Federal Court of Appeal | Cour d'appel fédérale

Date: 20230323

Docket: A-131-20

Citation: 2023 FCA 68

CORAM: **STRATAS J.A.**
GLEASON J.A.
WOODS J.A.

BETWEEN:

TEVA CANADA LIMITED

Appellant

and

JANSSEN INC. and
JANSSEN PHARMACEUTICA N.V.

Respondents

Heard at Toronto, Ontario on September 14, 2021.

Judgment delivered at Ottawa, Ontario, on March 23, 2023.

PUBLIC REASONS FOR JUDGMENT BY: THE COURT

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PUBLIC REASONS FOR JUDGMENT

This is a public version of confidential reasons for judgment issued to the parties. There are no redactions from the confidential reasons for judgment.

THE COURT:

[1] The appellant, Teva Canada Limited (Teva), appeals and the respondents, Janssen Inc. and Janssen Pharmaceutica N.V. (collectively, Janssen), cross-appeal from the judgment of the Federal Court (*per* Manson, J.) in *Janssen Inc. v. Teva Canada Ltd.*, 2020 FC 593, 321 A.C.W.S.

(3d) 539, which was rendered in an action Janssen brought pursuant to subsection 6(1) of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 (the PMNOC Regulations).

[2] In the judgment under appeal, the Federal Court found that:

- the claims asserted in the action, namely, claims 1 to 48 of Janssen's Canadian Patent No. 2,655,335 (the 335 Patent), were not obvious and were valid;

- the making, constructing, using or selling of prolonged release injectable suspensions of paliperidone palmitate by Teva in accordance with its submission to Health Canada in ANDS No. 210095 would infringe claims 1 to 16 and 33 to 48 of the 335 Patent, which the Federal Court found were product claims;

- Teva would not directly infringe claims 17 to 32 of the 335 Patent, which the Federal Court found were use claims, and

- Teva would not induce infringement of any of claims 1 to 48 of the 335 Patent.

[3] The Federal Court granted a permanent injunction that prohibits Teva, its subsidiary and affiliated companies, officers, directors, employees, agents, licensees, successors, assigns and any others over whom Teva exercises lawful authority, until the expiry of the 335 Patent on December 17, 2028, from:

- making, construction, using or selling its paliperidone injection in Canada in accordance with ANDS No. 210095;

- offering for sale, marketing or having marketed in Canada its paliperidone injection in Canada in accordance with ANDS No. 210095; and

- importing, exporting, distributing or having its paliperidone injection distributed in Canada in accordance with ANDS No. 210095.

[4] In this appeal, Teva submits that the Federal Court made reviewable errors in concluding that claims 1 to 48 of the 335 Patent were not obvious. It further submits in the alternative that, even if the Federal Court did not err in finding the 335 Patent was not obvious, it made reviewable errors in determining that Teva would directly infringe claims 1 to 16 and 33 to 48 of the 335 Patent.

[5] Janssen, in its cross-appeal, submits that the Federal Court erred in declining to find that it would induce infringement of claims 1 to 48 of the 335 Patent.

[6] For the reasons that follow, we agree with Janssen and would accordingly dismiss this appeal and grant the cross-appeal, both with costs.

I. The 335 Patent and Reasons of the Federal Court

[7] The 335 Patent describes and claims prefilled syringes, uses of dosage forms, and medicaments of what is known as a depot formulation of the drug paliperidone, formulated as paliperidone palmitate, for administration in accordance with the dosing regimens claimed in the 335 Patent for the treatment of schizophrenia and related disorders.

[8] Schizophrenia, as noted by the Federal Court, "… is a debilitating, lifelong disease estimated to afflict over 300,000 Canadians" (paragraph 4 of the Federal Court's reasons).

[9] Paliperidone is an atypical, or second generation, antipsychotic medication, an oral version of which was used in the treatment of schizophrenia and related illnesses prior to the priority date of the 335 Patent.

[10] The Federal Court found that schizophrenia requires lifelong management with antipsychotic medications and that a leading cause of relapse of those suffering from schizophrenia is non-adherence to taking prescribed medications. One strategy to ensure treatment adherence is the use of long acting formulations of antipsychotics. Intramuscular injections of depot formulations of long-acting injectables, which release slowly from the injection site to provide a prolonged dose of the drug, are one type of a long-acting formulation.

[11] The invention claimed in the 335 Patent relates to dosing regimens for long-acting injectable paliperidone palmitate formulations for the treatment of schizophrenia and related disorders.

[12] The Federal Court found that the goal of the inventors of the 335 Patent was to develop a dosing regimen that ensures an optimal plasma concentration-time profile for treating patients with paliperidone palmitate. To achieve this, the 335 Patent teaches a loading dose regimen comprising loading doses on day 1 and 8 in the deltoid muscle, followed by a maintenance dose regimen administered monthly thereafter in the deltoid or gluteal muscle. The dosing regimen incorporates dosing windows of ± 2 days for the second loading dose and ± 7 days for the maintenance doses to allow for flexibility while maintaining the desired therapeutic effect.

[13] The amount of paliperidone palmitate taught in the 335 Patent, for non-renally impaired patients, is: a first loading dose of about 150 mg-eq of paliperidone palmitate on day 1 of treatment; a second loading dose of about 100 mg-eq of paliperidone palmitate on day 8 ± 2 days; and, maintenance doses of about 75 mg-eq of paliperidone palmitate monthly ± 7 days after the second injection. Smaller doses are taught for renally impaired patients.

[14] The claims in suit are appended as an appendix to these reasons. For purposes of this appeal, it is only necessary to briefly summarize them.

[15] Claims 1 to 16 of the 335 Patent relate to prefilled syringes containing paliperidone palmitate adapted for administration in accordance with the claimed dosing regimens. Claim 1 is

an independent claim related to the prefilled syringes containing paliperidone palmitate adapted for administration for a dosing regime for non-renally impaired patients, and claim 2 is an independent claim related to the to prefilled syringes containing paliperidone palmitate adapted for administration for a dosing regime for renally impaired patients. Claims 3 to 16 are dependent claims, depending on either claim 1 or 2.

[16] Claims 17 to 32 of the 335 Patent relate to the use of a dosage form containing paliperidone palmitate in accordance with the claimed dosing regimens.

[17] Claims 33 to 48 of the 335 Patent are Swiss-type claims related to the use of paliperidone as paliperidone palmitate in the manufacture/preparation of a medicament adapted for administration according to the claimed dosing regimens.

[18] The Federal Court found that the person of ordinary skill in the art of the 335 Patent to whom the Patent is directed (the POSITA) is a skilled team comprised of a clinician, a pharmaceutical formulator, a pharmacometrician, and a pharmacokineticist. According to the Federal Court, the skilled team comprising the POSITA would have expertise in treating schizophrenia and related disorders, in formatting depot formulations, in developing drug dosing regimens to maximize effect while minimizing side effects, and in pharmacodynamic modelling, including PopPK modeling or the modelling used in several examples in the 335 Patent.

[19] The Federal Court further found, at paragraph 123 of its reasons, that, as of all relevant dates, including the priority date of the 335 Patent, the date for assessing obviousness, the POSITA's common general knowledge would include the following information:

i. Schizophrenia is a lifelong disease with no cure. The POSITA would have had knowledge of typical and atypical antipsychotics for treating schizophrenia.

ii Depot formulations are designed for intramuscular injection of a relatively large dose of a long acting drug. In the case of paliperidone palmitate, hydrolyzation of the palmitate ester provides the active compound paliperidone.

iii. Depot formulations could be oil or aqueous based, and prefilled syringes had been designed for ease of administration.

iv. Dosing of depot formulations varied from drug to drug.

v. PopPK modeling could be used to assist in designing dosing regimens.

vi. The risk of serious adverse effects was a concern with depot formulations due to their long-acting nature.

vii. A risperidone depot formulation was on the market.

viii. Paliperidone is a metabolite of risperidone.

ix. An extended release oral formulation of paliperidone was on the market.

x. Aqueous nanoparticle suspensions of paliperidone palmitate had been developed.

[20] The Federal Court further held at paragraph 145 of its reasons that the essential elements of claim 1 were:

- Prefilled syringes containing a depot formulation of paliperidone as paliperidone palmitate formulated as an aqueous nanoparticle suspension;

- For administration by intramuscular injection to a psychiatric patient in need of treatment for schizophrenia, schizoaffective disorder, or schizophreniform disorder;

- Wherein the prefilled syringes are adapted for administration in accordance with the following dosing regimen:
    - A first loading dose of about 150 mg-eq of paliperidone injected into the deltoid on treatment day 1;
    - A second loading dose of about 100 mg-eq of paliperidone injected into the deltoid on treatment day 8 ± 2 days;
    - Continuous maintenance doses of 75 mg-eq of paliperidone injected into the deltoid or gluteal monthly ± 7 days thereafter.

[21] Insofar as concerns the meaning to be given to "continuous", the Federal Court determined that the term did not mean or include merely a single dose but rather required maintenance dosing on an ongoing basis.

[22] The Federal Court held that the essential elements of claim 2 were the same as those for claim 1, "… except that the patient in need of treatment must have renal impairment, and the claimed dosage amounts are about 100 mg-eg, 75 mg-eq, and 50 mg-eq, respectively" (paragraph 146 of the Federal Court's reasons).

[23] Claims 17 to 32 mirror claims 1 to 16, except they are directed to use of a dosage form of paliperiodne palmitate, rather than prefilled syringes. Their essential elements therefore replace the reference to prefilled syringes with "use of a dosage form".

[24] The Federal Court found that the POSITA would understand the "use of a dosage form" "… to mean the use of a syringe containing a depot formulation of paliperidone as paliperidone palmitate to administer the formulation by intramuscular injection according to the dosing and administration schedule in the claims" (paragraph 152 of the Federal Court's reasons).

[25] Claims 33 to 48 also mirror claims 1 to 16, except they are directed toward the use of paliperidone palmitate for the preparation/manufacture of a medicament. At paragraph 161 of its reasons, the Federal Court outlined the following as being the essential elements of claims 33 to 48 of the 335 Patent:

> […] "use of paliperidone as paliperidone palmitate" for the preparation (claim 33) or in the manufacture (claim 34) of a medicament, wherein the medicament comprises loading and maintenance doses. That said, the claims also include as essential elements:
>
> i. the dosing schedule of days 1, 8, and monthly thereafter;
>
> ii. specific dose amounts of 150, 100, and 75 mg-eq for non-renally impaired patients, and 100, 75, and 50 mg-eq for renally impaired patients; and
>
> iii. injection sites of the deltoid (loading doses on days 1 and 8) and deltoid or gluteal (maintenance doses).

[26] Turning to obviousness, the Federal Court commenced its discussion of the issue by correctly setting out the applicable framework for assessing obviousness laid out by the Supreme Court of Canada in *Apotex Inc. v. Sanofi-Synthelabo Canada Inc.*, 2008 SCC 61, 298 D.L.R. (4th) 385 at para. 67 [*Sanofi*]. That framework is a four-part one, containing the following steps to assess an assertion of obviousness:

- Identify the POSITA and the relevant common general knowledge of the POSITA;

- Identify the inventive concept of the claim in question or, if that cannot readily be done, the Supreme Court directs that the court should "construe it";

- Identify what, if any, differences exist between the matter cited as forming part of the state of the art and the inventive concept of the claim as construed;

- Assess whether, when viewed without any knowledge of the alleged invention as claimed, those differences constitute steps that would have been obvious to the POSITA or whether they require any degree of invention.

[27] In areas of invention where advances are often achieved by experimentation, as in drug development work, the Supreme Court stated at paragraph 68 of *Sanofi* that an "obvious to try" test may be appropriate in consideration of the fourth of the above factors.

[28] In the case at bar, the Federal Court correctly outlined the factors relevant to the "obvious to try" test as follows at paragraph 167 of its Reasons:

i. Is it more or less self-evident that what is being tried ought to work? Are there a finite number of identified predictable solutions known to persons skilled in the art?

ii. What is the extent, nature and amount of effort required to achieve the invention? Are routine trials carried out or is the experimentation prolonged and arduous, such that the trials would not be considered routine?

iii. Is there a motive provided in the prior art to find the solution the patent addresses?

iv. What was the actual course of conduct which culminated in the making of the invention?

[29] The Federal Court construed the inventive concept of the claims in suit, at paragraphs 187 to 188, as being:

> "… a safe and effective dosing regimen using a depot formulation of paliperidone as paliperidone palmitate, formulated as an aqueous nanosuspension for treatment of schizophrenia patients, designed to reach the therapeutic range of plasma concentrations quickly, and maintain patients within that range. For non-renally impaired patients, the dosing regimen is as detailed in claims 1, 17, and 33:
>
> - 150 mg-eq of paliperidone as paliperidone palmitate injected into the deltoid on day 1;
> - 100 mg-eq of paliperidone as paliperidone palmitate injected into the deltoid on day 8 ± 2 days;
> - 75 mg-eq of paliperidone as paliperidone palmitate injected into the deltoid or gluteal monthly ± 7 days thereafter.
>
> For renally impaired patients, the dose amounts are adjusted downwards to loading doses of 100 and 75 mg-eq, and maintenance doses of 50 mg-eq, as detailed in claims 2, 18, and 34.

[30] The Federal Court found, at paragraph 197, that the differences between the state of the art and the inventive concept of the claims in suit were:

- A depot antipsychotic dosing regimen designed to quickly and safely reach therapeutic plasma concentrations without the need for oral run in, oral supplementation, or dose titration.
- The specified dose amounts of the claimed regimens;
- A loading dose regimen administered into the deltoid muscle;
- Maintenance doses administered interchangeably in the deltoid or gluteal muscle;
- Dosing windows of ± 2 days (second loading dose) and ± 7 days (maintenance doses); and
- An adjusted regimen for patients with renal impairment.

[31] The Federal Court held that the differences between the state of the art and the inventive concept of the claims in suit would not have been obvious to the POSITA considering the four factors from the "obvious to try" test.

[32] As concerns the first of these factors, the Federal Court made several factual findings that led it to conclude that "… it would not have been self-evident that some combination of the disclosed dose amounts, dosing schedule, and injection sites would quickly and safely achieve therapeutic plasma concentrations of paliperidone" (paragraph 204). These findings included the facts that:

- the necessary pharmacokinetic data in humans was not disclosed in the prior art, and, therefore, testing in animals and humans would have been required to confirm and adjust dosing;

- the prior art disclosed that loading doses could take the form of a higher initial dose, more frequent initial dosing, or both. The only piece of prior art that disclosed a loading dose regimen for paliperidone, L. Citrome, "Paliperidone: quo vadis?" (2007) Int. J. Clin. Practice 61:4 at 653-662 (the Citrome article), disclosed a loading dose using a fixed regimen as opposed to the claimed doses, which use two different loading doses and a lower continuous maintenance dose;

- The Citrome article disclosed a range of dose amounts up to and including 150 mg-eq and a loading dose regimen on days 1 and 8, but did not disclose whether this combination was safe and effective; and

- even if the POSITA decided to pursue a loading dose regimen, there were not a fixed number of identifiable solutions that would lead to the regimen claimed in the 335 Patent.

[33] As concerns the second of the factors in the "obvious to try" test, the Federal Court noted that the second and the fourth factors were closely tied to each other. It concluded that the POSITA would have been required to carry out "… prolonged and arduous experimentation [to discover the claimed dosing regimen] to the point that the trials would not be considered routine" (paragraph 218).

[34] As concerns the third factor of motive, the Federal Court found that "[…] there would have been a general motivation to develop a depot formulation of paliperidone, but not necessarily a specific motivation to develop the dosing regimens contained in the 335 Patent" (paragraph 219).

[35] As each of the four factors pointed to the conclusion that the claims in suit were not obvious, the Federal Court determined that the 335 Patent was not invalid for obviousness. Since that was the only basis upon which its validity was challenged, the Federal Court held that the 335 Patent was valid.

[36] Turning to infringement, the parties agreed before the Federal Court that Teva would not directly infringe the use claims set out in claims 17 to 32 of the 335 Patent as it would not administer the drug.

[37] The Federal Court commenced its discussion of infringement by correctly noting that, "[t]o determine whether a patent claim is infringed, having purposively construed the claims and identified the essential claim elements, the Court must determine whether the allegedly

infringing product falls within the scope of the claims ...” (paragraph 226). The Federal Court continued by noting that allegations of non-infringement under the PMNOC Regulations require consideration of whether the party that seeks approval under an abbreviated new drug submission (called the second person in the PMNOC Regulations)—here Teva—would either directly infringe claims of the patent in suit or induce their infringement.

[38] The Federal Court found that Teva would directly infringe the product claims in claims 1 to 16 (the prefilled syringe claims) and claims 33 to 48 (the medicament claims). More specifically, the Federal Court determined that the Teva product incorporates all the formulation and dosing elements of claims 1 to 16 and 33 to 48, including being adapted for use in accordance with the dosing regimen claimed in the 335 Patent.

[39] As concerns formulation, Teva advanced what the Federal Court characterized as a weak argument that its product would not infringe the product claims because its syringes contained slightly more product than the amounts claimed in the claims in suit. The Federal Court rejected this contention, finding that the dose referred to in the claims referred to the dose to be delivered to the patient, and that “… Teva’s PM [i.e., product monograph] and packaging … list[ed] the doses of paliperidone palmitate as 150, 100, 75, 50, and 25 mg-eq, not the increased amounts that account for overfill” (paragraph 229).

[40] With respect to the dosing elements of the product and medicament claims, the Federal Court found that the Teva product incorporates all the essential elements of the claims 1 to 16 and 33 to 48 of the 335 Patent.

[41] The Federal Court commenced its analysis of infringement of the dosing regimen with a discussion of claim 1 and found that the Teva product, if it came to market, would infringe this claim because it contained each of the essential elements of the claim. The Federal Court more specifically held as follows with respect to each such element:

- "**Prefilled syringes containing a depot formulation of paliperidone as paliperidone palmitate formulated as an aqueous nanoparticle suspension:**" the Federal Court found that "[t]he Teva PM and product labels indicate that the Teva product comes as individual, pre-filled syringes containing a prolonged-release injectable suspension of paliperidone palmitate" (paragraph 241);

- "**For administration by intramuscular injection to a psychiatric patient in need of treatment for schizophrenia, schizoaffective disorder, or schizophreniform disorder:**" the Federal Court found that the product label states "for intramuscular use only", that the PM identified the route of administration as "intramuscular injection", that the evidence of one of Teva's experts was to the effect that, if the Teva product came to market, it would be administered intramuscularly, that the product labels for the Teva product give dosing instructions for adults with schizophrenia and schizoaffective disorders, and that the Teva PM informs health care professionals that the Teva product is for the treatment of both disorders (paragraphs 242–43);

- "**A first loading dose of about 150 mg-eq of paliperidone injected into the deltoid on treatment day 1:**" the Federal Court found that Teva will sell prefilled syringes

containing a dose of about 150 mg-eq of paliperidone palmitate, which Teva's PM defines as the loading dose to be administered on treatment day 1 to the deltoid muscle and its product label states is to be administered day 1 into the deltoid muscle (paragraphs 244–45);

- "**A second loading dose of about 100 mg-eq of paliperidone injected into the deltoid on treatment day 8 ± 2 days:**" the Federal Court found that Teva will sell prefilled syringes containing a dose of about 100 mg-eq of paliperidone palmitate, that Teva's PM specifies a dose of 100 mg on day 8 administered in the deltoid muscle as part of the initiation regimen, that the product label states "Day 8 (one week later): 100 mg administered in the deltoid", and that the "Missed Doses" section of Teva's PM teaches that patients may be given the missed dose up to 4 days before or after the one week time point but that it recommends 2 of the 4 days on either side of the recommended dose to fall within the claimed schedule. This schedule includes the window of ± 2 days from day 8 that is set out in claim 1 of the 335 Patent (paragraphs 246–47);

- "**Continuous maintenance doses of 75 mg-eq of paliperidone injected into the deltoid or gluteal monthly ± 7 days thereafter:**" the Federal Court found that Teva will sell multiple prefilled syringes, including ones containing about 75 mg-eq of paliperidone palmitate, and that the Teva PM teaches that these syringes can be used as continuous monthly maintenance doses, administered in either the deltoid or gluteal muscle (paragraphs 248–49).

[42] The Federal Court, at paragraph 252, agreed with Janssen that "the capable, approved and intended use for the Teva product as specified in the Teva [PM] incorporates all dosing and administration elements" in claim 1. The Federal Court further stated that "[t]he Teva PM teaches that the prefilled syringes to be sold by Teva can be administered in combination according to the claimed dosing regimen" (paragraph 253). The Federal Court accordingly found that Teva would directly infringe claim 1. It noted in paragraph 254 of its reasons that:

> … Teva need not direct that the claimed dosing regimen is the only regimen, or even the recommended regimen, by which its syringes should be administered. Sale of prefilled syringes adapted for administration in accordance with the claimed dosing regimen, as taught in the Teva PM, will deprive Janssen of the full enjoyment of the 335 Patent monopoly (*Monsanto*, above, at para 34). Actual use of the syringes in accordance with the claimed dosing regimen is not required.

[43] Following the same reasoning, the Federal Court concluded that Teva would directly infringe claim 2 based on dose adjustments for renally impaired patients and would likewise directly infringe claims 33 and 34, the independent Swiss claims, by making and selling its paliperidone palmitate product. It therefore followed that it would likewise infringe the claims that depended on the independent claims, *i.e.*, claims 3 to 16 and 35 to 48 of the 335 Patent.

[44] Despite the forgoing factual determinations underpinning the Federal Court's conclusion that Teva would directly infringe claims 1 to 16 and 33 to 48 if its paliperidone palmitate product were to come to market, the Federal Court held that Teva would not induce infringement of any of the claims in suit.

[45] In assessing this issue, the Federal Court found that the decision of this Court in *Corlac Inc. v. Weatherford Canada Inc.*, 2011 FCA 228, 95 C.P.R. (4th) 101 [*Corlac*], sets out a more

stringent test than had previously been required such that a defendant now will not be found to induce infringement of a patent unless the patentee establishes that, "but for" the acts of the defendant, the infringement did not or, in the context of an application under the PMNOC Regulations, would not occur.

[46] *Corlac* set out a three-prong test for inducement, applicable to situations where infringement is alleged to have occurred. The tripartite test at paragraph 162 of *Corlac* requires a patentee to establish that:

i. the act(s) of infringement must have been completed by the direct infringer;

ii. the completion of the act(s) of infringement were influenced by the acts of the alleged inducer to the point that, without the influence, direct infringement would not take place; and

iii. the influence must knowingly be exercised by the inducer, that is, the inducer knows that this influence will result in the completion of the act of infringement.

[47] In the case at bar, which involved an action under the PMNOC Regulations, Teva had not yet come to market with its injectable paliperidone palmitate product. Thus, it was necessary for Janssen to establish that each of the three prerequisites for a finding of infringement would occur if the action were dismissed. The standard of proof applicable was the normal civil standard of the balance of probabilities.

[48] The Federal Court found that Janssen had established the first of the *Corlac* factors but not the second. It did not consider the third factor.

[49] More specifically, as concerns the first factor, the Federal Court found that at least some physicians would administer doses of paliperidone palmitate for the treatment of schizophrenia and related disorders encompassed within the dosing regimen claimed by the 335 Patent. The Federal Court premised this determination on evidence from the IMS data for Janssen's injectable paliperidone palmitate product that was already on the market as well as on testimony from the parties' experts as to the way physicians would be likely to administer the Teva product. While many other dosages might be administered, at least some would fall within the scope of the claims. The Federal Court therefore concluded that Janssen had established that there would be acts of direct infringement of the claims in suit.

[50] As concerns the second prong of the test from *Corlac*, the Federal Court found that Janssen had not established that "… the Teva PM influences physicians to prescribe the claimed maintenance doses to the point that, absent the dosing information in the Teva PM, direct infringement would not occur" (paragraph 289). The Federal Court made this determination because it found that the selection of maintenance doses would ultimately be made by physicians based on various factors beyond what was set out in the Teva PM. The Federal Court thus concluded that the "but for" requirement it found stemmed from *Corlac* was not met. The Federal Court reached this determination despite having found that:

- the Teva PM specifies the amount, location, and timing of the loading doses claimed in the claims in suit;

- the Teva PM recommends, among other maintenance doses, a 75 mg-eq maintenance dose for non-renally impaired and 50 mg-eq maintenance dose for renally impaired patients;

- "[t]he Teva PM [clearly instructs physicians that] the 75 mg-eq maintenance dose is one of the 'recommended' maintenance doses for non-renally impaired schizophrenia patients" (paragraph 275); and

- "[s]imilarly, for patients with renal impairment, the Teva PM directs physicians to follow the loading dose regimen with monthly injections of 50 mg-eq, adjusted within the range of 25 to 100 mg-eq, based on individual patient tolerability and efficacy" (paragraph 275).

[51] Having found the 335 Patent to be valid and that Teva would directly infringe it, the Federal Court granted the permanent injunction, outlined above.

II. Analysis

[52] The normal appellate standard of review applies to this appeal. Therefore, errors of law are reviewable for correctness, whereas errors of fact or of mixed fact and law that do not contain an extricable legal issue are reviewable under the standard of palpable and overriding error (*Housen v. Nikolaisen*, 2002 SCC 33, 211 D.L.R. (4th) 577 at paras. 8, 10, 36; *Hospira*

Healthcare Corporation v. Kennedy Institute of Rheumatology, 2016 FCA 215, 420 D.L.R. (4th) 497 at para. 66).

[53] Here, both Teva and Janssen submit that the Federal Court made only errors of law. However, as is more fully discussed below, at least some of the errors that Teva alleges the Federal Court made are factual as opposed to legal in nature.

A. *Did the Federal Court Err in Respect of Obviousness?*

[54] We turn first to the issue of obviousness.

[55] Teva submits that the Federal Court made two errors in its assessment of obviousness. It first says the Federal Court erred in requiring Teva to show that the dosing windows of the dosing regimen were obvious. It secondly asserts that the Federal Court erred in ignoring or overlooking evidence as to the starting point for establishing doses within the dosing regimen. The combined effect of these two errors, Teva says, required it to establish more than it was legally required to establish to prove that the claims in suit were invalid for obviousness.

[56] In respect of the former error, Teva submits that the Federal Court did not find the dosing window to be an essential element of the claims in suit, and that the Federal Court therefore erred in requiring Teva to show that each of the dosing windows was non-obvious. Teva contends that the effect of this alleged error was to require it to prove that every embodiment within the scope of the claims was obvious, rather than requiring it to establish that merely one embodiment was obvious, which it says amounts to an error of law.

[57] This submission cannot be accepted because it is premised on a misreading of the Federal Court's reasons. While it is true that the Federal Court did not refer to the dosing windows in paragraph 161 of its reasons when it set out the essential elements of the medicament claims, a reading of the entirety of the Federal Court's reasons makes it clear that this was an inadvertent omission.

[58] Elsewhere in its reasons, the Federal Court clearly stated that the presence of a dosing window for the first loading dose and for the maintenance doses was one of the essential elements of the claims in suit. This is particularly apparent from paragraphs 17, 126, 138, 141, 145 and 187 of the Federal Court's reasons, where it clearly indicated that the windows are essential elements of the claims.

[59] Thus, contrary to what Teva submits, the Federal Court did hold that the dosing windows were essential elements of the claims in suit. This is a determination that was open to the Federal Court to have made in light of the purposive reading that the Federal Court gave to the claims in suit, as well as the expert evidence that was before the Federal Court.

[60] In addition, as correctly noted by Janssen, the dosing windows played very little role in the Federal Court's obviousness analysis. It rather focussed on the other essential elements of the claims in suit, which would have been easier for Teva to show were obvious. The Federal Court found that Teva did not succeed in so doing.

[61] It follows that there is no merit to Teva's first submission on obviousness as it is premised on a misreading of the Federal Court's reasons.

[62] Teva's second obviousness submission, as noted, alleges that the Federal Court erred in ignoring or overlooking evidence as to the starting point for the obviousness analysis. This submission rests on Teva's contention that the Federal Court failed to appreciate that dosing information was already disclosed in the prior art because the pharmacokinetic profile of paliperidone was already known as of the priority date. Given this, Teva says that the only type of studies required to arrive at the solutions taught by the 335 Patent were routine. Teva submits that the fact that the Federal Court failed to mention this prior art in its decision means that it failed to take account of a critical piece of evidence, which it asserts is an error of law.

[63] However, this is not an issue of law at all, but rather one of fact.

[64] It is well settled that, absent an extricable error of law in construing the inventive concept or in setting out or applying the test for the assessment of obviousness, obviousness determinations are factual in nature as they rest on a trial judge's findings as to common general knowledge and state of the art, both of which are factual matters: see, *e.g.*, *Tetra Tech EBA Inc. v. Georgetown Rail Equipment Company*, 2019 FCA 203, 166 C.P.R. (4th) 1 at para. 133; *Bell Helicopter Textron Canada Limitée v. Eurocopter, société par actions simplifiée*, 2013 FCA 219, 120 C.P.R. (4th) 394 at para. 117 [*Bell Helicopter Textron*]; *Cobalt Pharmaceuticals Company v. Bayer Inc.*, 2015 FCA 116, 131 C.P.R. (4th) 99 at paras. 47–49 (citing to *Sanofi* at para. 63); *Newco Tank Corp. v. Canada (Attorney General)*, 2015 FCA 47, 133 C.P.R. (4th) 85 at paras.

10, 12; *Halford v. Seed Hawk Inc.*, 2006 FCA 275, 275 D.L.R. (4th) 556 at paras. 10 and 39 and *Corlac* at para. 24.

[65] Moreover, as noted in *Housen* at paragraph 46 and *Mahjoub v. Canada (Citizenship and Immigration)*, 2017 FCA 157, [2018] 2 F.C.R. 344 at para. 67, trial judges benefit from a presumption that they have considered all the evidence. This presumption is not rebutted by the mere failure to mention a piece of evidence, especially where, as here, that evidence was not crucial.

[66] The evidence in question that Teva says the Federal Court failed to consider related to the pharmacokinetic profile of paliperidone as opposed to that of paliperidone palmitate. However, the two are not the same thing as the experts of both Janssen and Teva agreed (see, *e.g.*, cross-examination of Teva's expert Richard F. Bergstrom, Federal Court's trial transcript, vol. 3, dated February 6, 2020, at 390, line 21, to 391, line 24; and direct examination of Janssen's expert Larry Ereshefsky, Federal Court's trial transcript, vol. 10, dated February 17, 2020, at 1168, lines 9–13). Both experts also stated that additional tests were required to understand the pharmacokinetic profile of paliperidone palmitate and its therapeutic concentration range. There was accordingly ample support in the evidence for the Federal Court's determination that discovering these matters required more than routine tests.

[67] This second error that Teva alleges the Federal Court made in respect of its assessment of obviousness is really no more than a request to this Court to reconduct the obviousness analysis and place different weight on the evidence. However, that is not something that an appellate

court can do, as noted by the Supreme Court of Canada in *Housen* at paragraph 3 (see also *Dnow Canada U.L.C. v. Grenke Estate*, 2020 FCA 61, 453 D.L.R. (4th) 676 at para. 19; *Eli Lilly Canada Inc. v. Teva Canada Limited*, 2018 FCA 53, 292 A.C.W.S. (3d) 146 at para. 96, leave to appeal to SCC refused [2018] 3 S.C.R. vi; *Nova Chemicals Corporation v. Dow Chemical Company*, 2016 FCA 216, 142 C.P.R. (4th) 339 at para. 14; *Pfizer Canada Inc. v. Apotex Inc.*, 2014 FCA 54, 117 C.P.R. (4th) 401 at para. 13; *Bell Helicopter Textron* at para. 71). Thus, this argument also fails.

[68] Accordingly, there is no basis for interfering with the Federal Court's findings in respect of obviousness.

B. *Did the Federal Court Err in Respect of Infringement?*

[69] Turning to infringement, we address first the Federal Court's finding of direct infringement.

(1) Direct Infringement

[70] Teva submits that the Federal Court erred in concluding that the Teva product will incorporate all the essential elements of claims 1 and 33 because this finding is inconsistent with its finding that an essential element of all the claims was that there be a fixed maintenance dose. Teva asserts that this error is a legal one.

[71] We see no such inconsistency in the Federal Court's reasons. Moreover, even if there were, it would not be an error of law.

[72] Infringement is a question of mixed fact and law, reviewable for palpable and overriding error, unless there is an extricable legal error or improper claims construction: *Whirlpool Corp. v. Camco Inc.*, 2000 SCC 67, 194 D.L.R. (4th) 193 at para. 76; *Tensar Technologies, Limited v. Enviro-Pro Geosynthetics, Ltd.*, 2021 FCA 3, 330 A.C.W.S. (3d) 796 at para. 30; *ABB Technology AG v. Hyundai Heavy Industries Co., Ltd.*, 2015 FCA 181, 132 C.P.R. (4th) 405 at para. 30.

[73] Teva does not allege any errors in the Federal Court's construction of the claims in suit.

[74] Further, we see no legal error in the Federal Court's analysis of direct infringement. Direct infringement may be established in an action like this, commenced under section 6 of the PMNOC Regulations, when the plaintiff establishes that the defendant proposes to use, make or sell a product that incorporates all the essential elements of the claim(s) at issue: *Free World Trust v. Électro Santé Inc.*, 2000 SCC 66, 194 D.L.R. (4th) 232 at paras. 31(f), 68; *Apotex Inc. v. Janssen Inc.*, 2021 FCA 45, 182 C.P.R. (4th) 233 at para. 56; *Zero Spill Systems (Int'l) Inc. v. Heide*, 2015 FCA 115, 130 C.P.R. (4th) 291 at para. 56, leave to appeal to S.C.C. refused, 36542 (14 January 2016); *Hershkovitz v. Tyco Safety Products Canada Ltd.*, 2010 FCA 190, 89 C.P.R. (4th) 101 at para. 11.

[75] This is the test that the Federal Court applied in the case at bar.

[76] Based on the evidence, the Federal Court found that all essential elements of claims 1 to 16 and 33 to 48 would be present in the Teva product. With respect to the maintenance doses more specifically, the Federal Court held that Teva will sell multiple prefilled syringes, including ones containing about 75 mg-eq of paliperidone palmitate, and that the Teva PM teaches that these syringes can be used as continuous monthly maintenance doses, administered in either the deltoid or gluteal muscle. These findings were sufficient for it to conclude that, with respect to this element of claims 1 to 16 and 33 to 48, the "capable, approved and intended use" of the Teva product incorporated the continuous maintenance dose element.

[77] In the context of product claims like those in claims 1 to 16 of the 335 Patent (*i.e.*, claims to a pharmaceutical preparation for use in the treatment of a condition), evidence that a generic company proposes to make or sell its product for the patented use (even if it is only one use among others) is enough to establish direct infringement in an action brought under section 6 of the PMNOC Regulations (*AB Hassle v. Canada (Minister of National Health and Welfare)*, 2001 FCT 1264, 16 C.P.R. (4th) 21 at paras. 6, 33, 35–36, aff'd 2002 FCA 421, leave to appeal to S.C.C. refused, 29533 (27 March 2003) [*AB Hassle*]; *Eli Lilly Canada Inc. v. Apotex Inc.*, 2019 FC 884, 166 C.P.R. (4th) 191 at paras. 24–33).

[78] Similarly, in the context of Swiss-type product claims like those in claims 33 to 48 of the 335 Patent (*i.e.*, claims to the use of a drug for the preparation of a medicament for use in treatment of a condition), evidence that a generic company proposes to make or sell its product for the patented use (even if it is only one use among others) is enough to establish direct infringement in an action brought under section 6 of the PMNOC Regulations (*AB Hassle*

(F.C.T.) at paras. 6, 33, 35–36; *Hospira Healthcare Corporation v. Kennedy Trust for Rheumatology Research*, 2018 FC 259 at paras. 152–153, 268–323, aff'd on that ground and rev'd in part in 2020 FCA 30, 316 A.C.W.S. (3d) 537 at paras. 16–18, leave to appeal to S.C.C. refused, 39099 (23 December 2020) [*Hospira*]).

[79] In some respects, this case is similar to *Hospira*. There, the generic company was found to have both directly infringed and induced infringement of the patent that claimed a product for use in an adjunctive therapy. The generic company produced the component claimed in the patent at issue in that case. Even though the infringing adjunctive therapy was only one of several potential uses mentioned in the generic company's PM, it was found to have directly infringed and induced infringement of the patent at issue in that case. The generic company's conduct in *Hospira* is analogous to that of Teva in the case at bar.

[80] We accordingly see no error in the Federal Court's analysis of direct infringement.

(2) Inducing Infringement

[81] We turn finally to consider whether the Federal Court erred in its assessment of whether Teva will induce infringement of the use claims set out in claims 17 to 32 of the 335 Patent.

[82] We agree with Janssen that the Federal Court erred in law in holding that the decision of this Court in *Corlac* changed the law by incorporating a higher degree of causality at the second step of the analysis for inducing infringement. This error led the Federal Court to incorrectly

apply an unduly onerous requirement at the second prong of the analysis for inducement and to incorrectly focus only on the skill and judgement of prescribing physicians to the exclusion of the role played by Teva in inducing infringement of the use claims in suit.

[83] Contrary to what the Federal Court found, the decision in *Corlac* incorporates the same principles for inducing infringement as were embraced in the previous cases from this Court, as a review of some of the leading cases from this Court and its predecessors on inducement demonstrates.

[84] Inducing infringement appears to have been first recognized as a form of infringement in *Copeland-Chatterson Co. v. Hatton* (1906), 10 Ex. C.R. 224, 1906 CarswellNat 10 (Ex. Ct.) aff'd 37 S.C.R. 651 (S.C.C.). The Exchequer Court held at paragraph 16 that inducement occurs when a putative inducer provides the materials for infringement and, for its own ends and benefit, induces another to infringe a patent, and the Court found that so doing constitutes infringement.

[85] These principles were applied several years later in *Windsurfing International Inc. v. Trilantic Corp*. (1985), 8 C.P.R. (3d) 241, 63 N.R. 218 (F.C.A.) [*Windsurfing*]. The appellant, Windsurfing International Inc., alleged infringement of its patent for a sailboard. Among the issues was whether the defendant induced infringement by selling unassembled sailboards accompanied by a diagram of the assembled boards. Counsel argued that the mere making, using or vending of components afterwards entered into a combination is not prohibited where the

patent is limited to the combination itself. Justice Urie, writing for the Court, disagreed and stated as follows at paragraph 73:

> That argument to me can only be termed specious. To suggest that a person purchasing components, the only known use for which are for assembling to provide the purchaser with what he obviously desires – a sailboard – has not been persuaded to do so by holding out of the desired result by both the manufacturer and the vendor thereof, stretches credulity to its limits. That, in my view, is inducement even where the printed instructions are limited to the extent disclosed in the evidence in this case. I think it beyond dispute that the only inference to be drawn from the voluminous evidence in this case is that the respondent knew and intended that the ultimate purchaser would utilize the sailboard parts for the assembly of a usable sailboard which, upon assembly, would infringe the appellant's patent. It thereby became a party to such infringement, in my view.

[86] *Slater Steel Industries Ltd. v. R. Payer Co. Ltd.* (1968), 38 Fox Patent Cases 139, 55 C.P.R. 61 (Ex. Ct.) [*Slater Steel*], appears to be the first case in which the tri-part test for inducement was set out. The test was first mentioned as "… whether it has been alleged and proved that the defendants (a) knowingly, (b) induced or procured, (c) another to infringe the plaintiffs' patent" (*Slater Steel* at 158). In examining whether inducement had occurred in *Slater Steel*, the Exchequer Court of Canada applied the tri-part test to the facts as follows (page 159):

> (a) that any purchaser from the defendants used the armour rods so purchased to *infringe* the plaintiffs' patents,
>
> (b) if any such purchaser did so infringe, was it *induced or procured* to do so by the defendants, and finally,
>
> (c) if any such purchaser was so induced or procured by the defendants, did the defendants do so "*knowingly*"?

[87] In *Warner-Lambert Co. v. Wilkinson Sword Canada Inc.* (1988), 19 C.P.R. (3d) 402, 19 F.T.R. 198 (F.C.T.D.) [*Warner-Lambert*], Associate Chief Justice Jerome, for the Federal Court—Trial Division, dismissed an appeal from a prothonotary's decision, declining to set aside

a grant of service *ex juris* on an English company on the basis that statements made by that company established facts showing an arguable case for inducing patent infringement. In so doing at paragraph 10, Associate Chief Justice Jerome quoted from an article authored by François Grenier and articulated the test for inducing infringement, in its current form, as requiring that the plaintiff prove:

> 1) That the act of infringement was completed by the direct infringer…
>
> 2) Completion of the act of infringement was influenced by the acts of the inducer. Without said influence, infringement would not otherwise take place…
>
> 3) The influence must knowingly be exercised by the seller, i.e. the seller knows his influence will result in the completion of the act of infringement.

[88] In considering whether the evidence as summarized supported an arguable case of infringement, Associate Chief Justice Jerome wrote at paragraph 11:

> … As noted above, all that had to be shown was a good, arguable case against the foreign defendant. … In my opinion, it does. There is a clear connection between the sale of the particular form of razor which is said to infringe and the requirements exacted by the parent company in the registered user agreement. The terms of that agreement certainly made it arguable that the sale (which is not denied here) may have been the direct result of the [parent company's] influence. …

[89] In *Dableh v. Ontario Hydro* (1996), 68 C.P.R. (3d) 129, 117 F.T.R. 160 (F.C.A.) [*Dableh*], the Court cited *Copeland-Chatterson* and wrote:

> We turn first to the issue of inducement. An early Canadian precedent in this area is *The Copeland-Chatterson Company v. Hatton* (1906), 10 Ex. C.R. 224 (Ex. Ct.). The Exchequer Court had this to say at page 245:
>
> > … it seems to me, that a declaration at law might be framed to meet the case of one who provided the materials for the infringement, and for his own ends and benefit procured or induced another to infringe a patent … I do not see that

> infringements of patents can in this respect be distinguished from other wrongs….
>
> This early statement has been little qualified over the years and lists the essential elements in an inducement action. …
>
> [Footnotes omitted.]

[90] *Dableh* then quoted the articulation of the test from *Warner-Lambert*, above:

> 1) That an act of infringement was completed by the direct infringer …
>
> 2) Completion of the act of infringement was influenced by the acts of the inducer. Without said influence, infringement would not otherwise take place …
>
> 3) The influence must knowingly be exercised by the seller, i.e. the seller knows his influence will result in the completion of the act of infringement.

[91] In *Dableh*, this Court only considered the application of the first prong of the test.

[92] *AB Hassle* (F.C.T.) involved an application for a prohibition order under the old PMNOC Regulations. In the Federal Court decision, Justice O'Keefe identified, at paragraph 68, the test for induced infringement as follows:

> A patentee wishing to rely on the doctrine of induced infringement must allege and prove each of the following elements:
>
> (a) that the act of infringement was completed by the direct infringer;
>
> (b) the completed act of infringement was influenced by the seller, to the point where without said influence, infringement by the buyer would not otherwise take place; and,
>
> (c) the influence must knowingly be exercised by the seller, such that the seller knows that his influence will result in the completion of the act of infringement.

[93] In summarizing the Federal Court decision in *AB Hassle* (F.C.A.), this Court, *per* Justice Sexton, set out the Federal Court's identification of the test as above and did not take issue with it. In the course of dismissing the appeal, this Court wrote at paragraphs 56 and 57:

> … I do not view Genpharm as being authority for the proposition that mere sale by a generic, without more, of a medicine subject to a use patent is sufficient to constitute infringement for the purpose of subparagraph 5(1)(b)(iv).
>
> Thus Apotex cannot be prevented from obtaining a NOC solely on the basis that it will sell omeprazole. If it were otherwise, then serious policy issues would arise. If there was any likelihood that a patient would consume a generic product for a patented use, then the generic product would not be approved. …

[94] In *AB Hassle v. Genpharm Inc*., 2003 FC 1443, 243 F.T.R. 6, aff'd 2004 FCA 413 [*Genpharm*], another application under the old PMNOC Regulations, one of the issues was whether Genpharm's sale of its omeprazole product would infringe two patents if it were put on the market. Justice Layden-Stevenson, the application judge, did not specifically frame this analysis as one of induced infringement and wrote at paragraph 127:

> Infringement of a use patent, under the Regulations, is not limited to the act of the generic producer; it includes infringement by patients. Infringement is made out when patients use a medicine sold by a generic producer even if there is no inducement or procurement by the generic producer: ***Genpharm Inc. v. Canada Minister of Health et al.*** (2002), 20 C.P.R. (4th) 1 (F.C.A.). The mere selling of its product by the generic producer, without more, will not be sufficient to establish infringement. Infringement will be established where there is evidence to conclude that the second person's actions and intentions would inevitably lead to the new use of the first person's product if the second person obtained a NOC. It is for the first person to establish, on a balance of probabilities, that future infringements will occur. To obtain an order for prohibition, the first person must prove that if a NOC issued and the second person were to sell its generic drug, patients or other third parties would infringe the first person's use patent: ***AB Hassle v. Canada (Minister of National Health & Welfare)*** (2002), *supra*.

[95] Justice Layden-Stevenson concluded that references (some of them subtle) to the patented use of omeprazole in Genpharm's PM was sufficient to establish that Genpharm would

infringe AB Hassle's patent if Genpharm's drug were allowed onto the market, and this, despite the fact that the product label indicated the tablets were for other non-patented uses.

[96] Genpharm was appealed to this Court. This Court, *per* Justice Rothstein, wrote in *Genpharm Inc. v. AB Hassle*, 2004 FCA 413, 38 C.P.R. (4th) 17 at para. 20:

> Genpharm strongly objects to Layden-Stevenson J.'s finding in respect of the product monograph. It says there was no evidence led by Astra to demonstrate that the product monograph would induce infringement of the '668 or '762 Patents. However, the product monograph was itself in evidence and it was open to Layden-Stevenson J. to draw an adverse inference from it.

[97] *Abbott Laboratories Limited v. Canada (Ministry of National Health and Welfare)*, 2006 FC 1411, aff'd 2007 FCA 251 [*Novopharm*], involved another application under the old PMNOC Regulations. The generic drug manufacturer, Novopharm Limited, sought the issuance of a NOC to allow it to produce a generic version of a drug for an old use. The application judge, Justice von Finckenstein, considered whether the PM would induce infringement. In finding inducement, he wrote at paragraphs 40 and 42:

> Admittedly, Dr. Graham also points out that: a) physicians rarely look at a PM when making a prescription; and b) that a pharmacist might, when filling out the prescription, note that Novo-Lansoprazole has no indication for triple therapy use. This however, does not detract from the fact that the Novopharm PM is set up in such a way that, by his own admission, it can be seen to be a prescription of Novo-Lansoprazole for triple therapy which would be an encouragement to infringe claim 16 of the 741 patent.
>
> …
>
> Accordingly, I find, based on the testimony of Novopharm's most renowned witness, that on a balance of probabilities the Novopharm PM would induce a physician to prescribe Novo-Lansoprazole for a triple therapy to fight H. pylori-caused infections.

[98] The application judge also found that the product label would induce infringement (paragraph 47):

> The Court is driven to the conclusion that the inclusion of the amount, the frequency and the duration of the dosage for triple therapy on the label for Novo-Lansoprazole under the rubric 'Adult dosage' and the absence of any other clinically indicated use for that dosage, on the balance of probabilities, will have the effect of inducing or encouraging physicians to prescribe Novo-Lansoprazole for triple therapy.

[99] *Novopharm* was affirmed on appeal. In reviewing the application judge's conclusion of inducement arising from the PM in *Novopharm Limited v. Abbott Laboratories Limited*, 2007 FCA 251, 61 C.P.R. (4th) 97, this Court, *per* Justice Nadon, quoted several of the above paragraphs and held that the application judge's conclusion was open on the evidence and did not demonstrate a palpable and overriding error. This Court similarly affirmed the application judge's conclusion of induced infringement based on the product label.

[100] *MacLennan v. Produits Gilbert Inc.*, 2008 FCA 35, 67 C.P.R. (4th) 161, involved an appeal of a Federal Court decision holding that the patent holder failed to demonstrate the first element required for induced infringement, being direct infringement by the third party. This Court, *per* Justice Noël (as he then was), noted the Federal Court's reliance on the three-pronged test for induced infringement (which this Court referred to as "contributory infringement") at paragraph 13:

> In a short judgment, Beaudry J. noted at the outset that a three-pronged test must be applied to establish contributory infringement. First, there must be an act of infringement by the direct infringer. Second, this act must be influenced by the seller to the point where, without this influence, infringement by the buyer would not otherwise take place. Last, the influence must be knowingly exercised by the seller, i.e., the seller knows that this influence will result in the completion of the act of infringement (see *Dableh v. Ontario Hydro* (1996), 68 C.P.R. (3rd) 129 at pp. 148 and 149 (F.C.A.) as well as *Halford v. Seed Hawk Inc*. (2004), 31 C.P.R.

> (4th) 434 at pp. 559 and 560 (F.C.T.D.); and *AB Hassle v. Canada (Minister of National Health & Welfare)* (2001), 16 C.P.R. (4th) 21 at p. 42 (F.C.T.D.); aff. (2002), 22 C.P.R. (4th) 1 at para. 17 (F.C.A.)…).

[101] This Court considered the second prong of the induced infringement test. It wrote at paragraphs 33 and 34:

> In Canada, the courts have consistently held that selling a component intended to be incorporated in a patented combination (or process) without anything further, does not constitute an inducement to infringement, even where this component cannot be used for any other purpose; *Copeland-Chatterson Company Limited v. Hatton* (1906), 10 Ex. C.R. 224, aff. 1906, 37 S.C.R. 651 ("*Copeland-Chatterson*") was the first Canadian decision on this issue, and it adopted the British jurisprudence that was the source of this rule; in *Slater Steel* [*Industries Ltd. v. R. Payer Co. Ltd.* (1968) 55 C.P.R. 61 (Ex. Ct.)], there is a complete history of the evolution of the jurisprudence until 1964; François Grenier's article "*Contributory and/or Induced Patent Infringement*" (1987) 4 C.I.P.R. 26 provides an overview of the decisions rendered until the date it was published; among the more recent decisions, the following should be noted: *Valmet Oy et al. v. Beloit Canada Ltd.*, (1988) 20 C.P.R. (3d) 1 (F.C.A.) at p. 15; *Permacon Quebec Inc. et al. v. Les Entreprises Arsenault & Freres Inc. et al.*, (1987) 19 C.P.R. (3d) 378 (F.C.) at pp. 384 and 385; *AB Hassle et al. v. Minister of National Health and Welfare et al.*, (2002) 22 C.P.R. (4th) 1 (F.C.A.) at para. 18).
>
> This rule, which may seem questionable at first glance, is explained by the fact that in all the decisions that have applied it, only a combination (or process) was protected by the patent in question; the constituent parts (in particular, the tooth, in the case before us) were not. At the very least, it would be incongruous if the sale of an article, which in itself is not protected and which is therefore legal, becomes illegal without any other action being taken by the seller. That explains why the courts have traditionally refused to recognize that infringement by inducement can be founded on the mere characteristics of the article sold.

[102] This Court reviewed English case law and then summarized as follows at paragraph 38:

> As stated above, British law was followed in Canada beginning in 1906 (see *Copeland-Chatterson*, *supra*). Thus, in Canada, where the *Patent Act* has remained unchanged, the sale of a constituent part of a patented combination, even if this part cannot be used for anything other than infringing the invention, is not sufficient to establish the element of inducement. Apart from the existence of direct infringement, the evidence must establish that the influence of the alleged inducer constitutes a sine qua non of the direct infringement, and this influence

> must be exercised knowingly, i.e., in circumstances where the alleged inducer knew that his or her influence would result in the act of infringement (*AB Hassle*, *supra*, at par. 17).

[103] This Court then applied the law to the facts at paragraphs 39 to 42:

> In the case before us, the evidence indicates that the Gilbert teeth have no other use other than working the patented invention, which is not sufficient in itself to establish infringement by inducement. However, there is also evidence that Produits Gilbert gave its clients a price list that identified by number the Quadco teeth that corresponded to the Gilbert teeth and that were intended to be replaced by the Gilbert teeth.
>
> While, for the reasons given above, it is true that the sale of a component of a patented combination, even if the component has no use other than working the patented combination, is not sufficient to establish infringement by inducement, this state of affairs becomes inculpatory when the seller indicates to its clients the use that should be made of the component. We are no longer talking here about the mere fact that the seller knows or ought to know, by the type of article sold, that it will be used to infringe a patented combination (see *Innes*, *supra*, *Townsend*, *supra* and *Dunlop*, *supra*). The seller is making its clients aware of the fact that its product is intended to work the patented invention, which is the only reason they are buying it.
>
> As evidenced by its price list, Produits Gilbert believed it was necessary to indicate the intended use of its teeth in order to sell them. The fact that forestry operators were then able to assemble the combinations without any further explanation, alleviates nothing (examination on discovery of Gilbert's representative, read in at trial, appeal book, vol. 6, at pp. 1893, 1894).
>
> In these circumstances, I must find that Produits Gilbert, through its influence, caused the infringement of the Quadco patent. I also must conclude that Produits Gilbert knew that, without this influence, there would have been no infringement.

[104] *Corlac* involved an appeal from a decision finding patent infringement. This Court, *per* Justice Layden-Stevenson, returned the issue of induced infringement to the trial judge for redetermination because he had found infringement of a claim that was not directly infringed by the defendant and had failed to consider whether the defendants had induced infringement. In the

course of doing so, this Court described the test for induced infringement as follows at paragraph 162:

> It is settled law that one who induces or procures another to infringe a patent is guilty of infringement of the patent. A determination of inducement requires the application of a three-prong test. First, the act of infringement must have been completed by the direct infringer. Second, the completion of 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. Third, the influence must knowingly be exercised by the inducer, that is, the inducer knows that this influence will result in the completion of the act of infringement: *Dableh v. Ontario Hydro*, [1996] 3 F.C. 751, paras. 42, 43 (C.A.), leave to appeal refused, [1996] S.C.C.A. No. 441; *AB Hassle v. Canada (Minister of National Health and Welfare*, 2002 FCA 421, 22 C.P.R. (4th) 1, para. 17 (C.A.), leave to appeal refused, [2002] S.C.C.A. No. 531; *MacLennan v. Les Produits Gilbert Inc.*, 2008 FCA 35, 67 C.P.R. (4th) 161, para. 13. The test is a difficult one to meet.

[105] Nowhere did this Court indicate that the test for inducing infringement was anything other than what had been recognized in the case law prior to that date.

[106] In *Hospira* (F.C.), among the many issues was whether the generic manufacturer's product monograph induced infringement. The Federal Court, *per* Justice Phelan, described the test for induced infringement at paragraphs 326 and 327:

> There is a three-prong test for inducing infringement as held in *Corlac Inc v Weatherford Canada Inc*, 2011 FCA 228 at para 162, 95 CPR (4th) 101:
>
> > First, the act of infringement must have been completed by the direct infringer. Second, the completion of 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. Third, the influence must knowingly be exercised by the inducer, that is, the inducer knows that this influence will result in the completion of the act of infringement[.]
>
> Inducement of infringement by others of a claim for a new use of a medicine was discussed by the Federal Court of Appeal in *Novopharm Ltd v Sanofi-Aventis Canada Inc*, 2007 FCA 167, 59 CPR (4th) 24:

> [11] A generic drug manufacturer may be implicated in the infringement by others of a claim for a new use of a medicine if the generic drug manufacturer induces that infringement. Infringement by inducement may be established, for example, by inferences reasonably drawn from the contents of the product monograph for the generic drug product, or evidence relating to the dosage form of the generic product, or its labelling or marketing. However, an inducement to infringe generally cannot be inferred from a mere reference to the new use in the product monograph, for example, in the course of explaining contraindications or drug interactions, or as part of a list of scientific references.

[107] Justice Phelan in *Hospira* (F.C.) applied the law to the facts at the second prong of the analysis, stating:

> (b) *Influence by Hospira*
>
> [332] In *Glaston Services Ltd Oy v Horizon Glass & Mirrors Ltd*, 2010 FC 1191, 378 FTR 228, Mandamin J stated as follows:
>
> > [89] Inducement has been found in cases where an article is sold to a customer for an infringing purpose, together with instructions to use the article in an infringing way. Inducement has also been found where a seller provides a purchaser with instructions or directions for using an infringing method: *Windsurfing International Inc. v. Triatlantic Corporation* (now Bic Sports Inc.), [1984] 63 N.R. 218, 8 C.P.R. (3d) 241 at 264 to 266 (F.C.A.), *Baker Petrolite Corp. et al. v. Canwell Enviro-Industries Ltd. et al.* 2001 FCT 889, [2002] 2 F.C. 3 at paras. 135 to 139 (F.C.T.D.), rev'd on other grounds 2002 FCA 148, [2002] 17 C.P.R. (4th) 478.
>
> [333] In this case, I conclude that the product monograph amounts to instructions or directions for infringement. As discussed in more detail above, it clearly indicates that Inflectra should be used for combination therapy with MTX for the treatment of RA. The product monograph is not speculative – it does not merely list combination treatment with MTX as one option for RA patients, but rather indicates that this is the only option for treating RA. Kron's evidence was that doctors were instructed on-label, meaning that they would not instruct a non-infringing (i.e., monotherapy) method of administering Inflectra for RA treatment.

[108] This Court, *per* Justice Locke, in *Hospira* (F.C.A.) reviewed the trial judge's reasoning and concluded that there was no error in respect of the induced infringement.

[109] From this review of the case law, it is clear that *Corlac* did not change the law regarding the requisite element for inducing infringement. At the second step of the analysis, what is required is proof that the putative infringer influenced the party that directly infringes to the point that, without such encouragement, infringement would not have occurred (or, in the context of an application under the PMNOC Regulations, would not occur).

[110] In the case of a generic drug, inclusion as one of the recommended uses within the PM for the drug of the alleged infringing use, among others, has been found to be sufficient to constitute the requisite encouragement to satisfy the second prong of the test for inducement in *Hospira*, *AB Hassle*, and *Novopharm*. In such circumstances, the infringing use is one of the bases for approval of the generic drug by Health Canada and one of the uses recommended to physicians. It matters not that physicians use their own skill and judgment in dispensing the drug, nor that they must make an active choice to perform the infringing use, as physicians invariably exercise similar skill and judgment whenever a drug is prescribed to a patient.

[111] The facts in the case at bar are, as noted, similar to those in *Hospira*, where the infringing use was but one of several taught in the generic company's PM and product label. In addition, the facts in the case at bar, if anything, point more strongly to inducing infringement than those in *Genpharm* and *Novopharm*, where the references to the infringing use in the PM were more subtle than in the instant case.

[112] Here, the Federal Court found that the capable, approved and intended use for the Teva product incorporated all the dosing and administration elements of the product claims, including the use of the continuous maintenance doses claimed in the 335 Patent. This finding inevitably leads to the conclusion that Teva would induce infringement of the use claims. Had the Federal Court properly understood and applied the test for induced infringement, no other conclusion was possible.

[113] We accordingly determine that the Federal Court made a reviewable error at the second step of the analysis for inducing infringement and ought to have concluded that this step was met.

[114] This requires us to consider the third step of the analysis for inducing infringement, which was not considered by the Federal Court. As noted, that step requires the plaintiff to establish that the influence was (or, in the context of an application under the PMNOC Regulations, would be) knowingly exercised by the inducer such that the inducer knows that the influence will result in the completion of the act of infringement. As this Court held in *Hospira* (F.C.A.) at paragraph 45, "… the knowledge at issue in the third prong of the test is knowledge that the influence is being exercised, rather than knowledge that the resulting activity will be an infringement". Here, as in *Hospira*, the third element for inducing infringement is easily met as Teva must be presumed to have been aware of the contents of its PM and what it recommended.

[115] Therefore, had the Federal Court properly applied the test for inducing infringement, it would have found that Teva induced infringement of the use claims in claims 17 to 32 of the 335 Patent as all three steps of the test for inducing infringement are met.

[116] We would accordingly grant the cross-appeal and, in addition to the declarations made by the Federal Court, would also declare that the making, constructing, using or selling of the Teva-Paliperidone Injection prolonged release injectable suspensions of paliperidone palmitate by Teva in accordance with ANDS No. 210095 would induce infringement of claims 17 to 32 of the 335 Patent.

III. Proposed Disposition

[117] In light of the foregoing, we would dismiss the appeal and grant the cross-appeal, both with costs, and amend paragraph 2 of the Federal Court's judgment to also make the declaration set out in paragraph 116 of these reasons.

"David Stratas"
J.A.

"Mary J.L. Gleason"
J.A.

"Judith Woods"
J.A.

Appendix

The claims of the 335 Patent in suit are as follows:

CLAIMS:

1. Prefilled syringes containing a depot formulation of paliperidone as paliperidone palmitate formulated as an aqueous nanoparticle suspension for administration by intramuscular injection to a psychiatric patient in need of treatment for schizophrenia, schizoaffective disorder, or schizophreniform disorder, wherein the prefilled syringes comprise:

a) a first prefilled syringe containing a first loading dose of the depot formulation comprising about 150 mg-eq. of paliperidone as paliperidone palmitate, wherein the first prefilled syringe is adapted for intramuscular administration into a deltoid muscle of the psychiatric patient on a first day of treatment;

b) a second prefilled syringe containing a second loading dose of the depot formulation comprising about 100 mg-eq. of paliperidone as paliperidone palmitate, wherein the second prefilled syringe is adapted for intramuscular administration into a deltoid muscle of the psychiatric patient one week ~ 2 days after the first loading dose; and

c) a prefilled syringe containing a maintenance dose of the depot formulation comprising about 75 mg-eq. of paliperidone as paliperidone palmitate, wherein the prefilled syringe is adapted for intramuscular administration into a deltoid or a gluteal muscle of the psychiatric patient according to a continuous schedule having a monthly ~ 7 days dosing interval after the second loading dose.

2. Prefilled syringes containing a depot formulation of paliperidone as paliperidone palmitate formulated as an aqueous nanoparticle suspension for administration by intramuscular injection for treating a renally impaired psychiatric patient in need of treatment for schizophrenia, schizoaffective disorder, or schizophreniform disorder, wherein the prefilled syringes comprise:

a) a first prefilled syringe containing a first loading dose of the depot formulation comprising about 100 mg-eq. of paliperidone as paliperidone palmitate, wherein the first prefilled syringe is adapted for intramuscular administration into a deltoid muscle of the psychiatric patient on a first day of treatment;

b) a second prefilled syringe containing a second loading dose of the depot formulation comprising about 75 mg-eq. of paliperidone as paliperidone

palmitate, wherein the second prefilled syringe is adapted for intramuscular administration into a deltoid muscle of the psychiatric patient one week ~ 2 days after the first loading dose;

c) a prefilled syringe containing a maintenance dose of the depot formulation comprising about 50 mg-eq. of paliperidone as paliperidone palmitate, wherein the prefilled syringe is adapted for intramuscular administration into a deltoid or a gluteal muscle of the psychiatric patient according to a continuous schedule having a monthly ~ 7 days dosing interval after the second loading dose.

3. The prefilled syringes of claim 1 or claim 2, wherein the nanoparticles have an average particle size, d50 of from 1600 nm to 400 nm.

4. The prefilled syringes of claim 1 or claim 2, wherein the depot formulation consists essentially of

(a) from 3 to 20% w/v of the paliperidone palmitate nanoparticles having an average particle size, d50 of from 1600 nm to 900 nm;

(b) from 0.5 to 3% w/v of a surfactant or a wetting agent;

(c) one or more buffering agents, in an amount sufficient to provide the depot formulation with a pH between neutral and 8.5;

(d) from 0.5 to 3% w/v of a suspending agent;

(e) up to 2% w/v preservatives; and

(f) water q.s. ad 100%.

5. The prefilled syringes of claim 4, wherein the surfactant or the wetting agent is polysorbate 20.

6. The prefilled syringes of claims 4 or 5, wherein the suspending agent is polyethylene glycol 4000.

7. The prefilled syringes of claim 1 or claim 2, wherein the depot formulation consists of:

(a) about 156 mg/ml of the paliperidone palmitate nanoparticles having an average particle size, d50 of from 1600 nm to 900 nm;

(b) about 12 mg/ml of a surfactant or a wetting agent;

(c) one or more buffering agents in an amount sufficient to provide the depot formulation with a pH between neutral and 8.5;

(d) a suspending agent; and

(e) water q.s. ad 100%.

8. The prefilled syringes of claim 7, wherein the surfactant or the wetting agent is polysorbate 20 .

9. The prefilled syringes of claim 7 or claim 8, wherein the suspending agent is polyethylene glycol 4000.

10. The prefilled syringes of claims 1 or claim 2, wherein the depot formulation consists essentially of:

(a) about 156 mg/ml of the paliperidone palmitate nanoparticles having an average particle size, d50 of from 1600 nm to 900 nm;

(b) about 12 mg/ml of a surfactant or a wetting agent;

(c) one or more buffering agents in an amount sufficient to provide the depot formulation with a pH between neutral and 8.5;

(d) about 30 mg/ml of a suspending agent; and

(e) water q.s. ad 100%.

11. The prefilled syringes of claim 10, wherein the surfactant or the wetting agent is polysorbate 20.

12. The prefilled syringes of claim 10 or claim 11, wherein the suspending agent is polyethylene glycol 4000.

13. The prefilled syringes of any one of claims 4 to 12, wherein the one or more buffering agents are selected from the group consisting of citric acid monohydrate, disodium hydrogen phosphate anhydrous, sodium dihydrogen phosphate monohydrate, and sodium hydroxide.

14. The prefilled syringes of any one of claims 4 to 13, wherein the pH of the depot formulation is in the range of 7 to 7.5.

15. The prefilled syringes of any one of claims 1 to 14, wherein the prefilled syringes are for administration to a psychiatric patient in need of treatment for schizophrenia.

16. The prefilled syringes of any one of claims 1 to 14, wherein the prefilled syringes are for administration to a psychiatric patient in need of treatment for schizoaffective disorder.

17. Use of a dosage form of paliperidone as paliperidone palmitate formulated as a depot formulation of an aqueous nanoparticle suspension for administration by intramuscular injection for treating a psychiatric patient in need of treatment

for schizophrenia, schizoaffective disorder, or schizophreniform disorder, wherein the dosage form comprises:

a) a first loading dose comprising about 150 mg-eq. of the depot formulation of paliperidone as paliperidone palmitate adapted for intramuscular administration into a deltoid muscle of the psychiatric patient on a first day of treatment;

b) a second loading dose comprising about 100 mg-eq. of the depot formulation of paliperidone as paliperidone palmitate in a dosage form adapted for intramuscular administration into a deltoid muscle of the psychiatric patient one week ~ 2 days after the first loading dose; and

c) a maintenance dose comprising about 75 mg-eq. of the depot formulation of paliperidone as paliperidone palmitate adapted for intramuscular administration into a deltoid or a gluteal muscle of the psychiatric patient according to a continuous schedule having a monthly ~ 7 days dosing interval after the second loading dose.

18. Use of a dosage form of paliperidone as paliperidone palmitate formulated as a depot formulation of an aqueous nanoparticle suspension for administration by intramuscular injection for treating a renally impaired psychiatric patient in need of treatment for schizophrenia, schizoaffective disorder, or schizophreniform disorder, wherein the dosage form comprises:

a) a first loading dose comprising about 100 mg-eq. of the depot formulation of paliperidone as paliperidone palmitate in a dosage form adapted for intramuscular administration into a deltoid muscle of the psychiatric patient on a first day of treatment;

b) a second loading dose comprising about 75 mg-eq. of the depot formulation of paliperidone as paliperidone palmitate in a dosage form adapted for intramuscular administration into a deltoid muscle of the psychiatric patient one week ~ 2 days after the first loading dose; and

c) a maintenance dose comprising about 50 mg-eq. of paliperidone as paliperidone palmitate in a dosage form adapted for intramuscular administration into a deltoid or a gluteal muscle of the psychiatric patient according to a continuous schedule having a monthly ~7 days dosing interval after the second loading dose.

19. The use of claim 17 or claim 18, wherein the nanoparticles have an average particle size, d50 of from 1600 nm to 400 nm.

20. The use of claim 17 or claim 18, wherein the depot formulation is an aqueous nanoparticle suspension consisting essentially of

(a) from 3 to 20% w/v of the paliperidone palmitate nanoparticles having an average particle size, d50 of from 1600 nm to 900 nm;

(b) from 0.5 to 3% w/v of a surfactant or a wetting agent;

(c) one or more buffering agents in an amount sufficient to provide the depot formulation with a pH between neutral and 8.5;

(d) from 0.5 to 3% w/v of a suspending agent;

(e) up to 2% w/v preservatives; and

(f) water q.s. ad 100%.

21. The use of claim 20, wherein the surfactant or the wetting agent is polysorbate 20.

22. The use of claim 20 or claim 21, wherein the suspending agent is polyethylene glycol 4000.

23. The use of claim 17 or claim 18, wherein the depot formulation consists essentially of:

(a) about 156 mg/ml of the paliperidone palmitate nanoparticles having an average particle size, d50 of from 1600 nm to 900 nm;

(b) about 12 mg/ml of a surfactant or a wetting agent;

(c) one or more buffering agents in an amount sufficient to provide the depot formulation with a pH between neutral and 8.5;

(d) a suspending agent; and

(e) water q.s. ad 100%.

24. The use of claim 23, wherein the surfactant or the wetting agent is polysorbate 20.

25. The use of claim 23 or claim 24, wherein the suspending agent is polyethylene glycol 4000.

26. The use of claim 17 or claim 18, wherein the depot formulation consists essentially of:

(a) about 156 mg/ml of the paliperidone palmitate nanoparticles having an average particle size, d50 of from 1600 nm to 900 nm;

(b) about 12 mg/ml of a surfactant or a wetting agent;

(c) one or more buffering agents in an amount sufficient to provide the depot formulation with a pH between neutral and 8.5;

(d) about 30 mg/ml of a suspending agent; and

(e) water q.s. ad 100%.

27. The use of claim 26, wherein the surfactant or the wetting agent is polysorbate 20.

28. The use of claim 26 or claim 27, wherein the suspending agent is polyethylene glycol 4000.

29. The use of any one of claims 20 to 28, wherein the buffering agent is selected from the group consisting of citric acid monohydrate, disodium hydrogen phosphate anhydrous, sodium dihydrogen phosphate monohydrate, and sodium hydroxide.

30. The use of any one of claims 20 to 29, wherein the pH of the depot formulation is in the range of 7 to 7.5.

31. The use of any one of claims 17 to 30, wherein the psychiatric patient is in need of treatment for schizophrenia.

32. The use of any one of claims 17 to 30, wherein the psychiatric patient is in need of treatment for schizoaffective disorder.

33. A use of paliperidone as paliperidone palmitate for the preparation of a medicament formulated as a depot formulation of an aqueous nanoparticle suspension for administration by intramuscular injection for treating a psychiatric patient in need of treatment for schizophrenia, schizoaffective disorder, or schizophreniform disorder, wherein the medicament comprises:

a) a first loading dose comprising about 150 mg-eq. of the depot formulation of paliperidone as paliperidone palmitate in a medicament form adapted for intramuscular administration into a deltoid muscle of the psychiatric patient on a first day of treatment;

b) a second loading dose comprising about 100 mg-eq. of the depot formulation of paliperidone as paliperidone palmitate in a medicament form adapted for intramuscular administration into a deltoid muscle of the psychiatric patient one week ~ 2 days after the first loading dose; and

c) a maintenance dose comprising about 75 mg-eq. of paliperidone as paliperidone palmitate in a medicament form adapted for intramuscular administration into a deltoid or a gluteal muscle of the psychiatric patient according to a continuous schedule having a monthly ~7 days dosing interval after the second loading dose.

34. Use of paliperidone as paliperidone palmitate in the manufacture of a medicament formulated as a depot formulation of an aqueous nanoparticle suspension for administration by intramuscular injection for treating a renally impaired psychiatric patient in need of treatment for schizophrenia, schizoaffective disorder, or schizophreniform disorder, wherein the medicament comprises:

a) a first loading dose comprising about 100 mg-eq. of the depot formulation of paliperidone as paliperidone palmitate in a medicament form adapted for intramuscular administration into a deltoid muscle of the psychiatric patient on a first day of treatment;

b) a second loading dose comprising about 75 mg-eq. of the depot formulation of paliperidone as paliperidone palmitate in a medicament form adapted for intramuscular administration into a deltoid muscle of the psychiatric patient one week ~ 2 days after the first loading dose; and

c) a maintenance dose comprising about 50 mg-eq. of the depot formulation of paliperidone as paliperidone palmitate in a medicament form adapted for intramuscular administration into a deltoid or a gluteal muscle of the psychiatric patient according to a continuous schedule having a monthly ~ 7 days dosing interval after the second loading dose.

35. The use of claim 33 or claim 34, wherein the nanoparticles have an average particle size, d50 of from 1600 nm to 400 nm.

36. The use of claim 33 or claim 34, wherein the depot formulation is an aqueous nanoparticle suspension consisting essentially of

(a) from 3 to 20% w/v of the paliperidone palmitate nanoparticles having an average particle size, d50 of from 1600 nm to 900 nm;

(b) from 0.5 to 3% w/v of a surfactant or a wetting agent;

(c) one or more buffering agents in an amount sufficient to provide the depot formulation with a pH between neutral and 8.5;

(d) from 0.5 to 3% w/v of a suspending agent;

(e) up to 2% w/v preservatives; and

(f) water q.s. ad 100%.

37. The use of claim 36, wherein the surfactant or the wetting agent is polysorbate 20.

38. The use of claim 36 or claim 37, wherein the suspending agent is polyethylene glycol 4000.

39. The use of claim 33 or claim 34, wherein the depot formulation consists essentially of:

(a) about 156 mg/ml of the paliperidone palmitate nanoparticles having an average particle size, d50 of from 1600 nm to 900 nm;

(b) about 12 mg/m1 of a surfactant or a wetting agent;

(c) one or more buffering agents in an amount sufficient to provide the depot formulation with a pH between neutral and 8.5;

(d) a suspending agent; and

(e) water q.s. ad 100%.

40. The use of claim 39, wherein the surfactant or the wetting agent is polysorbate 20.

41. The use of claim 39 or claim 40, wherein the suspending agent is polyethylene glycol 4000.

42. The use of claim 33 or claim 34, wherein the depot formulation consists essentially of:

(a) about 156 mg/ml of the paliperidone palmitate nanoparticles having an average particle size, d50 of from 1600 nm to 900 nm;

(b) about 12 mg/ml of a surfactant or a wetting agent;

(c) one or more buffering agents in an amount sufficient to provide the depot formulation with a pH between neutral and 8.5;

(d) about 30 mg/ml of a suspending agent; and

(e) water q.s. ad 100%.

43. The use of claim 42, wherein the surfactant or the wetting agent is polysorbate 20.

44. The use of claim 42 or claim 43, wherein the suspending agent is polyethylene glycol 4000.

45. The use of any one of claims 36 to 44, wherein the buffering agent is selected from the group consisting of citric acid monohydrate, disodium hydrogen phosphate anhydrous, sodium dihydrogen phosphate monohydrate, and sodium hydroxide.

46. The use of any one of claims 36 to 45, wherein the pH of the depot formulation is in the range of pH 7 to 7.5.

47. The use of any one of claims 33 to 46, wherein the medicament is for administration to a psychiatric patient in need of treatment for schizophrenia.

48. The use of any one of claims 33 to 46, wherein the medicament is for administration to a psychiatric patient in need of treatment for schizoaffective disorder.

[…]

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

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