

IN THE SUPREME COURT OF CANADA
(ON APPEAL FROM THE FEDERAL COURT OF APPEAL)

B E T W E E N:

PHARMASCIENCE INC.

APPELLANT

and

JANSSEN INC. and JANSSEN PHARMACEUTICA N.V.

RESPONDENTS

FACTUM

(JANSSEN INC. AND JANSSEN PHARMACEUTICA N.V., RESPONDENTS)

(Pursuant to Rule 42 of the *Rules of the Supreme Court of Canada*)

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PART I: OVERVIEW AND STATEMENT OF FACTS

A. Overview

1. The patent that is being challenged in this appeal involves the very type of “inventive solutions to practical problems” for which the patent regime was developed.¹

2. The “practical problems” addressed by the patent are the serious challenges that schizophrenia patients face in complying with a treatment plan that requires them to take pills every day. Schizophrenia is a serious mental health condition that affects more than 300,000 Canadians. Prior to the invention that is the subject of this appeal, up to 75% of schizophrenia patients experienced difficulty adhering to any of the treatment options that were available. Patients’ inability to adhere to the prior treatments often resulted in a worsening of symptoms, suboptimal responses, relapses and rehospitalizations, and sometimes even death.²

3. The “inventive solution” is INVEGA SUSTENNA[®], an injectable product comprised of a series of prefilled syringes of specified doses that, when administered according to the novel dosing regimens set forth in CA Patent No. 2,655,335 (the “**335 Patent**”), attain both long- and fast-acting efficacy without pills. The drug has dramatically improved the lives of schizophrenia patients in Canada and around the world.³ The heart of the invention is the dosing regimens, which make it significantly easier for patients with schizophrenia to adhere to their medication. The reason Pharmascience challenges the patentability of this invention is not a concern about “methods of medical treatment (“**MMT**”), but because it wishes to market its own generic commercial offering.

4. Inventing INVEGA SUSTENNA as a solution for the compliance challenges of schizophrenia patients required massive investments and two decades of research and development (“**R&D**”). Janssen persevered in the face of uncertainty after initial dosing approaches failed, eventually developing the novel dosing regimens described and claimed in the 335 Patent (one

¹ *Apotex Inc v Wellcome Foundation Ltd*, [2002 SCC 77](#) at para [37](#) [*AZT Case*].

² CA Patent No 2,655,335 at 2, lines 1-5, Appeal Book [AB], Volume [V] 1, Tab [T] 14 [335 Patent].

³ See e.g., *JL v Powe*, [2024 ONSC 5254](#) at paras [24](#), [34-35](#).

regimen for patients who do not have renal impairment, and one for those who do). The dosing regimens are the gravamen of the invention; they are the key to an effective treatment that solves the problem for which the drug was invented. In contrast with the non-economic nature of the professional field of treating physicians, drug manufacturers operate in a commercial field in which exclusive rights are critical to ensure that the R&D needed to discover medical innovations like the 335 Patent (and losses from unsuccessful efforts to invent new treatments) can be recouped. If there is no commercial value the R&D will not be undertaken, and patients will suffer.

5. The patent system is predicated on a bargain: in exchange for a time-limited monopoly, “inventive solutions to practical problems are coaxed into the public domain.”⁴ As this Court recently held, “[t]he rationale for the patent system is that it provides an incentive to invent.”⁵ Janssen fulfilled its end of the bargain by inventing and disclosing the useful, novel, and non-obvious dosing regimens described in the 335 Patent.

6. Pharmascience, a generic drug manufacturer, would like to benefit from the success of INVEGA SUSTENNA. To market a copycat product during the period when the *Patent Act*⁶ grants Janssen a monopoly, Pharmascience needs to have the 335 Patent declared invalid. The problem for Pharmascience is that the 335 Patent is unquestionably valid under the *Patent Act*’s rigorous criteria for patentability, including usefulness, novelty, and non-obviousness. As a result, the 335 Patent has repeatedly withstood validity challenges on inventiveness (i.e., obviousness) brought by generic drug companies that want to copy INVEGA SUSTENNA.⁷ No issue of novelty, obviousness, infringement, or any other question specific to the 335 Patent is at issue in this appeal.

7. Instead, Pharmascience claims that *all* dosing regimens, including the 335 Patent, are categorically unpatentable MMT.⁸ The premise of Pharmascience’s argument is that dosing regimen patents interfere with physicians’ treatment decisions. As the facts of this case illustrate, that premise is incorrect. No treatment decision made by a physician in prescribing INVEGA

⁴ *AZT Case* at para 37.

⁵ *Nova Chemicals Corp v Dow Chemical Co*, [2022 SCC 43](#) at para 177.

⁶ *Patent Act*, [RSC 1985, c P-4](#) [*Patent Act*].

⁷ See paras 30-35 below.

⁸ Pharmascience Factum at para 10.

SUSTENNA is ever constrained by Janssen's patent. A physician who uses Janssen's INVEGA SUSTENNA products in accordance with the patented dosing regimens has a licence from Janssen to do so and does not infringe the patent. A physician who prescribes the INVEGA SUSTENNA commercial offering but with a different dosing regimen that, in his or her medical judgment, is more appropriate for the patient does not infringe Janssen's patent, which narrowly covers only the specific patented dosing regimens.

8. Janssen's patent precludes only other manufacturers like Pharmascience from offering for sale a generic product for use in accordance with Janssen's patented dosing regimens prior to the expiry of the patent. That is why this case, like *all reported cases involving drug patents*, is a dispute between drug companies, to which no physician is a party. Far from worrying about interference with physicians' treatment decisions, Pharmascience is challenging Janssen's patent because it wants to share the commercial benefit of Janssen's investments and discoveries without allowing Janssen its statutorily allowed period of exclusivity.

9. The only questions in this appeal are: (i) whether MMT are ineligible for patents; and (ii) if so, whether Janssen's claims in the 335 Patent constitute unpatentable MMT.

10. Janssen submits that: (i) because s. 41 of the *Patent Act* upon which this Court previously relied in concluding that MMT were ineligible subject matter has been repealed, there is no longer a sound basis in the *Patent Act* to make MMT unpatentable; and (ii) to the extent this Court reads any MMT exclusion into the *Patent Act*, as in peer jurisdictions, it should be limited to activities of physicians that are "non-economic" in the sense of lacking practical application in commerce or industry.⁹ It should not extend to commercial offerings, such as drugs, medical devices and their uses, including dosing regimens such as those claimed in the 335 Patent. The rigorous criteria in the *Patent Act* (including the novelty, non-obviousness and utility requirements) are sufficient to ensure that any dosing regimen that would not fulfil the patent bargain would be invalid.

⁹ *Apotex Pty Ltd v Sanofi-Aventis Australia Pty Ltd*, [2013] HCA 50 at para 278 (Austl HC) [*Apotex v Sanofi AUS*]; see also *Shell Oil Co v Commissioner of Patents*, [1982] 2 SCR 536 at 554, 1982 CanLII 207 (SCC) [*Shell Oil*]; *AZT Case* at para 49; *Lawson v Commissioner of Patents* (1970), 1970 CarswellNat 361 at para 36, 62 CPR 101 [*Lawson*], Pharmascience Book of Authorities [BOA], Tab 3.

11. The *Patented Medicines (Notice of Compliance) Regulations* (“**PMNOC Regulations**”) further demonstrate that dosing regimens are patentable. These regulations, which govern the present proceedings, protect certain types of patent claims against generic entry prior to the expiry of the patent or a finding of non-infringement or invalidity.¹⁰ The Regulatory Impact Analysis Statement (“**RIAS**”) that accompanied amendments to the *PMNOC Regulations* that defined the types of drug patent claims eligible for protection specifically identifies dosing regimens as eligible.¹¹ Even if this Court decides to read an MMT preclusion into the *Patent Act*, it should not extend to claims that the government intended to protect in the *PMNOC Regulations*, such as dosing regimens.¹² This Court has previously held that a RIAS can be used to assist in interpreting the *Patent Act*.¹³

12. Pharmascience’s proposed legal test, which it acknowledges would make all dosing regimen patents invalid in Canada, is inconsistent with this Court’s prior decisions. While Pharmascience purports to rely on *Apotex Inc v Wellcome Foundation Ltd* (the “**AZT Case**”) as the basis for its “how and when” test, its proposed test would in fact overturn the result in that case. In the *AZT Case*, this Court held that the use of an existing medicine to treat a new condition is patentable because it has commercial value. The patent upheld by this Court included claims for a “pharmaceutical formulation for use in the treatment or prophylaxis of AIDS comprising an effective amount of 3'-azido-3'-deoxythymidine in association with a pharmaceutically acceptable carrier”, with some claims further specifying “an amount effective to provide a unit dose of 10 to 1500 mg.”¹⁴ The fact that the claims described when (i.e., when treating AIDS) and how (i.e., using effective amounts, including the specified dose range) to prescribe a previously known

¹⁰ *Patented Medicines (Notice of Compliance) Regulations*, [SOR/93-133](#) [*PMNOC Regulations*].

¹¹ *Regulatory Impact Analysis Statement*, SOR/2006-242, *Canadian Gazette Part II*, [Vol 140, No 21](#) at [1517](#) [*RIAS*].

¹² *PMNOC Regulations* at ss [2\(1\)](#), [4\(2\)\(a\)](#), [\(b\)](#), [\(c\)](#), [\(d\)](#).

¹³ *Bristol-Myers Squibb Co v Canada (Attorney General)*, [2005 SCC 26](#) at [para 46](#) (per Binnie J. for the majority) and at paras [155-156](#) (per Bastarache J. dissenting, but not on this point) [*Bristol-Myers Squibb*].

¹⁴ *Apotex Inc v Wellcome Foundation Ltd*, 1998 CarswellNat 458, at paras 294, 318, 323 [emphasis in original], [1998] FCJ No 382 [*AZT FC*], Janssen BOA, Tab 2, aff’d [2000 CanLII 16270](#) (FCA) [*AZT FCA*], aff’d *AZT Case*.

compound, did not make them unpatentable. Rather, what mattered was that the right sought was to provide a drug as a commercial offering. This Court held that such claims are not MMT.

13. Accepting Pharmascience’s invitation to declare dosing regimens ineligible for patent protection would isolate Canada from its peer jurisdictions. While comparable jurisdictions vary as to whether *non-commercial activities* of physicians are unpatentable, they are unanimous in granting patent protection to new and non-obvious *dosing regimens of medicines*. For example, in *Actavis v Merck*, the UK Court of Appeal emphasized the importance of the patent bargain to encourage research, including into more effective dosing regimens:

The reason is obvious—the 1 mg pill has only come about because of expensive unpredictable research. Patented things often cost more. And the reason is because the monopoly has been given as result of the research which led to it. Research into new and better dosage regimes is clearly desirable—and there is simply no policy reason why, if a novel non-obvious regime is invented, there should not be an appropriate patent reward[....]¹⁵

If this Court were to adopt Pharmascience’s test, Canada would be unique among its peers in denying patent protection to these beneficial inventions.

14. In a final effort to justify its sweeping proposal, Pharmascience raises the spectre of evergreening. As this Court has already held, generalized concerns about evergreening cannot justify excising an entire category of patents from the *Patent Act*.¹⁶ In *Whirlpool Corp v Camco Inc* (“*Whirlpool*”), this Court instead adopted a broad test for precluding “double patents” to address evergreening.¹⁷ Enforcement of the ordinary criteria in the *Patent Act* (including the *Whirlpool* test) ensures that only claims to inventions that actually fulfil the patent bargain are upheld.

15. INVEGA SUSTENNA demonstrates what would be lost to healthcare in Canada if R&D into inventive dosing regimens was no longer economical for innovative drug companies.

¹⁵ *Actavis UK Ltd v Merck & Co Inc*, [\[2008\] EWCA Civ 444](#) at para 29 [*Actavis*].

¹⁶ *Apotex Inc v Sanofi-Synthelabo Canada Inc*, [2008 SCC 61](#) at paras 98, 100 [*Sanofi*].

¹⁷ *Whirlpool Corp v Camco Inc*, [2000 SCC 67](#) at para 66 [*Whirlpool*]; *Sanofi* at paras 112-113.

Schizophrenia patients would still be struggling to comply with daily pill protocols, and many would still be losing that battle.

B. The 335 Patent

16. The 335 Patent is titled “Prolonged-Release Injectable Suspensions of Paliperidone Palmitate and Dosage Forms and Delivery Systems Incorporating Same.”¹⁸ It is listed on the Patent Register in respect of INVEGA SUSTENNA, a long-acting injectible (“LAI”) drug. All of the claims in the 335 Patent include the essential feature of a novel specific dosing regimen (and an adapted dosing regimen for renally-impaired patients) designed to ensure an optimum plasma concentration-time profile of the drug when used to treat patients with schizophrenia.¹⁹

- a. **Claims 1-16:** claim a combination of prefilled syringes of a depot formulation (i.e., LAI) of paliperidone palmitate, which are adapted for administration according to the claimed dosing regimens.²⁰ The Federal Court (“FC”) determined these were “product” claims.²¹
- b. **Claims 17-32:** claim the use of a “dosage form” (i.e., pre-filled syringe) of paliperidone palmitate formulated as a depot formulation in accordance with the claimed dosing regimens.²² The FC determined these were “use” claims.²³
- c. **Claims 33-48:** claim a use of paliperidone palmitate for the preparation of a medicament adapted for administration according to the claimed dosing regimens.²⁴ The FC determined these were Swiss-type “product” claims.²⁵

¹⁸ *Janssen Inc v Pharmascience Inc*, [2022 FC 1218](#) at para [28](#) [*Trial Decision*], Appellant’s Record [AR], T2.

¹⁹ *Trial Decision* at paras [31-35](#), AR, T2.

²⁰ *Trial Decision* at para [34](#), AR, T2; 335 Patent at claims 1-16, AB, V1, T14.

²¹ *Trial Decision* at para [99](#), AR, T2.

²² *Trial Decision* at para [34](#), AR, T2; 335 Patent at claims 17-32, AB, V1, T14.

²³ *Trial Decision* at para [104](#), AR, T2.

²⁴ *Trial Decision* at para [34](#), AR, T2; 335 Patent at claims 33-48, AB, V1, T14.

²⁵ *Trial Decision* at para [109](#), AR, T2.

d. **Claims 49-63:** claim a dosage form of paliperidone palmitate formulated as a depot formulation, adapted for administration according to the claimed dosing regimens.²⁶ The FC determined these were “product” claims.²⁷

17. The categorization of certain of these sets of claims as “product” claims, and claims 17-32 as “use” claims is not at issue in this appeal. Indeed, despite now arguing that it is “form over substance,” in the lower courts Pharmascience relied on construction of most of the claims as product claims as supporting its position that it was not infringing the 335 Patent.

18. Schizophrenia is a debilitating and incurable chronic illness affecting about 1% of the population.²⁸ Effective management requires life-long treatment to control symptoms, particularly with antipsychotic drugs.²⁹ These are generally classified as either “first-generation” or “second-generation” based on the receptors they target in the brain.³⁰ First-generation antipsychotics are associated with significant drawbacks.³¹

19. Prior to the 335 Patent, schizophrenia patients typically took second generation antipsychotics daily by oral tablet.³² The 335 Patent notes that “it is estimated that up to 75% have difficulty adhering to a daily oral treatment regime.”³³ Among other challenges, there were serious practical problems with patients believing they were well enough to stop taking them, and then becoming too ill to comply, resulting in a vicious cycle of illness. As found by the trial judge in a related case: “A leading cause of relapse is non-adherence, where patients do not take their

²⁶ *Trial Decision* at para [34](#), AR, T2; 335 Patent at claims 49-63, AB, V1, T14.

²⁷ *Trial Decision* at para [111](#), AR, T2.

²⁸ Expert Statement of Larry Ereshefsky at para 72, AB, V17, T97 [Ereshefsky Report]; *Trial Decision* at para [4](#), AR, T2.

²⁹ Ereshefsky Report at paras 78-83, 107, AB, V17, T97; Expert Statement of Pierre Chue at paras 47, 56 [Chue Report], AB, V18, T121; *Trial Decision* at paras [8](#), [11](#) AR, T2.

³⁰ *Trial Decision* at paras [8-10](#), AR, T2.

³¹ *Trial Decision* at para [9](#), AR, T2; Chue Report at para 50, AB, V18, T121; Ereshefsky Report at paras 108, 114, 370, 430, AB, V17, T97.

³² Ereshefsky Report at para 119, see also paras 115, 125, 353, AB, V17, T97. The only second-generation LAI at the time was a biweekly injection requiring supplementation with daily oral tablets for an extended period: Chue Report at paras 52-53, 57, 87, AB, V18, T121.

³³ 335 Patent at 2, lines 1-5, AB, V1, T14; see also Chue Report at para 56, AB, V18, T121; Ereshefsky Report at para 107, AB, V17, T97.

antipsychotic medication as prescribed, or at all.”³⁴ Oral medications led to more frequent and longer hospitalization.³⁵

20. INVEGA SUSTENNA is the first of its kind: a second-generation, monthly LAI antipsychotic formulation of the drug paliperidone palmitate,³⁶ which achieves rapid and sustained efficacy and does not need to be supplemented with oral medication.³⁷ The 335 Patent teaches that using the claimed dosing regimens will allow patients to quickly attain and maintain optimum therapeutic blood plasma concentrations of the drug targeted for efficacy and to minimize side effects.³⁸ The primary dosing regimen comprises:

- (a) a first loading dose of 150 mg administered in the deltoid muscle on day 1;
- (b) a second loading dose of 100 mg administered in the deltoid muscle on day 8 ± 2 days; and
- (c) monthly ± 7 days maintenance doses of 75 mg thereafter, administered either in the deltoid or gluteal muscle.

The 335 Patent also claims a separate dosing regimen for patients with renal impairment (loading doses of 100 and then 75 mg, and monthly maintenance doses of 50 mg).³⁹

C. The 335 Patent Invention Story

21. The path to bring INVEGA SUSTENNA to patients was long and challenging. The work spanned approximately 20 years⁴⁰ and involved a large R&D team with dozens of scientists and

³⁴ *Janssen Inc v Teva Canada Ltd*, [2020 FC 593](#) at para [11](#) [*Teva*].

³⁵ 335 Patent at 2, lines 1-5, AB, V1, T14.

³⁶ Paliperidone and paliperidone palmitate are distinct compounds, with paliperidone palmitate being the palmitate ester of paliperidone. See 335 Patent at 1, line 17, AB, V1, T14; Ereshefsky Report at paras 166-167, AB, V17, T97.

³⁷ *Trial Decision* at paras [25](#), [37](#), [133\(i\)](#), [139\(ii\)](#), [153](#), AR, T2; Affidavit of Ofer Agid [Agid Affidavit] at para 46, AB, V19, T127.

³⁸ 335 Patent at 2, lines 6-16, 11, lines 17-22, 12, lines 3-25, AB, V1, T14.

³⁹ *Pharmascience Inc v Janssen Inc*, [2024 FCA 23](#) at para [2](#), AR, T5 [*FCA Decision*].

⁴⁰ Affidavit of An Vermeulen at para 31 [Vermeulen Affidavit], AB, V10, T55; *Teva* at para [21](#).

specialists with expertise in multiple disciplines, including clinical pharmacology, formulation, pharmacometrics, biostatistics, clinical trials and regulatory requirements.⁴¹

22. A central goal of the project was to fulfil the longstanding clinical need for an LAI that was both rapidly effective and long acting.⁴² Achieving this objective depended to a large extent on discovering a novel approach to dosing. Even though it was known that paliperidone palmitate should work to treat schizophrenia, until Janssen spent decades developing an effective and safe dosing regimen, no drug could attain authorization to market from Health Canada.

23. Developing a dosing regimen for a LAI requires an understanding of complex pharmacokinetic (“PK”) and pharmacodynamic (“PD”) properties of the drug.⁴³ Information about these properties is derived from clinical trials, which are divided into three phases. The outcome of clinical trials is inherently uncertain; the overall “success rate of new drug development from conception to new drug registration is 7.9%.”⁴⁴

24. Janssen first conducted a number of Phase I clinical studies to determine safety.⁴⁵ Janssen initially hypothesized that deltoid and gluteal injections could be used interchangeably, which would provide flexibility to doctors and patients. However, deltoid injections resulted in a faster rise in blood plasma concentrations. Given the unexpected finding Janssen shelved the use of the deltoid injection site for safety reasons until it had more data.⁴⁶ Janssen then conducted preliminary tests of different dosing strategies in preparation for the Phase II clinical study, including (i) administering a double (maintenance) dose on day 1, and monthly dosing thereafter;

⁴¹ Vermeulen Affidavit at para 23, AB, V10, T55; Affidavit of Srihari Gopal at paras 12, 14 [Gopal Affidavit], AB, V1, T16.

⁴² Vermeulen Affidavit at paras 41, AB, V10, T55; Gopal Affidavit at paras 62, 86, AB, V1, T16.

⁴³ Ereshefsky Report at paras 136, 547, AB, V17, T97. PK properties describe how the drug enters, moves through, and then leaves the body: Ereshefsky Report at para 137, 145, AB, V17, T97. PD properties describe the effect drugs have on the body once administered, including how much drug is needed to elicit a response: Ereshefsky Report at para 153, AB, V17, T97.

⁴⁴ Eungdo Kim et al, “Factors Affecting Success of New Drug Clinical Trials” (2023) 11 Ther Innov Regul Sci 1 at 2, [online](#); Ereshefsky Report at para 162, AB, V17, T97; Chue Report at paras 140, 165, AB, V18, T121.

⁴⁵ Vermeulen Affidavit at paras 31-42, 46-60, AB, V10, T55.

⁴⁶ Vermeulen Affidavit at paras 56-58, AB, V10, T55.

and (ii) administering the same “fixed” (maintenance) dose on days 1 and 8 with monthly dosing thereafter, where all doses were administered into the gluteal muscle.⁴⁷ Only the dosing regimen with fixed dosing on days 1 and 8 resulted in sufficient blood plasma drug concentrations within the first month of treatment, which was surprising to the inventors.⁴⁸

25. This dosing strategy was studied in the Phase II clinical study, which showed promising results.⁴⁹ The Phase III clinical trials program was designed based on this same dosing schedule.⁵⁰ Janssen’s Phase III program consisted of multiple large-scale clinical studies enrolling over 850 patients across 74 study center locations around the world.⁵¹

26. Unfortunately, the results of the Phase III clinical trials were unexpectedly poor.⁵² The dosing regimens did not achieve rapid efficacy, resulted in low blood plasma concentrations, and there were high rates of patients discontinuing the trial, primarily due to low efficacy.⁵³ The inventors described this as a “crisis situation” as they believed “all the work [they] had done so far was now at risk”⁵⁴ and they “didn’t even know if [they] would be able to overcome these findings, and if [they] would find a solution in a reasonable time frame.”⁵⁵ Following statistical, PK, and clinical analyses, the inventors identified the problem: a correlation between high patient body mass index and slower release of the drug.⁵⁶ This was an unanticipated and surprising outcome, resulting in the team creating a special task force in the company to consider many potential

⁴⁷ Vermeulen Affidavit at paras 48-49, AB, V10, T55.

⁴⁸ Vermeulen Affidavit at paras 47-50, AB, V10, T55; Vermeulen In-chief, Trial Transcript Day 3 at 334:15-336:10, AB, V20, T135; Ereshefsky Report at para 148, AB, V17, T97.

⁴⁹ Vermeulen Affidavit at paras 61-63, AB, V10, T55; Vermeulen In-chief, Trial Transcript Day 3 at 336:20-337:10, AB, V20, T135; Gopal Affidavit at paras 26-29, AB, V1, T16.

⁵⁰ Vermeulen Affidavit at para 64, AB, V10, T55.

⁵¹ Vermeulen Affidavit at para 64, AB, V10, T55; Gopal Affidavit at para 29, AB, V1, T16; Janssen Production [Prod] 47 at 261, AB, V5, T24; Janssen Prod 48 at 1, AB, V6, T25; Janssen Prod 49 at 65, AB, V6, T26; Janssen Prod 50 at 1, AB, V7, T27.

⁵² See Vermeulen Affidavit at paras 72-74, AB, V10, T55; Gopal Affidavit at para 40, AB, V1, T16; Affidavit of Mahesh Samtani at para 17 [Samtani Affidavit], AB, V17, T85.

⁵³ Vermeulen Affidavit at paras 64, 67, 69, 73, AB, V10, T55.

⁵⁴ Vermeulen In-chief, Trial Transcript Day 3 at 338:17-18, AB, V20, T135.

⁵⁵ Vermeulen In-chief, Trial Transcript Day 3 at 338:21-23, AB, V20, T135.

⁵⁶ Vermeulen Affidavit at paras 79, 80, AB, V10, T55; Gopal Affidavit at paras 32-35, 45-47, AB, V1, T16.

options to overcome the problem.⁵⁷ Given the prior findings regarding deltoid injections leading to a faster initial rise in blood plasma concentrations, at this stage the team considered the possibility of all patients receiving injections into the deltoid.⁵⁸

27. The INVEGA SUSTENNA inventors ultimately built a complex population PK model that leveraged a vast amount of confidential internal Janssen data obtained through its clinical trials.⁵⁹ They then used the new model to design a new dosing regimen for paliperidone palmitate that included a 150 mg first dose in the deltoid muscle and a 100 mg dose on day 8 in the deltoid, followed by maintenance dosing in either of two injection sites.⁶⁰ Notably, both outside advisors and the FDA were skeptical of using a 150 mg loading dose and suggested lower doses.⁶¹ The inventors' persistence was vindicated when new Phase III clinical trials succeeded where earlier dosing regimens had failed, achieving both rapid and sustained efficacy.

28. Based on the results of the new PK modelling and the new successful Phase III clinical trials, with results from approximately 1850 patients across over 160 study locations around the world,⁶² regulatory approval was sought for the claimed dosing regimens.⁶³ Janssen received approval for INVEGA SUSTENNA in the United States in 2009 and in Canada in 2010.⁶⁴ This

⁵⁷ Vermeulen Affidavit at paras 76-77, 79, 83, AB, V10, T55, Gopal Affidavit at para 63, AB, V1, T16; *Trial Decision* at para 18, AR, T2.

⁵⁸ Vermeulen Affidavit at para 83, AB, V10, T55.

⁵⁹ Vermeulen Affidavit at para 7, AB, V10, T55; Ereshefsky Report at para 547, AB, V17, T97.

This unique model was based on a combined dataset comprised of 15,754 blood samples from 1,401 patients, plus an additional 2,776 samples from 394 patients set aside for external validation: Samtani Affidavit at paras 24-28, AB, V17, T85.

⁶⁰ Samtani Affidavit at paras 74-75, AB, V17, T85.

⁶¹ Vermeulen Affidavit at paras 93-95, AB, V10, T55; Samtani Affidavit at paras 21-22, 86, AB, V17, T83; Gopal Affidavit at paras 69-70, 84, AB, V1, T16.

⁶² Janssen Prod 53 at 2, AB, V7, T28; Janssen Prod 54 at 67-68, AB, V7, T29; Janssen Prod 5579 at 66, AB, V8, T40. The FDA was also skeptical of Janssen's initial recommendation of a 100 mg first loading dose and instead suggested 75-100 mg.

⁶³ Samtani Affidavit at para 87, AB, V17, T85.

⁶⁴ Agid Affidavit at para 47, AB, V19, T127; Gopal Affidavit at para 90, AB, V1, T16.

was an important new option for doctors in the treatment of patients with schizophrenia. It has been described as “one of the most common ‘go-to’ injectable antipsychotics.”⁶⁵

29. It is important to note that, because paliperidone palmitate (i.e., the INVEGA SUSTENNA LAI) was not an approved drug before the 335 Patent,⁶⁶ only physicians who were investigators in the clinical trials that *Janssen* (and the inventors) were conducting had access to it. Pharmascience’s suggestion that “physicians were *already* exploring”⁶⁷ how and when paliperidone palmitate should be administered is misleading. The “multiple clinical trials” evaluating different dosing regimens that it refers to were *Janssen’s own clinical trials* which ultimately resulted in the invention claimed in the 335 Patent.⁶⁸ There is no evidence that doctors were independently exploring dosing regimens of paliperidone palmitate.

⁶⁵ *Janssen Inc and Janssen Pharmaceutica NV v Pharmascience Inc*, [2022 FC 62](#), Confidential Judgment and Reasons at para [66](#) [*Confidential FC Summary Trial Decision*], AB, V1, T4.

⁶⁶ Chue Report at para 76, AB, V18, T121; Ereshefsky Report at para 267, AB V17, T97. By using “paliperidone” as shorthand for “paliperidone palmitate” throughout its factum (see e.g., at para 9), Pharmascience confuses what drugs were available before the 335 Patent, and what drug the patent is directed to. Paliperidone was available to physicians prior to the 335 Patent’s filing as an oral (tablet) formulation. Paliperidone palmitate, which is the subject of the 335 Patent, is not the same drug as paliperidone (it is the palmitate ester of paliperidone, formulated as a depot injection). There were no injectable formulations of paliperidone palmitate available to physicians prior to the 335 Patent. Janssen only had approval to market its injectable paliperidone palmitate (INVEGA SUSTENNA) after it developed the dosing regimens included in the 335 Patent. The 335 Patent thus has no impact on sale or use of paliperidone oral tablets, including the generic versions of paliperidone.

⁶⁷ Pharmascience Factum at para 16 (emphasis in original).

⁶⁸ Canadian Patent No 2,309,629 (see AB, V9, T54, Schedule 10 to the Expert Report of Dr. Pardeep Gupta [Gupta Report] at 1) and 2,236,691 (see AB, V9, T54, Schedule 9 to the Gupta Report at 1) are Janssen patents; Clinicaltrial.gov protocol registries NCT00210548 (in AB, V9, T49, Exhibit 8 to Confidential Expert Report of Dr. Joel Jeffries [Jeffries Report] at 3), and NCT00210717 (in AB, V9, T49, Exhibit 9 to Jeffries Report at 2), which are protocol summaries respecting Janssen’s clinical trials; Citrome paper (in AB, V9, T49, Exhibit 7 to Jeffries Report at

D. The Underlying and Prior PMNOC Proceedings Relating to the 335 Patent

30. INVEGA SUSTENNA has been the subject of separate proceedings under the *PMNOC Regulations* against generic drug companies Apotex and Teva, as well as Pharmascience. In each case the FC found that the 335 Patent was valid and infringed.

i) Teva

31. Claims 1-48 of the 335 Patent were the subject of an action against Teva, which was heard and decided prior to this action (“*Teva*”).⁶⁹ The trial judge found that the 335 Patent was not obvious and that Teva would directly infringe claims 1-16 and 33-48 (the “**product claims**”).⁷⁰ The trial judge found that Teva would not induce infringement of claims 17-32 (the “**use claims**”).⁷¹ Teva’s appeal (on issues of direct infringement and validity) was dismissed and Janssen’s cross-appeal (on the issue of inducing infringement) was allowed.⁷² Teva did not seek leave to appeal to this Court.

ii) Apotex

32. Claims 1-63 of the 335 Patent were at issue in an infringement action against Apotex. The trial judge determined that Apotex’s product monograph would induce infringement of the 335 Patent.⁷³ Apotex’s appeal was dismissed.⁷⁴ Apotex’s motion for leave to appeal to this Court was also dismissed.⁷⁵ Apotex then provoked new infringement actions in which it sought to include an invalidity defence.⁷⁶ Janssen’s motions for summary judgment were granted by the Federal

656), discusses other Janssen clinical trials; Chue Report at paras 77-78, 98-105, AB, V18, T121; Ereshefsky Report at paras 267-268, 270, AB, V17, T97.

⁶⁹ *Trial Decision* at para 39, AR, T2; Teva proceedings: [Teva](#), aff’d (in part) *Teva Canada Limited v Janssen Inc*, [2023 FCA 68](#) [*Teva FCA*].

⁷⁰ *Teva* at paras [35](#), [252-256](#), [291](#), Judgment paras [1](#), [2](#), aff’d (in part) [Teva FCA](#).

⁷¹ *Teva* at paras [35\(B\)](#), [148-153](#), [290](#), Judgment para [2](#), aff’d (in part) [Teva FCA](#).

⁷² *Teva FCA* at paras [4-6](#), [117](#).

⁷³ *Janssen Inc v Apotex Inc*, [2022 FC 107](#) at para [161](#), Judgment para [2](#).

⁷⁴ *Apotex Inc v Janssen Inc*, [2024 FCA 9](#) at paras [5-6](#).

⁷⁵ *Apotex Inc v Janssen Inc, et al*, [2024 CanLII 58478](#) (SCC).

⁷⁶ *Janssen Inc v Apotex Inc*, [2023 FC 912](#) at paras [15](#), [17](#).

Court of Appeal (“FCA”) on the basis of abuse of process.⁷⁷ Apotex did not seek leave to appeal that decision to this Court.

iii) Pharmascience

33. In the underlying action, Pharmascience alleged both that it would not infringe any of the claims of the 335 Patent and that the claims were invalid for obviousness and unpatentable subject matter as MMT.⁷⁸ It brought a motion for summary trial on non-infringement.⁷⁹ The FC found that Pharmascience would induce infringement of the claims of the 335 Patent.⁸⁰ This finding was upheld on appeal.⁸¹ Pharmascience’s motion for leave to appeal to this Court was dismissed.⁸²

34. At a separate trial on validity issues raised by Pharmascience, the trial judge again found that the claims of the 335 Patent were non-obvious and were directed to patentable subject matter.⁸³ The trial judge followed the settled jurisprudence that claims to a vendible product are patentable subject matter pursuant to s. 2 of the *Patent Act*, and accordingly found that claims 1-16, 33-48, and 49-63 were not MMT.⁸⁴ With respect to claims 17-32 (which are directed to “use of a ‘dosage form’ according to the claimed regimens”) the trial judge found, as fact, that these claims have fixed dosage amounts and do not include choices having clinical implications and thus “do not require professional skill and judgment,”⁸⁵ to practice and are patentable subject matter.⁸⁶ The trial judge issued a declaration that Pharmascience’s proposed generic drugs infringe the 335

⁷⁷ *Janssen Inc v Apotex Inc*, [2023 FCA 253](#) at para 71.

⁷⁸ *Confidential FC Summary Trial Decision* at paras [26](#), [145](#), [Judgment](#), AB, V1, T4.

⁷⁹ Pharmascience expressly relied on the claims construction from *Teva* that most of the claims are product (rather than use) claims to argue that it would not infringe the 335 Patent: *Confidential FC Summary Trial Decision* at paras [1](#), [36](#), [83-85](#), [88](#), AB, V1, T4.

⁸⁰ *Confidential FC Summary Trial Decision* at paras [26\(a\)](#), [145](#), AB, V1, T4.

⁸¹ *Pharmascience Inc v Janssen Inc*, [2024 FCA 10](#) at paras [30-33](#) [*FCA Summary Decision*], leave to appeal ref’d [2024 CanLII 58472](#) (SCC).

⁸² *Pharmascience Inc v Janssen Inc and Janssen Pharmaceutica NV*, [2024 CanLII 58472](#) (SCC).

⁸³ *Trial Decision* at paras [172](#), [173](#), AR, T2.

⁸⁴ *Trial Decision* at paras [34](#), [163](#), AR, T2.

⁸⁵ *Trial Decision* at paras [34\(ii\)](#), [163](#), [168](#), [170](#), AR, T2.

⁸⁶ *Trial Decision* at paras [168-172](#), [173](#), AR, T2.

Patent and granted an injunction with respect to the infringing drugs until the expiry of the 335 Patent on December 17, 2028.⁸⁷

35. The FCA upheld the trial decision.⁸⁸ The FCA noted that this Court has already decided “that a vendible product has economic value and is distinguishable from the skilled work of a physician, and hence outside the realm of methods of medical treatment.”⁸⁹

PART II: STATEMENT OF ISSUE

36. Pharmascience states that the “sole issue on this appeal is whether the 335 Patent is invalid in that it claims an unpatentable method of medical treatment.”⁹⁰ Janssen agrees that this is the sole issue. Despite significant portions of Pharmascience’s factum being dedicated to relitigating claims construction (see for e.g., paragraphs 39, 42, and 105), whether the development of the dosing regimens was obvious (see for e.g., paragraphs 9, 15-16 and 30-31), and whether Pharmascience’s proposed product would infringe the 335 Patent (see for e.g., paragraphs 36 and 49),⁹¹ those are not issues before this Court.

PART III: STATEMENT OF ARGUMENT

A. Outline

37. Section 2 of the *Patent Act* defines the subject matter that qualifies as an “invention” as “any new and useful art, process, machine, manufacture or composition of matter, or any new and

⁸⁷ *Trial Decision* at [Judgment, items 3-4](#), AR, T2.

⁸⁸ *FCA Decision* at paras [51-53](#), [64](#), AR, T5.

⁸⁹ *FCA Decision* at para [26](#), AR, T5.

⁹⁰ Pharmascience Factum at para 51.

⁹¹ Pharmascience’s references (at paras 36 & 49) to infringing acts being “few and far between” are not references to the underlying action but to *Teva* at para [272](#). The quantum of infringement is not relevant to the FC and FCA’s conclusions that Pharmascience infringes the 335 Patent. In any event, this Court denied Pharmascience leave to appeal the question of whether it infringes the 335 Patent: *Pharmascience Inc v Janssen Inc and Janssen Pharmaceutica NV*, [2024 CanLII 58472](#) (SCC).

useful improvement in any art, process, machine, manufacture or composition of matter.”⁹² To qualify for patent protection, the invention must also be novel, non-obvious, useful, sufficiently described, not overbroad, not ambiguous and not a “double patent” on the same invention. Pharmascience has not appealed the validity of the 335 Patent on any of these grounds.

38. Pharmascience’s only remaining attack on the 335 Patent is to argue that it is directed to unpatentable subject matter as MMT. As set out in section B below, the MMT doctrine in Canada originated from a section of the *Patent Act* that has been repealed. As addressed in section C, there is no basis in the text, context or purpose of the Act for continuation of any *a priori* disallowance of MMT from patentability now that its statutory basis has been repealed. There is certainly no basis to dramatically expand the doctrine to invalidate all dosing regimens.

39. Alternatively, even if a MMT exclusion exists in Canada, it should not be expanded to render all inventions related to dosing regimens unpatentable subject matter, as Pharmascience suggests.⁹³ Pharmascience’s arguments lack sound foundation in Canadian law (section D), the law of peer jurisdictions (section E), or public policy (section F), and should be rejected. Its proposed test is not viable (section G).

40. If this Court reads any MMT preclusion into the *Patent Act*, it should be limited to the professional skills of physicians (the equivalent of a lawyer seeking to patent a method of advocacy), and should not extend to commercial offerings (sections D and H). Doctors who treat patients and innovative pharmaceutical companies who discover new treatment options operate from distinct but complementary vantage points: they occupy two sides of the same coin. Without pharmaceutical innovation, doctors would have far fewer tools to treat their patients.

⁹² *Patent Act*, RSC 1985, c P-4, s 2.

⁹³ Pharmascience Factum at para 10.

B. The *Tennessee Eastman* MMT Exclusion Rests on a Repealed Provision

41. Pharmascience has not accurately summarized this Court’s MMT jurisprudence. Among other errors, it cites a dissenting judgment without identifying it as such,⁹⁴ and cites propositions from lower court decisions as if they were findings of this Court.⁹⁵

42. Contrary to Pharmascience’s assertions, it is not well-established that MMT are unpatentable. *Tennessee Eastman Co et al v Commissioner of Patents* (“*Tennessee Eastman*”), this Court’s only decision holding a patent to be ineligible as MMT, was based on s. 41 of the *Patent Act*, which has now been repealed. Section 41 was enacted for the purpose of restricting the scope of patents “relating to substances prepared or produced by chemical processes and intended for food or medicine.”⁹⁶ Given s. 41, the substance being applied in *Tennessee Eastman*, a bonding compound for use in surgery, was clearly unpatentable. The question before this Court was whether a *method* for using that unpatentable compound in surgery could be patented.

43. This Court found that it could not, as patenting the method would undermine s. 41. As Justice Pigeon explained: “if a method of treatment consisting in the application of a new drug could be claimed as a process apart from the drug itself, then the inventor, by making such a process claim, would have an easy way out of the restriction in s. 41(1).”⁹⁷

44. Pharmascience’s assertion that s. 41 was not the *ratio* of *Tennessee Eastman* is inaccurate.⁹⁸ This Court has repeatedly observed that *Tennessee Eastman* rested primarily on s. 41. In the *AZT*

⁹⁴ Pharmascience Factum at para 55 (quoting the dissenting judgment in *Monsanto Canada Inc v Schmeiser*, [2004 SCC 34](#) at paras [133-134](#)).

⁹⁵ Pharmascience Factum at para 63(b) and (c).

⁹⁶ *Tennessee Eastman Co et al v Commissioner of Patents*, [\[1974\] SCR 111](#) at [118-119](#), 1972 CanLII 167 (SCC) [*Tennessee Eastman*]; see also at [115](#) (“41. (1) In the case of inventions relating to substances prepared or produced by chemical processes and intended for food or medicine, the specification shall not include claims for the substance itself, except when prepared or produced by the methods or processes of manufacture particularly described and claimed or by their obvious chemical equivalents.”)

⁹⁷ *Tennessee Eastman* at [119](#).

⁹⁸ Pharmascience Factum at para 62, footnote 79.

Case, this Court held that *Tennessee Eastman* “was based on the former s. 41 of the Patent Act, now repealed.”⁹⁹ In *Harvard College v Canada* (“**Harvard College**”), a majority of this Court questioned whether the *Tennessee Eastman* exclusion of MMT remains good law following the repeal of s. 41, as it is no longer “justified by reference to explicit provisions of the *Patent Act*.”¹⁰⁰

C. Excluding MMT from Patent Eligibility Lacks a Basis in the *Patent Act*

45. What is and is not patentable must find its foundation in the *Patent Act*.¹⁰¹ Without a statutory basis, there should be no MMT exclusion — and certainly no exclusion that would extend to novel and non-obvious dosing regimens such as claimed in the 335 Patent.

46. As with all statutes, the *Patent Act* must be interpreted consistent with the “modern approach.”¹⁰² The text, context and purpose of the *Patent Act* all indicate that useful discoveries relating to medical treatment, especially those related to the use of a drug, merit patent protection.

47. **Text:** There is no statutory bar to the patenting of MMT in the *Patent Act*. Where Parliament intends to exclude a potential subject matter from patentability, it does so expressly.¹⁰³

48. Patents are granted for an “invention,” which is broadly defined to mean “any new and useful art, process, machine, manufacture or composition of matter,” or an “improvement” thereof.¹⁰⁴ In drafting the *Patent Act* broadly, Parliament signaled a clear intention to include a wide range of patentable subject matter and “improvements” of subject matter already known.

49. “Art” means “learning” or “knowledge.” As this Court held in *Shell Oil Co v Commissioner of Patents* (“**Shell Oil**”), “art” is a word of very wide connotation that was not intended to be confined to new processes or products but extends as well to innovative methods of applying skill or knowledge, provided they produce effects commercially useful to the public.¹⁰⁵

⁹⁹ *AZT Case* at para [49](#).

¹⁰⁰ *Harvard College v Canada (Commissioner of Patents)*, [2002 SCC 76](#) at para [145](#) [*Harvard College*].

¹⁰¹ *Sanofi* at para [12](#).

¹⁰² *Rizzo & Rizzo Shoes Ltd (Re)*, [\[1998\] 1 SCR 27](#) at para [21](#); *Bell ExpressVu Limited Partnership v Rex*, [2002 SCC 42](#) at para [26](#); *R v Wolfe*, [2024 SCC 34](#) at para [32](#).

¹⁰³ See e.g., *Patent Act*, s [27\(8\)](#).

¹⁰⁴ *Patent Act*, s [2](#); *Harvard College* at para [120](#).

¹⁰⁵ *Shell Oil* at [554-555](#), citing *Tennessee Eastman and Lawson*.

A method is also a “process.”¹⁰⁶ Based on the text of s. 2 of the *Patent Act*, new and useful medical methods, including new and useful dosing regimens, plainly qualify as inventions.

50. **Context:** The statutory and regulatory framework surrounding s. 2 of the *Patent Act* demonstrate Parliament’s intent that MMT are patentable. Subsection 41(1) was repealed in 1987, among further measures introduced to re-balance the patent regime in Canada to promote innovation. The amendments “were made with the political intent of helping to recreate a climate in which pharmaceutical research and an innovative pharmaceutical industry can exist once again in Canada.”¹⁰⁷ If Parliament had intended the *Patent Act* to now include medical compounds but exclude medical methods, it could have inserted language relating to medical methods when it repealed s. 41. It did not.

51. That silence is particularly striking given that the *Agreement on Trade-Related Aspects of Intellectual Property Rights* (the “**TRIPS Agreement**”) expressly authorizes (but does not require) signatories to exclude “diagnostic, therapeutic and surgical methods for the treatment of humans” from patentability.¹⁰⁸ Some signatories, like the UK, have enacted statutes expressly providing for this exclusion.¹⁰⁹ Canada has not. Indeed, Canada made other amendments to the *Patent Act* and other statutes in light of the *TRIPS Agreement*,¹¹⁰ but not in relation to MMT. The fact that Canada, having repealed s. 41 and signed the *TRIPS Agreement*, has chosen not to amend the *Patent Act* to

¹⁰⁶ *Tennessee Eastman* at [117](#).

¹⁰⁷ Robert A Wilkes, “The New Canadian Patent Act” (1989) 71:3 J Pat & Trademark Office Soc’y 202 at 226, Janssen BOA, Tab 10.

¹⁰⁸ *Agreement on Trade-Related Aspects of Intellectual Property Rights TRIPS Agreement*, Art. [27\(3\)\(a\)](#), Annex 1C to the Marrakesh *Agreement Establishing the World Trade Organization*, 15 April 1994, [1867 UNTS 154](#) (entered into force 1 January 1995) [*TRIPS Agreement*].

¹⁰⁹ [Patents Act 1977](#), 1977 c 37, s [4A\(1\)](#) [*UK Patents Act*]. As discussed further below, even *TRIPS Agreement* signatories whose statutes expressly exclude MMT from patentability recognize that dosing regimens such as those claimed in the 335 Patent are important innovations and are patentable.

¹¹⁰ See e.g., Library of Parliament, Parliamentary Research Branch, “Bill S-17: An Act to Amend the Patent Act” by Margaret Smith (Law and Government Division), 31-1 (1 March 2001) at 4, [online](#); *Patent Act*, ss [21.01-21.09](#); [Food and Drug Regulations](#), CRC, c 870, [C.08.004.1\(2\)](#).

exclude MMT from patent eligibility is highly significant. It indicates that no such exclusion exists under current law.

52. With respect to dosing regimens in particular, the health regulatory regime for drugs is also relevant context. To obtain Health Canada approval to market a drug in Canada, the manufacturer must recommend a dosage of the drug.¹¹¹ Once approved, the drug cannot be sold with a “significantly different” recommended dose,¹¹² unless a new notice of compliance approval is obtained. The manufacturer is also required to include on the drug’s label adequate directions for use, which is interpreted to include recommended doses.¹¹³ This is why Janssen could not obtain market authorization for INVEGA SUSTENNA without having developed both the paliperidone palmitate formulation and an effective dosing regimen. As a practical matter, the commercial offering is a package of the medicine and the instructions for its use.

53. The *PMNOC Regulations* governing this proceeding (which have the same force as the *Patent Act*)¹¹⁴ lend further support to the patentability of dosing regimens in Canada. The *PMNOC Regulations* were adopted in connection with s. 55.2(1) of the *Patent Act*, which provides an exception to infringement (known as the “early working exception”) for generic drug companies to develop generic products and prepare regulatory submissions to Health Canada relying on the R&D of innovative drug companies while the patent(s) for the innovative drug are still in force.¹¹⁵ To avoid abuse of this exception, approval to market the copycat is not granted until all eligible patents for the innovative drug (as set out in the *PMNOC Regulations*) have expired or been declared invalid or not infringed by the generic product.¹¹⁶ The purpose of the PMNOC regime is effectively to maintain a balance between protecting the rights of patent holders of innovative drugs and the public interest of having timely market entry for generic drugs.¹¹⁷

¹¹¹ *Food and Drug Regulations*, CRC, c 870, [C.01.014.1\(2\)\(j\)](#), [C.08.002\(2\)\(k\)\(ii\)](#).

¹¹² *Food and Drug Regulations*, CRC, c 870, [C.08.003\(2\)\(h\)\(ii\)](#).

¹¹³ *Food and Drug Regulations*, CRC, c 870, [C.01.004\(1\)\(c\)\(iii\)](#). See also Health Canada, “Guidance Document: Labelling of Pharmaceutical Drugs for Human Use” (18 December 2024) at s [3.5.4](#) (“Adequate directions for use”), [online](#).

¹¹⁴ *Patent Act*, s [12\(2\)](#); *Monsanto Canada Inc v Ontario (Superintendent of Financial Services)*, [2004 SCC 54](#) at para [35](#) [*Monsanto v Ontario*].

¹¹⁵ *Patent Act*, s [55.2](#).

¹¹⁶ *Bristol-Myers Squibb* at paras [11](#), [46-48](#).

¹¹⁷ *Bristol-Myers Squibb* at paras [45-50](#).

54. Under the *PMNOC Regulations*, the Minister of Health maintains a patent register which lists eligible patents. The following types of patent claims are eligible to be listed for protection against a generic manufacturer: a claim for (i) the medicinal ingredient; (ii) the formulation that contains the medicinal ingredient; (iii) the dosage form (i.e., the delivery system for the medicine, e.g., controlled-release tablets or transdermal patches); and (iv) the use of the medicinal ingredient.¹¹⁸ The RIAS that accompanied amendments to the *PMNOC Regulations* in 2006 to add and define these phrases specifically refers to dosing regimen claims as among the “kinds of so-called ‘use patents’ which exist in the pharmaceutical realm.”¹¹⁹ The RIAS can be used to interpret the government’s intention; indeed, this Court did so in relation to the *PMNOC Regulations* in *Bristol-Myers Squibb*.¹²⁰ In light of the broader regulatory context, it is clear that Canada intended and understood that dosing regimens are patentable subject matter under s. 2 of the *Patent Act*.

55. **Purpose:** Allowing patentability of new and useful MMT is consistent with the patent bargain. The *Patent Act* encourages and protects the discovery of new and non-obvious inventions that have economic value in any field of trade, industry and commerce. Since the repeal of s. 41, the *Patent Act* no longer provides less protection in the medical field compared with other fields of science. A new medical method that provides previously unforeseen benefits to patients and has practical application merits the same patent protection as any other discovery that meets the requirements of the *Patent Act*. Those requirements (including novelty, utility, non-obviousness) ensure that medical claims that do not fulfil the patent bargain will be invalid. *A priori* disallowance of patent protection for MMT would undermine rather than advance the purpose of the patent bargain, which is to coax inventive solutions to practical problems into the public domain in return for a time limited monopoly.¹²¹ A dosing regimen that solves the problem of non-adherence with schizophrenia treatments is exactly the type of invention that the *Patent Act* was intended to encourage.

¹¹⁸ See *PMNOC Regulations*, ss [2\(1\)](#), [4\(2\)\(a\)](#), [\(b\)](#), [\(c\)](#), [\(d\)](#).

¹¹⁹ *RIAS* at [1517](#).

¹²⁰ *Bristol-Myers Squibb* at para [46](#) (*per* Binnie J. for the majority) and at paras [155-56](#) (*per* Bastarache J. dissenting, but not on this point); *References re Greenhouse Gas Pollution Pricing Act*, [2021 SCC 11](#) at para [607](#) (*per* Rowe J. dissenting, but not on this point).

¹²¹ *AZT Case* at para [37](#).

56. The *Patent Act* should also be interpreted in a manner consistent with Parliament’s goal of incentivizing innovation specifically in the area of advancing public health.¹²² If patent protection is not available for innovative dosing regimens, pharmaceutical companies would lack incentives to invest in the R&D required to study and develop such inventions.

57. Contrary to Pharmascience’s assertions, reading an MMT exclusion into the *Patent Act* to reduce drug costs is not justified by the purpose of the Act. Parliament has carefully balanced incentives to introduce new treatments with measures to prevent excessive prices of drugs. The Patented Medicine Prices Review Board (“PMPRB”) ensures the prices charged by patentees for patented drug products are not excessive.¹²³ In addition, robust provincial regulations exert strong controls on drug prices.¹²⁴ The higher (but not excessive) cost of patented drugs is justified by the R&D expenses required to innovate.¹²⁵ That justification applies with full force to patents on new and useful MMTs. Reading an expansive exclusion on patent eligibility into the *Patent Act* is not a reasonable approach to reducing drug costs.

D. Any Surviving MMT Exclusion Should Not Extend to Dosing Regimen Claims

58. In light of the foregoing, there are strong arguments that there is no longer any categorical exclusion of MMT as patentable subject matter. In any event, if this Court reads a MMT exclusion into the *Patent Act*, it should be narrowly focused on non-economic medical activities unrelated to commercial products. As in peer jurisdictions, it should not extend to dosing regimen patents such as the 335 Patent.

¹²² *Harvard College* at para [185](#).

¹²³ *Patent Act*, ss [83-85](#); House of Commons Committees, “Minutes of Proceedings and Evidence of the Legislative Committee on Bill C-22 An Act to amend the Patent Act and to provide for certain matters in relation thereto” (19 February 1987) at 6:66–16:68 (Mr. Dingwall), [online](#); *Celgene Corp v Canada (Attorney General)*, [2011 SCC 1](#) at paras [1](#), [17-19](#), [26-29](#), [31](#).

¹²⁴ See e.g., *Ontario Drug Benefit Act*, [RSO 1990, c O.10](#), s [12](#) and *Act Respecting Prescription Drug insurance*, [CQLR c A-29.01](#), [60.0.1](#), which set out mechanisms by which the provinces and drug manufacturers may enter into product listing agreements providing for rebates to the provinces. The Pan-Canadian Pharmaceutical Alliance also negotiates reductions of drug prices on behalf of the provinces collectively.

¹²⁵ *Actavis* at para [29](#).

59. With s. 41 of the *Patent Act* no longer providing a foundation for the MMT doctrine, any surviving exclusion would rest on comments in *Shell Oil* and the *AZT Case*, where, in the course of distinguishing *Tennessee Eastman* and upholding the patents at issue, this Court observed that the surgical method, without the compound, was “essentially non-economic and unrelated to trade, industry or commerce. It was related rather to the area of professional skills.”¹²⁶ Under this reasoning the 335 Patent’s claims are patentable as they are commercial offerings, not non-economic professional skills.

60. ***Shell Oil***. In *Shell Oil*, this Court discussed the Exchequer Court decisions in *Tennessee Eastman* and *Lawson v Commissioner of Patents* (“**Lawson**”) holding that methods of using professional skill, such as performing surgery or conducting cross-examinations, are not patentable under the *Patent Act*:¹²⁷

If a surgeon were to devise a method of performing a certain kind of operation he cannot obtain an exclusive property or privilege therein. Neither can a barrister who has devised a particular method of cross-examination or advocacy obtain a monopoly thereof so as to require imitators or followers of his methods to obtain a licence from him.¹²⁸

In *Lawson*, a method for describing parcels of land was found to be a skill of professionals (including solicitors), and thus an art belonging to the professional field to which the *Patent Act* was not intended to apply.¹²⁹

61. The *Shell Oil* Court distinguished the unpatentable professional skills at issue in *Tennessee Eastman* and *Lawson* from the discovery of a new use of a known compound as a plant growth regulator.¹³⁰ *Shell Oil* is best known as the first decision of this Court holding that the discovery of a new use of a known compound is patentable. The discovery that the old compounds could be used as plant growth regulators “added to the cumulative wisdom on the subject of these compounds” and as such fell “within the words ‘any new and useful art’.”¹³¹ Because the

¹²⁶ *Shell Oil* at [554](#); *AZT Case* at para [49](#); See also *Apotex v Sanofi AUS* at para [278](#).

¹²⁷ *Lawson*, at paras 35-36, Pharmascience BOA, Tab 3, following *National Research Development Corp v Commissioners of Patents* (1960), (1959) 1A IPR 63 at 74, [1961] RPC 134 (Austl HC), Janssen BOA, Tab 5.

¹²⁸ *Lawson* at paras 35-36, Pharmascience BOA, Tab 3.

¹²⁹ *Lawson* at paras 37-38, Pharmascience BOA, Tab 3.

¹³⁰ *Shell Oil* at [554-555](#).

¹³¹ *Shell Oil* at [548-549](#) [emphasis added].

discovery had “economic value in the field of trade, industry and commerce,” it was a patentable invention; rather than an unpatentable method of using professional skill as in *Lawson* and *Tennessee Eastman*, which were “essentially non-economic and unrelated to trade, industry or commerce.”¹³²

62. By any measure, the inventions described in the 335 Patent, comprising the use of novel and non-obvious dosing regimens of paliperidone palmitate to provide a fast and long-acting injectable treatment that is embodied in the commercial product INVEGA SUSTENNA, have “economic value in the field of trade, industry and commerce,” and are not “essentially non-economic and unrelated to trade, industry or commerce.” They also “add[] to the cumulative wisdom on the subject of [this] compound[],” namely paliperidone palmitate.¹³³ The 335 Patent is therefore patentable under the reasoning of *Shell Oil* and should be upheld even if this Court were to conclude that an MMT exclusion survives the repeal of s. 41.

63. Contrary to Pharmascience’s argument, the fact that the 335 Patent includes product claims having dosing regimens as an essential element does not elevate “form over substance” or otherwise render them patent ineligible.¹³⁴ In fact, the manner in which Janssen has made its claims is entirely consistent with *Shell Oil*. In *Shell Oil*, the inventive concept supported claims both for the *use* of the compound and for *products* embodying that use in practical form.¹³⁵ Similarly here, both the *use* of the product in accordance with the dosing regimens and the product itself — a syringe pre-filled with medication that embodies the novel dosing regimens¹³⁶ — are patentable claims. Both types of claims describe the practical application of Janssen’s invention.¹³⁷

¹³² *Shell Oil* at [554-555](#).

¹³³ *Shell Oil* at [549](#), [555](#).

¹³⁴ Pharmascience Factum at paras 39, 46, 112.

¹³⁵ *Shell Oil* at [553-554](#).

¹³⁶ *Teva* at paras [124-128](#), [145-148](#), [152-153](#), [159-163](#).

¹³⁷ As discussed below, the *PMNOC Regulations* provide for both product and use claims. See also *Apotex v Sanofi AUS* at para [282](#), holding that product, use, and combined product/use claims all have economic utility.

64. *The AZT Case*. In the *AZT Case*,¹³⁸ this Court applied *Shell Oil* to a pharmaceutical context, holding that a new use of a known drug to treat a new disease is patentable. Notably, in the FCA, Justice Rothstein (as he then was) cast doubt on the *Imperial Chemical* case that is relied upon by Pharmascience as it “was decided without reference to the Supreme Court of Canada decision in *Shell Oil*.”¹³⁹

65. AZT was a known compound, initially tested as a potential cancer treatment. Glaxo/Wellcome’s patent claimed a hitherto unrecognized utility of AZT in the treatment and prophylaxis of HIV/AIDS.¹⁴⁰

66. Justice Binnie, writing for this Court, observed that “[t]here is no serious challenge in this case to subject matter patentability.”¹⁴¹ Patentability of a new use of an existing drug fell squarely within *Shell Oil*, as the monopoly sought by the manufacturer was to provide a commercial product to be used for the new purpose:¹⁴²

At trial, the present appellants argued that the patent was invalid as seeking to monopolize a method of medical treatment contrary to *Tennessee Eastman, supra*, but this was rightly rejected. *Tennessee Eastman* was concerned with the patentability of a surgical method for joining incisions or wounds by applying certain compounds. The decision was based on the former s. 41 of the Patent Act, now repealed. The Court concluded that the method (apart from the compounds) was not patentable. The policy rationale, as explained by Wilson J. in *Shell Oil, supra*, at p. 554, was that the unpatentable claim was

essentially non-economic and unrelated to trade, industry, or commerce. It was related rather to the area of professional skills.

The AZT patent does not seek to “fence in” an area of medical treatment. It seeks the exclusive right to provide AZT as a commercial offering. How and when, if at all, AZT is employed is left to the professional skill and judgment of the medical profession. [emphasis added]

67. Although Pharmascience relies on this passage as the basis for its proposed “how and when” test for MMT eligibility, this Court did not establish a “how and when” test for patentability

¹³⁸ [AZT Case](#).

¹³⁹ Pharmascience Factum at para 3, footnote 1 and para 62, footnote 79; *AZT FCA* at para [75](#).

¹⁴⁰ *AZT Case* at paras [1](#), [10](#), [52](#).

¹⁴¹ *AZT Case* at para [48](#).

¹⁴² *AZT Case* at paras [49-50](#).

in the *AZT Case*. To the contrary, Pharmascience’s proposed “how and when” test is inconsistent with this Court’s core holding that the patent claims at issue were valid. The claims included those for a “pharmaceutical formulation for use in the treatment or prophylaxis of AIDS comprising an effective amount” of AZT and for “an amount effective to provide a unit dose of 10 to 1500 mg.”¹⁴³ These valid claims “relate to how and when a drug or treatment is to be administered by a medical practitioner” and would be ineligible under Pharmascience’s reasoning.¹⁴⁴ Indeed, Pharmascience explicitly argues that “claims to ‘the use of compound X to treat disease Y by administering a dose range of P to Q on days R to S’ are not” patentable, overlooking the fact that some of the claims in the *AZT Case* were structured in similar ways.¹⁴⁵

68. The reason the AZT patent was valid was not that its claims lacked information about how and when to use AZT, but rather that it sought the “exclusive right to provide AZT as a commercial offering.”¹⁴⁶ As in *Shell Oil*, the fact that the patent was commercial in nature, rather than seeking exclusivity over professional skills such as more effective surgery, distinguished *Tennessee Eastman* (to the extent doing so was necessary) and rendered the patent valid.

69. The 335 Patent is not meaningfully distinguishable from the patent at issue in the *AZT Case*. Here, as there, Janssen does not seek “simply to increase the efficacy of the day to day practice of physicians and other medical professionals,”¹⁴⁷ but rather to market a new commercial pharmaceutical product. When INVEGA SUSTENNA is distributed to healthcare practitioners, they have a license to use the patent, and their treatment options are not constrained but enhanced. Although the benefits of the claimed dosing regimen are available to them, “[h]ow and when, if at all,” INVEGA SUSTENNA is used is “left to the professional skill and judgment of the medical profession.”¹⁴⁸ There is simply no basis in the reasoning or the result of the *AZT Case* to suggest that novel and non-obvious dosing regimens that provide exclusive rights to offer drugs as commercial offerings are unpatentable subject matter.

¹⁴³ *AZT FC* at paras 318, 323, Janssen BOA, Tab 2.

¹⁴⁴ Pharmascience Factum at para 7.

¹⁴⁵ Pharmascience Factum at para 69.

¹⁴⁶ *AZT Case* at paras [49-50](#).

¹⁴⁷ *AZT FC* at para 74, Janssen BOA, Tab 2.

¹⁴⁸ *AZT Case* at para [50](#).

70. ***The Patent Act and TRIPS Agreement.*** The holding of *Shell Oil* and the *AZT Case* that commercial inventions are broadly patentable is required by the *TRIPS Agreement* and the *Patent Act*. Article 27(1) of the *TRIPS Agreement* requires Canada to make patents available for inventions “in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.”¹⁴⁹ “[C]apable of industrial application” is synonymous with “useful.”¹⁵⁰ The “useful” requirement of the *Patent Act* is thus directly tied to the concept of “industrial application.” In *Lawson, Shell Oil* and the *AZT Case*, professional fields were categorized as outside of “fields of technology” and industrial application/usefulness (just as the fine arts fall outside the *Patent Act*).¹⁵¹

71. From a purposive perspective, this distinction between professional services and commercial offerings is beneficial for patients. Physicians and surgeons can hone their skills with no concern that exceptional skills or creative approaches to the professional field are subject to a monopoly by another physician. However, commercial offerings like pharmaceuticals and medical devices are “useful” in the *Patent Act* sense, and are incentivized to give physicians and patients the broadest range of safe and effective treatment options.

E. Dosing Regimens Are Patentable Subject Matter in Peer Jurisdictions

72. Allowing Pharmascience’s appeal would put Canada out of step with all of its peer jurisdictions, which have uniformly found that novel, non-obvious dosing regimens are patentable. Harmonizing patent rights with peer jurisdictions advances the purposes of the *Patent Act*, particularly when many of the commercial offerings that would benefit Canadians were invented in those peer jurisdictions.

¹⁴⁹ *TRIPS Agreement*, Art [27\(1\)](#).

¹⁵⁰ *TRIPS Agreement*, Art [27\(1\)](#), [Note 5](#).

¹⁵¹ See generally Ken Bousfeld, “The Progress of Science and the Useful Arts: Misadventures in Canadian Law on Patent-Eligible Subject Matter” (2012) [10:2 CJLT 130](#) at 132-41, 147-51.

73. **USA:** Dosing regimens are generally considered a “process” that is patentable under the US Patent Act,¹⁵² if all of the general criteria for patentability are met.¹⁵³ Dosing regimen patents are regularly obtained and enforced in the United States.¹⁵⁴

74. The US has no exclusion of MMT from patentability. By statute, medical practitioners are exempt from any remedies against them “[w]ith respect to a medical practitioner’s performance of a medical activity that constitutes an infringement.”¹⁵⁵ The exemption does not extend to use of pharmaceuticals, including dosing regimens. Section 287(c)(2) of the U.S. Code provides:

For the purposes of this subsection: (A) the term “medical activity” means the performance of a medical or surgical procedure on a body, but shall not include (i) the use of a patented machine, manufacture, or composition of matter in violation of such patent, (ii) the practice of a patented use of a composition of matter in violation of such patent, or (iii) the practice of a process in violation of a biotechnology patent.¹⁵⁶

Although for a different purpose, this definition of “medical activity” is broadly consistent with the distinction made in *Shell Oil*, the *AZT Case* and *Lawson* between patenting a professional skill and use of a commercial offering.

75. **Australia:** Novel and non-obvious dosing regimens are patentable in Australia. For example, in *Neurim Pharmaceuticals (1991) Ltd v Generic Partners Pty Ltd (No 5)* (“*Neurim*”) the Federal Court of Australia recently found patent claims covering a method of treating a patient by administration of melatonin within a particular dosage range to be valid and infringed.¹⁵⁷

¹⁵² *Patent Act*, s [2](#); 35 USC § [101](#), Janssen BOA, Tab 1; see e.g., *Vanda Pharmaceuticals Inc v West-Ward Pharmaceuticals Int’l Ltd* (2018), [887 F3d 1117](#) (US Fed Cir) (holding that claims reciting treating schizophrenia by administering specified amount of drug were patentable).

¹⁵³ A dosing regimen, like all patent claims, must not attempt to claim laws of nature, physical phenomena or abstract ideas: *Mayo Collaborative Services v Prometheus Laboratories, Inc.* (2012), [566 US 66](#) (US Sup Ct) at 70, 72-73.

¹⁵⁴ See e.g., *Endo Pharmaceuticals Solutions, Inc v Custopharm Inc* (2018), [894 F3d 1374](#) (US Fed Cir); *AstraZeneca LP v Apotex, Inc* (2010), [633 F3d 1042](#) (US Fed Cir).

¹⁵⁵ 35 USC § [287\(c\)\(1\)](#), Janssen BOA, Tab 1.

¹⁵⁶ 35 USC § [287\(c\)\(2\)](#), Janssen BOA, Tab 1.

¹⁵⁷ *Neurim Pharmaceuticals (1991) Ltd v Generic Partners Pty Ltd (No 5)*, [\[2024\] FCA 360](#) at para [474](#) (Austl FC).

76. MMT are not even raised in dosing regimen cases like *Neurim* given the leading Australian case on MMT, *Apotex v Sanofi-Aventis*.¹⁵⁸ Like the *AZT Case*, *Apotex v Sanofi-Aventis* dealt with a new use of a known drug. Like our *Patent Act*, the Australian statute has been amended multiple times after Australia signed the *TRIPS Agreement*, but still has no express exclusion of MMT.¹⁵⁹ After a detailed examination of caselaw in Australia, the UK, EU, US and Canada, as well as the various policy rationales that have been advanced for a preclusion against MMT, the High Court concluded that a medical method is eligible for a patent if “it is a contribution to a useful art having economic utility,”¹⁶⁰ including a new use of a known drug.¹⁶¹

77. In reaching this conclusion, Justices Crennan and Kiefel, who wrote the primary reasons of the majority, concluded that (i) claims for a new product suitable for a therapeutic use, (ii) combined product/method claims and (iii) method claims relating to such products “cannot be distinguished in terms of economics or ethics. In each case the subject matter in respect of which a monopoly is sought effects an artificially created improvement in human health, having economic utility.”¹⁶² However, they held that method claims relating to a pharmaceutical can be distinguished from the activities or procedures of doctors when physically treating patients. While the latter were not categorized as ineligible *per se* for a patent, the Court noted that such activities are unlikely to meet the general requirements for patentability, as they “are not capable of being practically applied in commerce or industry.”¹⁶³ In Australia it is clear that when the claims include a drug, they meet the practical application test.

78. **UK:** The UK *Patents Act 1977* defines MMT as “a method of treatment of the human or animal body by surgery or therapy.”¹⁶⁴ However, it also explicitly provides that pharmaceuticals for use in any such method of treatment are not excluded from patent protection.¹⁶⁵ The UK Court

¹⁵⁸ *Apotex v Sanofi AUS* at para [1](#).

¹⁵⁹ *Apotex v Sanofi AUS* at paras [279](#), [280](#).

¹⁶⁰ *Apotex v Sanofi AUS* at para [286](#).

¹⁶¹ *Apotex v Sanofi AUS* at paras [288-289](#).

¹⁶² *Apotex v Sanofi AUS* at para [282](#).

¹⁶³ *Apotex v Sanofi AUS* at para [287](#).

¹⁶⁴ *UK Patents Act*, s [4A\(1\)\(a\)](#); see also s [4A\(1\)\(b\)](#).

¹⁶⁵ *UK Patents Act*, s [4A\(2\),\(3\) and \(4\)](#). See also Intellectual Property Office, *Manual of Patent Practice* (updated January 2025), [online](#); see also *Abbott Respiratory/Dosage regime* (G 02/08), [\[2010\] 10 OJ EPO 456](#) (EPO Enlarged Board of Appeal) at para [5.9.1.2](#) [*Abbott Respiratory*].

of Appeal has adopted the European Patent Office (“EPO”)’s reasoning that the intention behind the MMT exclusion “is only to free from restraint non-commercial and non-industrial medical and veterinary activities.”¹⁶⁶ In *Actavis v Merck* the Court held that a novel, non-obvious dosing regimen is patentable: “Research into new and better dosage regimes is clearly desirable—and there is simply no policy reason why, if a novel non-obvious regime is invented, there should not be an appropriate patent reward.”¹⁶⁷

79. **European Patent Convention (“EPC”):** The EPC definition of MMT is identical in substance to that in the UK.¹⁶⁸ In the *Abbott Respiratory* case, the Enlarged Board of Appeal of the EPO considered whether patenting is possible when the only novel feature of a treatment is the dosage regime.¹⁶⁹ The Board found that novelty and non-obviousness can derive from “the

¹⁶⁶ *EISAI/Second Medical Indication* Decision (G 0005/83), [\[1985\] OJ EPO 64](#) at para [22](#) [emphasis added], quoted with approval in *Actavis* at para [29](#) [emphasis added].

At para 125 of its factum, Pharmascience includes a block quote purportedly from *Bristol-Myers Squibb Company v Baker Norton Pharmaceuticals Inc, Napro Biotherapeutics Inc* [\[1998\] EWHC Patents 300](#), aff’d [\[2000\] EWCA Civ 169](#). The “quote” stitches together sentences and phrases from three different paragraphs, out of order. In any event, the section of the judgment from which the “quote” was fashioned relates to novelty, which is not at issue in this appeal.

¹⁶⁷ *Actavis* at paras [28-31](#), [44](#), [49](#); see also *Actavis Group PTC EHF v ICOS Corporation* [\[2019\] UKSC 15](#) at paras [74-77](#).

In the UK and among other European Patent Convention signatories, certain phrasing of the claim is required, initially “Swiss form” (“the use of compound X in the manufacture of a medicament for a specified (and new) therapeutic use ...”) and now “EPC 2000 claim” form (“compound X for use in the treatment of Y”): *Actavis* at para [7](#); *Abbott Respiratory* at para [5.10.4](#). The same linguistic formula is not required in Canada, as confirmed by the range of patent claims listed in the *PMNOC Regulations* as eligible.

¹⁶⁸ *Convention on the Grant of European Patents (European Patent Convention 2000)*, 5 October 1973, [UNTS vol 1065](#), No 16208, arts [53\(c\)](#), [54\(4\)](#) and [\(5\)](#).

¹⁶⁹ *Abbott Respiratory* at para [I.1.2\(2\)](#). See e.g., European Patent Office, Interlocutory Decision in Opposition Proceedings, Application No 08863534.7-1109/2234617/ (10 May 2024) at ss II, III, Janssen BOA, Tab 3, in which the EPO maintained the equivalent of the 335 Patent (none of the 20 opponents raised MMT as an issue).

purpose the claimed substance or composition is related to, namely from its intended therapeutic use.”¹⁷⁰ In particular, a new dosing regimen is a potentially novel “specific use.”¹⁷¹

80. The Board concluded that “concerns with respect to undue prolongations of patent rights potentially resulting from patent protection for claims purporting to derive their novelty and inventive step only from a not hitherto so defined dosage regime for treatment by therapy of an illness already treated by the same drug” could be resolved by all of the general requirements for patentability.¹⁷² The Board thus expressly rejected the same suggestion Pharmascience is making to this Court that concerns about evergreening justify categorically excluding dosing regimens from patentability.

81. **New Zealand:** New Zealand’s *Patents Act* provides, “An invention of a method of treatment of human beings by surgery or therapy is not a patentable invention.”¹⁷³ Despite this explicit exclusion of certain types of MMT from patentability, dosing regimens are patentable in New Zealand.¹⁷⁴ In *Merck & Co Inc v Arrow Pharmaceuticals (NZ) Ltd*, the New Zealand High Court considered a claim in which the novelty rested in the dosage regime, and found such claims to be “valid in principle.”¹⁷⁵ The dosage regimen in issue in that case was found not to be obvious, as skilled physicians would have expected it to result in unacceptable side effects. “Merck’s inventiveness existed in going against the understanding of the skilled addressee ... and developing an effective treatment for osteoporosis.”¹⁷⁶

82. **Israel:** Pharmascience relies on an out-of-context quote from a 1974 decision of the Supreme Court of Israel.¹⁷⁷ Pharmascience fails to acknowledge that the majority in that case ultimately concluded that the European approach is a fair compromise and that the MMT

¹⁷⁰ *Abbott Respiratory* at para [5.10.9](#).

¹⁷¹ *Abbott Respiratory* at para [6.1](#).

¹⁷² *Abbott Respiratory* at [6.3](#).

¹⁷³ *Patents Act 2013*, s [16\(2\)](#).

¹⁷⁴ The claim must be drafted in “Swiss-style.” See footnote 167 above.

¹⁷⁵ *Merck & Co Inc v Arrow Pharmaceuticals (NZ) Ltd* (2006), CIV-2006-485-817 at para 10 (NZ HC WN) [*Merck & Co Inc v Arrow*], Janssen BOA, Tab 4.

¹⁷⁶ *Merck & Co Inc v Arrow* at para 37, Janssen BOA, Tab 4.

¹⁷⁷ Pharmascience Factum at para 94; *The Wellcome Foundation Ltd v Plantex Ltd*, 1974 RPC 514 (Supreme Court of Israel) [*Wellcome v Plantex*], Janssen BOA, Tab 8.

preclusion in Israel should be similarly restricted.¹⁷⁸ The Court unanimously found a new use of a known compound to be patentable. In a concurring opinion, Justice Witkon would not have continued any MMT disallowance: “There is thus no ground, either in law or in logic, for holding that a method of therapeutic treatment is unpatentable and any consideration that at one time might possibly have justified such a holding, is nowadays devoid of any substance.”¹⁷⁹

83. The decision that Pharmascience relies upon was decided on the basis of the law that predates the current Israeli Patents Law. Subsection 7(1) of the current statute provides that no patent shall be granted for “a method for the therapeutic treatment of the human body.”¹⁸⁰ As in the UK, EPC jurisdictions and New Zealand, this language has been held not to extend to dosing regimens of pharmaceuticals. As in those jurisdictions, certain drafting requirements apply, but novel, non-obvious dosing regimens qualify for patent protection.¹⁸¹

F. There Are No Sound Policy Reasons to Exclude Dosing Regimens

84. None of the policy rationales advanced by Pharmascience justify departing from peer jurisdictions and disqualifying dosing regimens from patentability. To the contrary, the purposes of the *Patent Act* are best served by incentivizing R&D into new medical commercial offerings.

i) Dosing Regimens Require Expensive Coaxing into the Marketplace

85. Innovation in the pharmaceutical sector is costly and arduous. The development of a drug costs on average US \$2.6 billion, and 92% of pharmaceutical R&D projects fail.¹⁸²

¹⁷⁸ *Wellcome v Plantex* at 540, Janssen BOA, Tab 8.

¹⁷⁹ *Wellcome v Plantex* at 536, Janssen BOA, Tab 8.

¹⁸⁰ [Patents, Law, 08/08/1967—5727](#), s 7(1).

¹⁸¹ See *Teva Pharmaceutical Industries Ltd and Unipharm Ltd v Merck & Co, Inc* (2010), (Patent App No. 153109) at para 49 (The Registrar of Patents, Designs and Trademarks) (Israel), aff’d Jerusalem District Court and Israeli Supreme Court) (but Registrar’s conclusion on patentable subject matter not appealed), Unofficial Translation, Janssen BOA, Tab 7, Official version, Janssen BOA, Tab 6; Israel Patent Office *Examination Guidelines* (Official Ed 8) (28 February 2023) at para 6.1, Janssen BOA, Tab 9.

¹⁸² Joseph A DiMasi et al, “Innovation in the pharmaceutical industry: New estimates of R&D costs,” (2016) 47 *Journal of Health Economics* 20–33, [online](#) (pdf); Kim et al at [1-2](#).

86. These risks and expenditures are undertaken by innovative pharmaceutical companies, such as Janssen, because the result of this R&D has commercial value. The role of innovators is, indeed, to develop new drugs, find new uses for known drugs, and develop better formulations and dosing regimens for those drugs, all of which are the kinds of innovations that “require coaxing into the marketplace.” Dosing regimen discoveries are an important part of drug R&D, as demonstrated by the fact that INVEGA SUSTENNA could not have been brought to market without the long and costly efforts needed to invent the patented dosing regimens.

87. Contrary to Pharmascience’s submissions, dosing regimens are not merely “how-to” guides, such as would accompany a remote control¹⁸³ — they are important discoveries that provide physicians with new, evidence-based tools to better treat their patients.

ii) Dosing Regimens Do Not Interfere with a Doctor’s Skill and Judgment

88. Pharmascience alleges that patents for medical methods have a chilling effect on doctors, whom it argues may refrain from administering a drug dosing regimen or modifying a drug treatment schedule for fear of infringing a patent.¹⁸⁴ As this Court recognized in the *AZT Case*, drug patents do not prevent doctors from delivering optimal treatment. Doctors regularly prescribe patented drugs with no fear of being sued. Indeed, the new use patent upheld in the *AZT Case* gave Glaxo a broader scope of exclusivity than the 335 Patent gives to Janssen. Glaxo’s AZT patent covered all uses of AZT for HIV (i.e., any doses or dosing regimens of AZT, as long as the AZT was used for HIV). Despite this broad scope, as Justice Binnie observed in the *AZT Case*, “How and when, if at all, AZT is employed is left to the professional skill and judgment of the medical profession.”¹⁸⁵ Here, the 335 Patent is narrowly limited to its specified dosing regimens. That patent does not circumscribe the physician’s skill and judgment in prescribing INVEGA SUSTENNA. Any decision that the doctor makes as to how and when to use INVEGA SUSTENNA is either: a) licensed; or b) non-infringing.

89. The purchase of the patented series of doses of INVEGA SUSTENNA from Janssen includes an implied licence to use them (indeed, that is the whole purpose of making the drug

¹⁸³ Pharmascience Factum at paras 82-88.

¹⁸⁴ Pharmascience Factum at paras 93-94.

¹⁸⁵ *AZT Case* at para [50](#).

available).¹⁸⁶ In prescribing one of the patented dosing regimens for INVEGA SUSTENNA, the doctor is merely recommending a licenced use of the product. In the infringement proceedings in this case (from which leave to this Court was denied), the FCA described both prescribing physicians and patients as Janssen’s “customers” for purposes of the implied licence, and held that sale of the patented combination of doses includes the implied right to use the dosing regimens.¹⁸⁷

90. If the doctor, exercising his or her skill and judgment, prescribes a *different* dosage regime, Janssen’s patent, of which its approved dosing regimen is an essential element of every claim, is not infringed.¹⁸⁸ As Pharmascience acknowledges at paragraph 92 of its factum, infringement of a patent requires appropriation of *every* essential element of the claim. If a doctor prescribes a 150/100/100 mg series of INVEGA SUSTENNA instead of the patented 150/100/75 mg series, Janssen’s patent is not infringed. If the doctor starts the second loading dose on Day 14, rather than the patented Day 8 ± 2 days, Janssen’s patent is not infringed.¹⁸⁹

91. Indeed, the only way that a doctor could infringe the 335 Patent would be by prescribing a claimed dosing regimen with a generic copycat of INVEGA SUSTENNA. No such drug is currently available.

¹⁸⁶ *Eli Lilly & Co v Novopharm Ltd*, [1998 CanLII 791](#) at para 100 (SCC), [1998] 2 SCR 129 [*Eli Lilly v Novopharm*]; *Signalisation de Montréal Inc v Services de Béton Universels Ltée*, [1992 CanLII 2427](#) at 355 (FCA).

¹⁸⁷ *FCA Summary Decision* at paras 21 and 29, leave to appeal ref’d [2024 CanLII 58472](#) (SCC).

¹⁸⁸ *FCA Summary Decision* at paras 13-17, 28-29, leave to appeal ref’d [2024 CanLII 58472](#) (SCC); *Eli Lilly v Novopharm* at paras 99-101.

¹⁸⁹ The same is true of patent claims to “variable” dosing ranges. If the doctor prescribes anywhere within the patented range, they have a license to do so. If the doctor prescribes outside the patented range, they are not infringing the patent. Janssen agrees with Pharmascience that the distinction made by the courts below, between fixed and variable ranges, is unsound — but for a different reason. *Neither* type of dosing regimen patent restricts how or when the doctor prescribes the patented drug. As intended by the *Patent Act*, the monopoly restricts generic companies that seek to copy an innovative product, not the doctors and patients who are the intended beneficiaries of the innovator’s R&D.

92. As described above, there have been *PMNOC Regulation* proceedings with three generic companies, all of which were unsuccessful in seeking findings of invalidity or non-infringement in relation to their proposed versions of INVEGA SUSTENNA. Litigation under the *PMNOC Regulations* is conducted prior to the approval of the generic copycat (and solely between the innovative and generic drug companies; it does not involve individual potential users of the proposed generic drug).¹⁹⁰ If the generic company wins the litigation, they are able to offer the copycat with no risk of infringement by the generic company or physicians. If the innovator wins, like Janssen in this case, the generic product cannot be sold until the valid patents have expired. Even if the generic launches “at risk” and is ultimately found to infringe (e.g., if the generic wins at trial, and markets its product during an appeal that subsequently overturns the trial decision), innovative pharmaceutical companies never sue physicians or patients for prescribing or using the product that the generic chose to market at risk. Janssen is not aware of a single patent case brought by a drug company against a doctor or patient.

93. As the foregoing makes plain, this appeal is not really about the freedom of doctors to practice their profession. It is about Pharmascience’s desire to profit from Janssen’s invention by selling a generic copycat version of INVEGA SUSTENNA that has been found to infringe the 335 Patent (on a final basis, leave to this Court having been denied).

iii) A Concern for Evergreening Does Not Justify Ineligibility of All Dosing Regimen Patents

94. Contrary to what Pharmascience suggests, obtaining patents that build on past discoveries is not in itself evergreening. Section 2 of the *Patent Act* defines an “improvement” (of an “art”, etc.) as an invention. The Act permits an inventor to obtain a patent for each invention.¹⁹¹

95. However, an inventor cannot “double patent” the same invention.¹⁹² The concern about evergreening would arise if a patentee could obtain successive patents on “obvious or uninventive

¹⁹⁰ *PMNOC Regulations*, s 6 (“First person” and/or owner of the patent is the innovative drug company. The “second person” is the generic drug company).

¹⁹¹ *Whirlpool* at para 63; *Patent Act*, s 36(1).

¹⁹² *Whirlpool* at para 63.

additions [which] prolongs its monopoly beyond what the public has agreed to pay.”¹⁹³ As in peer jurisdictions, any concern about inappropriately extending a patentee’s monopoly can be addressed through the general requirements in the *Patent Act*.¹⁹⁴ The consistent international response to this policy argument is that evergreening is to be dealt with through the novelty and “inventive step” (non-obviousness) requirements, rather than limiting patentable subject matter.

96. This Court reached a similar conclusion in *Apotex v Sanofi-Synthelabo Canada*, finding that the risk that a patentee might attempt to evergreen should not disqualify *an entire category of patents* from protection. This Court determined that “a generalized concern about evergreening is not a justification for an attack on the doctrine of selection patents.”¹⁹⁵ Rather, to prevent evergreening, this Court has prohibited not only “same invention” double patenting, but also “obviousness” double patenting, precluding the issuance of a patent with claims that are not “patentably distinct” from those of an earlier patent.¹⁹⁶

97. The 335 Patent illustrates the wisdom of this Court’s approach. Janssen’s claims withstood challenges from multiple generic manufacturers, and the 335 Patent has consistently been found to be non-obvious. As such, it cannot constitute evergreening.¹⁹⁷ The 335 Patent is clearly a breakthrough advancement in the treatment of schizophrenia for physicians, patients and Canada’s healthcare system generally.

98. Follow-on innovation, such as multiple generations of technologies or medicines, is to be encouraged. Part of the reason that the *Patent Act* requires detailed disclosure of inventions is to

¹⁹³ *Whirlpool* at para [37](#). There is no evidence in this case about the 250 patents that Pharmascience alleges that AbbVie obtained on HUMIRA. Moreover, the allegation appears to relate to the number of US (not Canadian) patents AbbVie applied for (not obtained): *In re Humira (Adalimumab) Antitrust Litigation* (2020), [465 F. Supp. 3d 811](#) (N Dist Ill) at [822-823](#), aff’d (2022) [42 F. 4th 709](#) (7th Cir).

¹⁹⁴ See e.g., *Abbott Respiratory* at para [6.3](#).

¹⁹⁵ *Sanofi* at para [98](#).

¹⁹⁶ *Whirlpool* at para [66](#); *Sanofi* at paras [112-113](#).

¹⁹⁷ *Trial Decision* at paras [158-159](#), AR, T2.

facilitate further R&D that builds on the initial discovery.¹⁹⁸ If the *Patent Act* halted innovation after the first patentable idea, many life-saving or life-transforming treatments would never have been uncovered.

99. Pharmascience’s attempt to draw a distinction between the (patentable) discovery of new uses for drugs and the (purportedly unpatentable) discovery of new ways of “how and when” to use drugs is untenable.¹⁹⁹ The suggestion that “physicians and other clinicians” are in the position to invent novel dosing regimens is simply not borne out by the facts, either in the case at bar (see *supra* para 26), or in the industry at large, where dosing regimen patents for drugs are universally asserted by and against pharmaceutical companies rather than healthcare practitioners.²⁰⁰ Furthermore, dosing regimens and other discoveries as to “how and when” to use drugs are critically important to healthcare outcomes and should not be carved out of Canada’s public policy of encouraging pharmaceutical innovation.

G. Pharmascience Has Not Proposed a Viable Test for MMT

100. Pharmascience asks this Court to adopt a results-oriented test for MMT that is specifically designed to exclude all dosing regimens from patentability. Its proposed test rests precariously on three words from one sentence taken out of context from the *AZT Case*, which, as discussed above, was not presented as a test for MMT. Among other problems, the proposed test:

- (a) *Is ambiguous and unworkable*: The proposed “how and when” test suffers from the same problem as the current “skill and judgment” test: it is ambiguous and difficult to apply. Taking each element of “how” and “when” in turn, it is not clear what would and would not constitute an MMT. In particular, “how” a drug should be used could mean by a specific route of administration, using a specific dosage form, or taking it with another drug. Similarly, “when” a drug should be used could mean with a certain dosing regimen, at a specific time of day, when a patient has a certain disease or clinical presentation, or in

¹⁹⁸ *Sanofi* at paras [100](#), [104](#), [106](#); *Harvard College* at paras [4](#), [106](#) (*per* Binnie J., dissenting but not on this point).

¹⁹⁹ Pharmascience Factum at paras 83-84.

²⁰⁰ *PMNOC Regulations*, s [6](#).

conjunction with another treatment. Adopting Pharmascience’s proposed test would not eliminate the uncertainty around the law of MMT, but rather *add* to the uncertainty.

- (b) *Is absurdly overbroad and inconsistent with this Court’s decision in the AZT Case:* Despite acknowledging that the many patents that exist over pharmaceuticals and their uses comprise patentable subject matter,²⁰¹ Pharmascience proposes an extremely broad test for MMT that would invalidate or call into question many of those patents. Indeed, its “how and when” test is so open-ended it would capture the claims in the *AZT Case* relating to how (i.e., by capsule or tablet in an amount from 10 to 1500mg)²⁰² and when (i.e., for treatment or prophylaxis of AIDS) it should be used.

As stated by the FC, and affirmed on appeal, “[t]aken to its logical end [... the ‘how and when test’ ...] would prevent an inventor from patenting any subsequent use for a known compound, as this would monopolize the “how and when” of using the compound for treatment — a proposition that is clearly at odds with the system and jurisprudence which allows such new use patents.”²⁰³

- (c) *Is inconsistent with peer jurisdictions:* Under Pharmascience’s proposed test, surgical therapeutic and diagnostic methods that do not involve drugs would not be MMT, but dosing regimens would be — the opposite of UK law and the EPC. As noted above, the UK Court of Appeal and the EPO have held that their express MMT exclusions relate solely to non-commercial and non-industrial medical and veterinary activities and that novel drug dosing regimens are patentable subject matter. By proposing a gerrymandered MMT test to make the 335 Patent invalid, Pharmascience seeks to have this Court do the reverse of comparator jurisdictions and disallow drugs rather than skills.

H. Conclusion: The INVEGA SUSTENNA Patent Is Valid

101. Rather than adopting the Pharmascience test that suffers from these multiple frailties, Janssen proposes that this Court should hold either:

²⁰¹ Pharmascience Factum at para 76.

²⁰² *AZT FC* at para 323, Janssen BOA, Tab 2.

²⁰³ *Hospira Healthcare Corporation v Kennedy Trust for Rheumatology Research*, [2018 FC 259](#) at para [147](#), aff’d [2020 FCA 30](#).

- (a) There is no basis in the *Patent Act* for an exclusion of MMT if the specific claim satisfies the general *Patent Act* criteria; or
- (b) If this Court reads an MMT exclusion into the *Patent Act*, it should be limited to attempts to patent non-commercial professional activities and not extend to commercial offerings. Such an approach would not preclude patents on pharmaceutical dosing regimens as long as they satisfy all of the *Patent Act* criteria.

102. Put differently, where a claim is directed towards a pharmaceutical or medical product (such as INVEGA SUSTENNA), it constitutes valid subject matter, but where a claim is merely directed towards the activity of a physician unrelated to any article of trade, industry, or commerce, it does not. Another way of expressing the distinction is that a discovery is not MMT if, as in *Shell Oil*, it “has added to the cumulative wisdom on the subject of [the] compounds” (here to the cumulative wisdom about the medicine).²⁰⁴ A discovery is only MMT if it adds solely to the cumulative wisdom on surgical or medical skills “unrelated to trade, industry or commerce”²⁰⁵ or to any commercial offering.

103. At a minimum, the various types of claims relating to medicinal ingredients and their uses that are listed in the *PMNOC Regulations* as eligible for protection must not constitute MMT, or the *Patent Act* would be internally inconsistent. (The *PMNOC Regulations* having the same force as the statute itself.)²⁰⁶

104. Under any of these approaches to MMT, the 335 Patent is valid. It has been held to be non-obvious and meets all of the statutory criteria for patentability. All of the claims in the 335 Patent relate to a commercial offering. Every claim falls within the *PMNOC Regulations* categories.

105. The decision of the courts below that claims 1 to 16, 33 to 48 and 49 to 63 are product claims and have “economic value and [are] distinguishable from the skilled work of a physician, and hence outside the realm of methods of medical treatment as contemplated by the Supreme

²⁰⁴ *Shell Oil* at [549](#) [emphasis added].

²⁰⁵ *Shell Oil* at [554](#).

²⁰⁶ *Patent Act*, s [12\(2\)](#); see also e.g. *Monsanto v Ontario* at para [35](#).

Court of Canada”²⁰⁷ is a correct and reasonable conclusion.²⁰⁸ Claims 17 to 32 are no different, as those claims relate to the use of the same commercial product, and clearly also have economic value, similar to the claims in the *AZT Case*. Accordingly, the appeal should be dismissed.

106. The invention described in the 335 Patent is a hard-won improvement in the treatment options for psychiatrists. It is a new, economically valuable article of trade, industry or commerce invented by a manufacturer — not a new or improved non-economic professional skill developed by a physician. As a “new and useful” invention, the 335 Patent is valid.

PART IV: STATEMENT CONCERNING COSTS

107. The Respondents respectfully request that costs in this Court be granted, including costs relating to the leave motion, which were granted in the cause.

PART V: ORDER SOUGHT

108. The Respondents respectfully request that the appeal be dismissed.²⁰⁹

PART VI: STATEMENT CONCERNING CASE SENSITIVITY

109. Although certain footnotes in this factum cite to portions of the sealed record,²¹⁰ none of the information in the text of the factum is confidential. Any facts set out in the text of this factum could be included in this Court’s reasons, if any, in the appeal.

²⁰⁷ *FCA Decision* at paras [26](#), [41-42](#).

²⁰⁸ *AZT Case* at paras [41-44](#).

²⁰⁹ If this Court were to remand any issue to the FC, Janssen requests that the *status quo* as set out in paras [3](#) and [4](#) of the Judgment in *Trial Decision*, AR, T2, be maintained with respect to: (i) the injunction; and (ii) the declaration of infringement pursuant to s [6\(1\)](#) of the *PMNOC Regulations*.

²¹⁰ With respect to the confidential record, see in relation to the Appellant’s Record, Pharmascience’s Form 23B, in relation to the Appeal Book, Pharmascience’s Amended Form 23B, which supplements its initial Form 23B, and Confidentiality Order of the FCA dated 6 December 2022, filed by Pharmascience pursuant to Rule 19.1(1).

ALL OF WHICH IS RESPECTFULLY SUBMITTED this 24th day of February, 2025.

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