decided the appropriateness of summary judgment or summary trial on a written record and without *viva voce* evidence [see for example *Flatworks Technology LLC (Powerblanket) v. Brierley*, 2020 FC 997; *Gemak Trust v. Gempack Corp.*, 2020 FC 644; *Canmar Foods Ltd. v. TA Foods Ltd.*, 2019 FC 1233, aff'd 2021 FCA 7].

[41] Finally, Janssen submits that they have been prejudiced by not being provided full discovery of relevant information that lies exclusively within the knowledge of Pharmascience on issues central to this motion. The product monograph for the PMS Product dated August 31, 2020, that was provided by Pharmascience for this motion, has since been updated. Furthermore, Pharmascience's fact witness appears to have been unaware which product monograph he was

providing evidence for during his cross-examination. In addition, at the time of filing their response, Janssen was awaiting an order of this Court on a motion brought by Pharmascience to compel Janssen to answer certain questions refused during discovery examination, which Janssen intended to appeal.

[42] In response, Pharmascience argues that it is not clear what relevant information Janssen is seeking. Pharmascience has updated its product monograph in the normal course of discovery and claims that the opinions of Janssen's experts have not changed with the update.

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

[44] Pursuant to *Rule* 216(6), I am satisfied that there is sufficient evidence for the adjudication of the issue put forward by the Parties and it is an appropriate proceeding for summary trial. The issue in this motion is narrow and any issues of credibility and conflicting evidence can be determined on the written record before the Court.

[45] 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 Pharmascience is not seeking approval for [redacted] prefilled syringes of the PMS Product?*

(1) Burden and Onus of Proof

[46] At the commencement of the hearing for this motion, Pharmascience raised the 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. Pharmascience submits that the burden on the merits in this motion reflects that of the underlying action. That is, Janssen bears the normal civil burden of proof with respect to their allegation of infringement – namely, to prove Pharmascience's infringement of the 335 Patent on a balance of probabilities.

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

[48] There is conflicting jurisprudence on which party bears the burden on the merits of the issue(s) should they proceed to be decided by way of summary trial.

[49] Justice Russell conducted a review of this issue in *Louis Vuitton Malletier S.A. v. Singga Enterprises (Canada) Inc.*, 2011 FC 776 [*Louis Vuitton*] at paragraphs 92 to 97:

> [92] *Federal Courts Rules* 213 and 216 provide that a party may apply to the court for summary trial judgment in an action for which a defence has been filed but before the time and place for trial have been fixed.
>
> [93] Rule 216(6) provides as follows:
>
> | | |
> |---|---|
> | If the Court is satisfied that there is sufficient evidence for adjudication, regardless of the amounts involved, the | Si la Cour est convaincue de l a suffisance de la preuve pour trancher l'affaire, indépendam ment des sommes en cause, d |

| | |
|---|---|
| complexities of the issues and the existing of conflicting evidence, the Court may grant judgment either generally or on an issue, unless the Court is of the opinion that it would be unjust to decide the issues on the motion. | e la complexité des questions en litige et de l'existence d'un e preuve contradictoire, elle p eut rendre un jugement sur l'e nsemble des questions ou sur une question en particulier à moins qu'elle ne soit d'avis q u'il serait injuste de trancher l es questions en litige dans le c adre de la requête |

[94] The Regulatory Impact Analysis Statement (which can be used in interpreting the purpose and intended application of regulatory amendments) that accompanied the amendments to current Rules 213 and 216, confirms that the summary trial rules were modelled after Rule 18A of the British Columbia Rules of Court. This was done in order to allow the Court to dispose summarily of actions in a greater range of circumstances than previously allowed under prior Federal Courts Rule 216(3), which allowed for summary judgment only in matters where there was "no genuine issue for trial", and had been judicially interpreted to prevent summary judgment where credibility was an issue, where the evidence was conflicting and/or where the outcome of the motion turned on the drawing of inferences. Hence, the **British Columbia jurisprudence with respect to Rule 18A is instructive and may be persuasive in consideration of a motion for summary trial under Rule 216 of the Federal Courts Rules.** See Rules Amending the Federal Courts Rules (Summary Judgment and Summary Trial), S.O.R./2009-331, Regulatory Impact Analysis Statement, C. Gaz. 2009. II. 2603 – 2604; and Bristol-Myers Squibb Co. v. Canada (Attorney General), 2005 SCC 26, [2005] 1 S.C.R. 533 at paragraphs 155 – 157.

[95] **British Columbia jurisprudence confirms that the onus of proof on a summary trial application under Rule 18A is the same as at trial, that being that the party asserting the claim or defence must prove it on a balance of probabilities.** See Miura v. Miura (1992), 1992 CanLII 1040 (BC CA), 66 B.C.L.R. (2d) 345, 1992 Carswell 113 at paragraph 14 (C.A.).

[96] Further, the British Columbia Court of Appeal has confirmed that if the judge on a Rule 18A application can find the facts as he or she would upon a trial, the judge should give judgment, unless to do so would be unjust, regardless of complexity or conflicting evidence. In determining whether summary trial is appropriate, the court should consider factors

> such as the amount involved, the complexity of the matter, its urgency, any prejudice likely to arise by reason of delay, the cost of taking the case forward to a conventional trial in relation to the amount involved, the course of the proceedings and any other matters that arise for consideration. See Inspiration Management Ltd. v McDermind St. Lawrence Ltd. (1989), 1989 CanLII 229 (BC CA), 36 B.C.L.R. (2d) 202, [1989] B.C.J. No. 1003 at paragraphs 48 and 53-57 (C.A.).
>
> [97] The Federal Court has confirmed the application of such British Columbia jurisprudence to the consideration of summary trial applications. See Wenzel Downhole Tools Ltd. v National-Oilwell Canada Ltd. 2010 FC 966, 87 C.P.R. (4th) 412 at paragraph 34.
>
> [Emphasis added].

[50] The British Columbia decision *Miura v. Miura*, [1992] 66 B.C.L.R. (2d) 345 (BCCA), cited by Justice Russell at paragraph 95 in *Louis Vuitton* above, provides further support for the position taken in that case on the onus of proof.

[51] The British Columbia Court of Appeal found that the trial judge erred when he required the husband to demonstrate duress:

> 13 In my view, the trial judge did err when he required the husband to demonstrate that the wife executed the agreement without duress. **If this action had proceeded to trial in the ordinary way, complete with viva voce evidence, the wife, as plaintiff, would have carried the burden of proving on a balance of probabilities that there was duress in the execution of the agreement. There is no reason why the onus should be reversed simply because the defendant moves for judgment under R. 18A, thus requiring the plaintiff to prove her case in a summary trial proceeding.** This was not a case where the defendant moved for summary judgment under R. 18(6), in which event he would have been required to establish that there was no merit in the claim of duress.
>
> 14 While the question of the onus of proof in a R. 18A summary trial proceeding does not seem to have been directly addressed in this

> court, it has been the subject of comment in several decisions in the court below: Adia S.A. v. MacLean (October 10, 1985), Doc. Vancouver C851797 [6 C.P.C. (2d) 42], and American Pyramid Resources Inc. v. Royal Bank (1986), 2 B.C.L.R. (2d) 99. In both of those cases the court concluded, as I have, that **the onus of proof does not shift simply because a trial is conducted summarily under R. 18A. As in an ordinary trial, the party asserting the affirmative of an issue must prove it on a balance of probabilities**. I believe that such a result is also consistent with what was said by McEachern C.J.B.C. in Inspiration Management Ltd. v. McDermid St. Lawrence Ltd. (1989), 36 B.C.L.R. (2d), 202, 36 C.P.C. (2d) 199 (C.A.), at p. 215 [B.C.L.R.] of the report:
>
> > The test for R. 18A, in my view, is the same as on a trial. Upon the facts being found the chambers judge must apply the law and all appropriate legal principles. If then satisfied that the claim or defence has been established according to the appropriate onus of proof, he must give judgment according to law unless he has the opinion that it will be unjust to give such judgment.
>
> [Emphasis added.]

[52] Pharmascience has provided further British Columbia jurisprudence in support of its position that, on the merits in a summary trial, the burden reflects that of the underlying action [*Nickel v. Phoenix Construction Systems Ltd.*, 2021 BCCA 268 at paragraph 31, citing *Gichuru v. Pallai*, 2013 BCCA 60 [*Gichuru*] at paragraphs 28-32 and 35].

[53] In *Teva Canada*, Justice Hughes also highlights the question of burden at motions for summary trial:

> [35] There are several burdens to consider. First, the party seeking a summary trial bears the burden of demonstrating that a summary trial is appropriate (Trevor Nicholas Construction, supra at para 44). This is the usual level of burden which the moving party here, the Plaintiff Teva, has satisfied.

> [36] **Once the matter is before the Court for determination by summary trial, the usual burden in a civil trial applies.** In brief, the party making an assertion must prove it by relevant evidence and the application of appropriate law.
>
> [37] Here, the Plaintiff Teva asserts that it is entitled to damages under the provisions of section 8 of the NOC Regulations. It bears that burden. The Defendants Wyeth assert that by reason of the amalgamation, the Novopharm licence, and other events, Teva is disentitled to such damages. They bear that burden. In each instance, **the burden is the usual burden in civil cases – a balance of probabilities.**
>
> [Emphasis added.]

[54] Some confusion has developed in light of the decision in *Teva Canada*. It appears that Justice Hughes interprets the usual civil burden of a balance of probabilities to be on each party for their assertions made in their motion memoranda, and arguably not in accordance with the underlying action [*Teva Canada* at paragraph 22-23 and 35-37].

[55] In *Viiv*, I found that the defendant, Gilead Science Canada Inc., bore the burden of proving non-infringement as asserted in their motion for summary trial [*Viiv* at paragraph 20]. However, based on the arguments and evidence now before the Court, I am satisfied that the correct approach is that set out below.

[56] When *Rules* 213 and 216 are read in light of the intent of the regulatory amendments and jurisprudence, the burden for the determination of the merits of a summary trial reflects that of the underlying trial [*Premium Sports Broadcasting Inc. v. 9005-5906 Quebec Inc. (Resto-bar Mirabel)*, 2017 FC 590; *0871768 B.C. Ltd. v. Aestival (The)*, 2014 FC 1047 [*Aestival*]; *Collins v. Canada*, 2014 FC 307].

[57] 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.

[58] To be clear, 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.

[59] As stated previously, *Rule* 213 allows a party to bring a motion for summary trial on all or some of the issues raised in the pleadings. Therefore, which claims or defences of the underlying action are before the Court in a motion for summary trial are determined and limited to the issue(s) raised in the motion.

[60] As stated above, Pharmascience argues the sole issue in this motion is whether Janssen's infringement action should be dismissed because Pharmascience is not seeking approval for [redacted], which is an essential element of every claim of the 335 Patent as per *Teva Paliperidone*. Therefore, Janssen has the burden of proving infringement on a balance of probabilities.

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

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

(2) The Experts

(a) *Pharmascience's Expert*

(i) Dr. Alina Iosif

[63] Dr. Iosif is a Forensic Psychiatrist at the Centre for Addiction and Mental Health [CAMH] in Toronto. In addition, she is a Staff Psychiatrist in the Law and Mental Health Program at CAMH and is a Lecturer in the Department of Psychiatry in the Faculty of Medicine at the University of Toronto. She also holds the position of Consultant Psychiatrist in the Diversion Program at the Mental Health Court in Toronto.

[64] Dr. Iosif obtained her Doctor of Medicine degree from the Faculty of Medicine at the University of Calgary and has been a Fellow of The Royal College of Physicians of Canada since she completed her residency in psychiatry. She also holds a Forensic Psychiatrist Certification.

[65] In her present roles, Dr. Iosif consults with, diagnoses, and treats male and female psychiatric patients on both an inpatient and outpatient basis. The majority of the patients that she treats suffer from severe mental illness, usually schizophrenia or bipolar disorder, and most of them are treated with some type of antipsychotic medication.

[66] Dr. Iosif has prescribed INVEGA SUSTENNA® frequently and describes it as one of the most common "go-to" injectable antipsychotics for those who require or prefer an injectable antipsychotic preparation. She believes that her approach to prescribing INVEGA SUSTENNA® to patients with schizophrenia, and the extent to which these decisions are influenced by its product monograph, reflects the general practice of Canadian psychiatrists.

(b) *Janssen's Experts*

(i) Dr. Ofer Agid

[67] 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.

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

[69] Dr. Agid's psychiatry practice focusses on the diagnosis, treatment, and management of psychotic disorders, including schizophrenia, schizoaffective disorder, schizophreniform

disorder, and other complex mental disorders. He is actively involved in schizophrenia research, a large aspect of which focusses on the pharmacology of antipsychotics.

[70] Dr. Agid claims expertise in the areas of schizophrenia, schizoaffective disorder, and schizophreniform disorder, including the diagnosis of these disorders and their pathophysiology, and the treatment and management of patients suffering from any one of these disorders.

(ii) Dr. Pierre Chue

[71] 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.

[72] Dr. Chue obtained his Bachelor of Medicine, Bachelor of Surgery (MBBCh) from the Welsh National School of Medicine.

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

[74] 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.

(iii) Mr. Richard Jones

[75] 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.

[76] 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.

[77] Through his education, training, and over thirty years of experience as a pharmacist in the healthcare industry (including nearly 20 years as a hospital pharmacist), Mr. Jones claims expertise in pharmacy practice, medication management in a hospital setting, including prescribing methods, drug formulary management, drug dispensing practices, and clinical practice in a hospital pharmacy.

[78] Based on the evidence before the Court, the relevant third parties who may be sufficiently influenced by the product monograph for the PMS 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.

(c) *Pharmascience's Fact Witness*

(i) Brian Des Islet

[79] Mr. Des Islet is the Vice-President of Scientific Affairs at Pharmascience. His affidavit outlines his knowledge of the INVEGA SUSTENNA® product monograph and the product monograph for the PMS Product. He also speaks to Pharmascience's "deliberately and knowingly" not seeking approval [redacted] prefilled syringes of paliperidone palmitate.

(3) Claim Construction

[80] Claim construction is a matter of law for the Court [*Whirlpool Corp.v Camco Inc.*, 2000 SCC 67 at paragraph 61]. Where the judge can construe the patent as it would be understood by a skilled person, expert evidence is not required [*Pfizer Canada Inc. v. Canada (Minister of Health)*, 2007 FC 446 at paragraphs 25, 35, and 36; *Excalibre Oil Tools Ltd. v. Advantage Products Inc.*, 2016 FC 1279 at paragraph 119].

[81] The principles of claim construction were recently 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)).

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

[83] Pharmascience asserts that there can only be one correct construction of a patent claim and that a departure from an earlier construction should be rare and only when necessary and supported by cogent reasons.

[84] Pharmascience relies on the construction of claims 1 to 48 as outlined in *Teva Paliperidone*. Namely, the finding that [redacted] of paliperidone is an essential element of claims 1 to 48. Pharmascience also notes that this finding is not being challenged on appeal.

[85] Pharmascience submits that claims 49 to 63 simply mirror, and are nearly identical, to the earlier claims. Therefore, claims 48 to 63 also require as an essential element [redacted]. In addition, they claim that the Court does not require expert evidence since these claims can be construed by their plain and ordinary meaning.

(4) Infringement

[86] Pharmascience argues that given its ANDS is not seeking approval of [redacted] doses of paliperidone palmitate, Pharmascience cannot directly infringe the 335 Patent.

[87] Pharmascience grounds its submissions in the principle that there will only be infringement where the accused product takes all of the essential elements of the claims asserted in the action. The relevant inquiry then becomes whether the PMS Product will incorporate all essential elements of any of the 335 Patent claims if Pharmascience makes, uses, or sells its product in Canada.

[88] Pharmascience states that its product cannot directly infringe the 335 Patent because its ANDS is not seeking approval of [redacted] or prefilled syringe of paliperidone palmitate – an essential element of the 335 Patent claims, as determined in *Teva Paliperidone*.

[89] Pharmascience argues that the 335 Patent does not provide Janssen with the exclusive rights to manufacture and sell prefilled syringes of a paliperidone palmitate depot formulation, but only exclusive rights to dosing regimens employing at least [redacted] of paliperidone administered at a specific injection site, according to a specific schedule. I agree.

[90] Janssen does not argue against the above positon of Pharmascience. Instead, Janssen's position is that Pharmascience will be inducing infringement of the 335 Patent.

[91] 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].

[92] Aside from direct infringement, a defendant may be liable for indirect infringement where, by their actions, they induce or procure a third party to infringe the patent.

[93] 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*]].

[94] As stated previously, 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 Pharmascience must also put its best foot forward on this motion in respect of the issue of alleged non-infringement [*Kobold Corporation et al. v. NCS Multistage Inc.*, 2021 FC 1437 at paragraph 148; *Everest Canadian Properties Ltd. v. Mallmann*, 2008 BCCA 275 (BC CA) at paragraph 34].

(a) *Prong 1: Direct Infringement*

[95] 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]. In this case, Janssen must establish on a balance of probabilities that prescribers of paliperidone palmitate will prescribe the claimed dosing regimen.

[96] Pharmascience argues that, as recognized by the Supreme Court of Canada, a purchaser of a patented article is allowed to deal with the goods as they please without the fear of infringement [*Eli Lilly & Co. v. Novopharm Ltd.*, [1998] SCR 129 [*Eli Lilly*]]. Therefore, since Janssen has put its [redacted] INVEGA SUSTENNA® into the Canadian marketplace, it has renounced any exclusive right in [redacted] of INVEGA SUSTENNA®.

[97] Janssen submits that *Eli Lilly* does not apply to the present case. In *Eli Lilly*, the Court found that a license exhausted the whole of the claimed subject matter – *i.e.* nizatidine and the process to make it – not whether the sale of one component of a claimed combination exhausts the patentee's rights to the claimed combination.

[98] I agree that *Eli Lilly* does not apply in this matter. *Eli Lilly* appears to speak to the question of whether a sub-licence was created between Novopharm and Apotex, and how that would affect Eli Lilly's patent. This is all in the context of a compulsory licence that Novopharm had under old legislation that has since been repealed.

[99] As Janssen stated at the hearing of this motion, there is no licence here. In addition, it appears that a purchase and sale agreement (as would be between the pharmacy and Janssen)

would not then allow the purchaser (the pharmacy) to use [redacted] in a way that infringes the 335 Patent [*Eli Lilly* at paragraph 68].

[100] Janssen claims the inducer need not supply all the components or elements of the claimed invention in order for there to be direct infringement [*Copeland-Chatterson Company v. Hatton*, 10 Ex CR 224 (Ex Ct); *MacLennan v. Les Produits Gilbert Inc.*, 2006 FC 1038, rev'd 2008 FCA 35 [*MacLennan*]; *Hospira Healthcare Corporation v. Kennedy Trust for Rheumatology*, 2018 FC 259, rev'd in part 2020 FCA 30 [*Hospira*]; *Janssen Inc. v. Apotex Inc.*, 2019 FC 1355, aff'd 2021 FCA 45].

[101] In the present case, [redacted] alone is not the patented article of the asserted claims. Rather, the dosing regimen claimed in the 335 Patent includes at least three different doses and [redacted] the doses of the claimed dosing regimens.

[102] Janssen states that the Federal Court of Appeal decision in *MacLennan* governs the present case. In *MacLennan*, the Court found liability for inducement despite the inducer supplying only one-half of the claimed invention. The patent claimed a combination of a repositionable saw tooth and detachable tooth holder. The defendant, Gilbert, manufactured and sold the saw tooth component (a replica of the plaintiff's saw tooth), which on its own was not infringing (the individual components were not claimed). However, the defendant's saw tooth component was meant to be used in combination with the plaintiff's tooth holder to form the patented combination. Although the defendant did not supply the detachable tooth holder

component of the invention, the Court found that direct infringement occurred when the plaintiff's tooth holder was combined with Gilbert's saw tooth component. Inducement was established on the basis of a distributed price list that compared Gilbert's saw tooth component to that of the plaintiff.

[103] According to the opinion of Pharmascience's expert Dr. Iosif, no direct infringement of the 335 Patent will occur if Pharmascience sells its PMS Product. I disagree.

[104] Upon review of the product monograph for the PMS Product and the product monograph for INVEGA SUSTENNA®, Dr. Iosif states that, while the INVEGA SUSTENNA® product monograph [redacted]

[105] However, during cross-examination, Dr. Iosif admitted that the product monograph for the PMS Product [redacted]

[106] According to Janssen's experts, prescribers in practice may continue to prescribe the dosing regimen claimed in the 335 Patent using the PMS Product for [redacted] and INVEGA SUSTENNA® for [redacted]

[107] Dr. Agid opines that the product monograph instructs clinicians to use the PMS Product in the same manner as INVEGA SUSTENNA®. In turn, the PMS Product will be prescribed and administered for the same indications and according to the same dosing and administration schedule as INVEGA SUSTENNA® if it becomes available on the market in Canada.

[108] Based on the product monograph for the PMS Product, physicians are directed to prescribe, and will prescribe (and, in turn, patients will receive), the PMS Product in combination with INVEGA SUSTENNA® for regimens that include [redacted].

[109] Dr. Agid points to five instances in the product monograph for the PMS Product where it instructs physicians to prescribe [redacted] of paliperidone palmitate:

1) [redacted]

2) [redacted]

3) [redacted]

4) [redacted]

5) [redacted]

[110] During cross-examination, Dr. Agid agreed that Pharmascience is not seeking approval to sell [redacted] of its product and does not explicitly recommend the use of [redacted] of INVEGA SUSTENNA®. He also agreed that a layperson may not explicitly recognize the recommendation of [redacted] from the pharmacokinetics.

[111] Dr. Chue provides a third expert opinion that the product monograph for the PMS Product will influence some physicians to follow the recommended initiation regimens and prescribe [redacted]

[112] Dr. Chue opines that the [redacted] of the claimed dosing regimen as claimed in the 335 Patent.

[113] In addition, it is Dr. Chue's opinion that, if the PMS Product comes to market and a physician prescribes a dosing regimen that includes [redacted], pharmacies could substitute [redacted] with INVEGA SUSTENNA®, since it is [redacted] of paliperidone palmitate available on the Canadian market.

[114] Notwithstanding Dr. Chue's acknowledgment on cross-examination that the PMS Product would not be sold in [redacted] prefilled [redacted] and that [redacted] is not

explicitly recommended in the product monograph for the PMS Product, he was consistent in holding that it is a therapeutic option within the recommended range as set out in the product monograph.

[115] In Mr. Jones' opinion, if the PMS Product is added to hospital formularies it will be added as interchangeable with INVEGA SUSTENNA®. Although the PMS Product will not be supplied as [redacted] prefilled [redacted], the PMS product monograph recommends the use of [redacted] as part of the range of [redacted] for patients with schizophrenia or schizoaffective disorder, and as the [redacted] for renally impaired patients.

[116] Pharmascience confirmed it will seek interchangeability for its product with INVEGA SUSTENNA® and will take steps to have its product listed on formularies.

[117] Furthermore, it is Mr. Jones' opinion that the product monograph for the PMS Product, if a prescriber prescribes paliperidone palmitate in a regimen utilizing [redacted] will lead to the administration of the PMS Product with INVEGA SUSTENNA® in accordance with the claimed dosing regimen. For instance, for the treatment of non-renally impaired patients, a [redacted]

[118] In addition, the PMS product monograph specifically recommends [redacted]

[redacted]

[119] On cross-examination, Mr. Jones also recognizes that it is ultimately the prescriber (*i.e.* physician or possibly a nurse practitioner) that would decide what doses of a drug to prescribe, following discussion with a pharmacist where necessary.

[120] 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 Pharmascience will not being supplying [redacted] paliperidone palmitate in prefilled syringes. There appear to be several instances in the PMS product monograph, as outlined above, that will influence a physician to prescribe [redacted] as part of the claimed dosing regimen leading to direct infringement of the 335 Patent.

(b) *Prong 2: Inducement*

[121] The crux of Pharmascience's argument related to this second prong is that the experts all agree that the ultimate dosing decision is based on the physician's skill and judgment, not the language in the product monograph. Further, Pharmascience's product monograph [redacted]

[122] In response, Janssen argues that the cases clearly establish that instructions from the alleged inducer 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 in every instance. Express instructions to use a product in an infringing manner are not required for the second prong of the test [*AB Hassle FCA*; *Windsurfing International Inc. v. Trilantic Corp* (1985), 8 CPR (3d) 241 (FCA) at paragraphs 264, 265-266; *AB Hassle v. Genpharm Inc.*, 2003 FC 1443 at paragraph 155 [*AB Hassle FC*], aff'd 2004 FCA 413; *Abbott Laboratories Limited v. Canada (Ministry of National Health and Welfare)*, 2006 FC 1441 at paragraph 40, aff'd 2007 FCA 251].

[123] 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].

[124] 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 233 and 242].

[125] 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*].

[126] Pharmascience submits that Janssen's experts seek to rely on "subtle references" in the product monograph of the PMS Product, which do not meet the high bar for inducing infringement. Pharmascience asserts that Janssen's experts agree that the product monograph for the PMS Product does not specifically or explicitly recommend [redacted]

[127] However, all four experts acknowledged on cross-examination that while the product monograph for the PMS Product does not explicitly recommend [redacted], it is a therapeutic option [redacted] Moreover, [redacted]

[128] As previously stated, Dr. Agid and Dr. Chue opine that the [redacted] demonstrate an explicit instruction to use [redacted]. The PMS product monograph also instructs [redacted]

[129] 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*;

*Abbott Laboratories Limited v. Canada (Ministry of National Health and Welfare)*, 2006 FC 1441 at paragraph 40, aff'd 2007 FCA 251].

[130] Janssen claims that Pharmascience's product monograph, which will be used by healthcare professionals in several ways, contains several recommendations to prescribe the claimed dosages and administration schedules. Pharmascience's product monograph recommends [redacted]

[131] As outlined previously, each expert agrees that patients may receive the claimed dosage regimen as a result of referring to the Pharmascience product monograph.

[132] Janssen also states that Pharmascience'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 also 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.

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

[134] For non-renally impaired patients, the PMS product monograph recommends [redacted]

[135] For those patients with renal impairment, the PMS product monograph recommends [redacted] As mentioned by Dr. Chue in his evidence, INVEGA SUSTENNA® is the only [redacted] paliperidone palmitate available on the Canadian market.

[136] For those patients [redacted] paliperidone palmitate tablet to the PMS Product, the product monograph recommends [redacted]

[137] Notwithstanding the exercise of skill and judgment by prescribing physicians in determining the appropriate [redacted] doses, Janssen has shown that the acts of infringement will be influenced by the acts of the alleged inducer, Pharmascience, to the point that, without the influence, direct infringement will not take place. Pharmascience's product monograph will influence at least some prescribers and patients to implement the claimed dosage regimen, thereby directly infringing the 335 Patent.

[138] 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 PMS product will be influenced by the PMS product monograph to induce infringement by those prescribing physicians.

(c) *Prong 3: Knowledge of Influence*

[139] The third prong of the inducement test requires that the inducer have 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].

[140] 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* at paragraph 44].

[141] Pharmascience argues that it has taken every available step to ensure that the 335 Patent is not infringed – it has removed all references to [redacted] of the PMS Product from its product monograph. In addition, Pharmascience claims it does not market its products.

[142] Janssen submits that the third prong of the inducement test is met as Pharmascience authored its product monograph. Pharmascience is also aware that its product monograph contains information on the intended use of the PMS Product and intends physicians to follow the recommendations in the document.

[143] Janssen asserts that Pharmascience's submission that it cannot knowingly exert influence because it removed specific recommendations to [redacted] in the product monograph is incorrect. The Pharmascience product monograph still contains clear and explicit recommendations [redacted]

[144] The third prong of the *Corlac* test is met. Pharmascience is aware that its product monograph for the PMS Product contains guidance on implementing the claimed dosage regimen, notwithstanding that it does not supply [redacted] doses of paliperidone palmitate and does not market its products. Pharmascience has knowledge of its influence.

## V. Conclusion

[145] For the foregoing reasons, this motion is allowed to proceed as a summary trial. Janssen has shown on a balance of probabilities that Pharmascience's product monograph for the PMS Product will induce infringement of Janssen's 335 Patent. Janssen's action is not dismissed and will proceed on the defences of alleged invalidity as pleaded only. Costs are awarded to Janssen.

**JUDGMENT in T-1441-20**

**THIS COURT'S JUDGMENT is that:**

1. The motion is dismissed.

2. The Defendant's proposed PMS Paliperidone Palmitate product will infringe the claims of the 335 Patent.

3. The action will proceed to trial with respect to the pleaded defences of invalidity only.

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**

| | |
|---|---|
| **DOCKET:** | T-1441-20 |
| **STYLE OF CAUSE:** | JANSSEN INC. v PHARMASCIENCE INC. |
| **PLACE OF HEARING:** | TORONTO, ONTARIO |
| **DATE OF HEARING:** | NOVEMBER 10, 2021 |
| **PUBLIC JUDGMENT AND REASONS:** | MANSON J. |
| **DATED:** | JANUARY 19, 2022 |

**APPEARANCES:**

| | |
|---|---|
| PETER WILCOX<br>MARIAN WOLANSKI<br>MEGAN POCALYUKO<br>JULIETTE SAKRAN | FOR THE PLAINTIFFS |
| MARCUS KLEE<br>SCOTT BEESER | FOR THE DEFENDANT |

**SOLICITORS OF RECORD:**

| | |
|---|---|
| BELMORE NEIDRAUER LLP<br>TORONTO, ONTARIO | FOR THE PLAINTIFFS |
| AITKEN KLEE LLP<br>TORONTO, ONTARIO | FOR THE DEFENDANT |