

Court File No. 41209
(A-205-22)
(T-1441-20 / T-558-22)

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

B E T W E E N :

PHARMASCIENCE INC.

Appellant
(Appellant/Defendant)

- and -

JANSSEN INC. and JANSSEN PHARMACEUTICA N.V.

Respondents
(Respondents/Plaintiffs)

APPELLANT'S MEMORANDUM OF FACT AND LAW

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PART I – OVERVIEW AND STATEMENT OF FACTS

A. Overview

1. The sole issue on this appeal is whether Canadian Patent No. 2,655,335 (the “335 Patent”) is invalid for claiming an unpatentable method of medical treatment.
2. The patentability of methods of medical treatment raises two questions:
 - (a) are methods of medical treatment patentable in Canada? and
 - (b) what is a method of medical treatment or what test should guide its determination?
3. On the first question, the answer is clearly “no”. Fifty years ago, this Honourable Court held that methods of medical treatment are not patentable in Canada.¹ Since that time, this Court, lower courts and the Canadian Intellectual Property Office (“CIPO”) have repeatedly affirmed this view.² To date, Parliament has not amended the *Patent Act* to authorize the patenting of such methods.³
4. But, on the second question, decisions from the Federal Court and the Federal Court of Appeal have produced inconsistent and confusing results, of which the current case is the latest example.⁴ This is the problem that requires addressing by this Court.
5. A rule that methods of medical treatment are not patentable will continue to produce these inconsistent results absent a workable test. At present, however, no such test exists. Rather, the

¹ *Tennessee Eastman v Commissioner of Patents*, [1974] SCR 111 (“*Tennessee Eastman*”) at pp. 118-119; *Shell Oil Co. v. Canada*, [1982] 2 S.C.R. 536 (“*Shell Oil*”) at pp. 554-555; *Imperial Chemical Inc. v. Commissioner of Patents*, [1986] 3 F.C. 40 (FCA) (“*Imperial Chemical*”) at p. 50.

² See e.g.: *Monsanto v. Schmeiser*, 2004 SCC 34 at para. 133; *Novartis v. Cobalt*, 2013 FC 985 (“*Novartis*”) at paras. 70-101, aff’d 2014 FCA 17 at paras. 2-3; *Axcan v. Pharmascience*, 2006 FC 527 (“*Axcan*”) at paras. 42-51; Manual of Patent Office Practice (“MOPOP”), sections 16.10.02, 17.03.02 and 23.01.

³ Parliament may be presumed to be aware of the interpretation of a statute provided by courts. See, e.g.: *CTV v. Canada*, 1993 CarswellNat 206 (FCA) at para. 29.

⁴ *Janssen v. Pharmascience*, 2022 FC 1218 (the “Trial Decision”), aff’d *Pharmascience v. Janssen*, 2024 FCA 23 (the “FCA Decision”), Appeal Record, (“AR”), Tabs 3 and 5.

jurisprudence related to methods of medical treatment has been marred by formulaic distinctions that raise more questions than answers. The Appellant (“Pharmascience”) asks this Court to fashion a legal test that answers the question, “what, for the purposes of the *Patent Act*, is a method of medical treatment?”

6. Pharmascience respectfully submits that an appropriate test can be devised by formalizing Justice Binnie’s holding in *Apotex v. Wellcome*⁵, namely, that a patent cannot “fence in” how and when a drug should be used. This idea – that methods of medical treatment are directed at *how* and *when* a drug should be administered – provides the foundation for a principled approach to identifying methods of medical treatment.

7. Specifically, Pharmascience proposes the following three-pronged test:

- (a) construing the claims of the patent according to the existing canons of patent claim construction;
- (b) identifying whether any of the essential elements of the claims as construed can properly be said to be “therapeutic” or “medical”; and
- (c) identifying whether any of those essential elements relate to how and when a drug or treatment is to be administered by a medical practitioner.

8. If both steps (b) and (c) are satisfied, then presumptively the patent is directed at improper subject matter, namely, a method of medical treatment. In the result, the patent is invalid. As detailed below, the adoption of this test will lend much needed clarity to this area of the law and is consistent with the structure and purpose of the *Patent Act*.

9. The application of this approach to the case at bar is straightforward. Paliperidone palmitate (“paliperidone”) is a drug that was known to be useful to treat schizophrenia well before the 335 Patent came into being. In particular, the 335 Patent claims:

- (a) *how* paliperidone should be used (*i.e.* by injecting long-acting formulations in certain dose amounts into the deltoid or gluteal muscles of a patient and adjusting those amounts if a patient has renal impairment); and

⁵ *Apotex v. Wellcome*, [2002 SCC 77](#) (“*Apotex v. Wellcome*”) at para. [50](#).

- (b) *when* it should be used (*i.e.* according to a three-part dosing regimen where different identified amounts are injected at different times).

10. Dosing regimens, however formulated, engage the “how” and “when”. They amount to methods of medical treatment and are thus unpatentable. At its simplest, they are not an “invention” under s. 2 of the *Patent Act*.

11. As the 335 Patent claims a dosing regimen, it has all the touchstones of a patent directed at a method of medical treatment, and it meets the above test. Pharmascience submits that it is plain that, in the decisions below, the Federal Court and the Federal Court of Appeal (“FCA”) erred in holding that the 335 Patent did not monopolize a method of medical treatment.

B. Background Facts

1. Schizophrenia

12. Schizophrenia is a debilitating psychiatric disorder that afflicts over 300,000 Canadians.⁶ Schizophrenia is incurable and requires life-long management with antipsychotic medications. Adherence to such medications is critical. A leading cause of relapse is the failure of schizophrenic patients to take medication as prescribed.⁷

13. One strategy to ensure treatment adherence is the use of long-acting formulations of antipsychotics. One type of long-acting formulation is intramuscular injections of antipsychotic drugs, known as “depot formulations” or “long-acting injectables”. Once injected, the drug releases from the injection site slowly, providing the patient with prolonged drug exposure.⁸

2. The 335 Patent

i. The disclosure of the 335 Patent

14. The 335 Patent was issued on September 6, 2016, from an application filed by Janssen in Canada on December 17, 2008 (with a priority date of December 19, 2007), and was published on

⁶ Trial Decision at para. 4, AR, Tab 3.

⁷ Trial Decision at para. 11, AR, Tab 3.

⁸ Trial Decision at para. 12, AR, Tab 3.

June 19, 2009.⁹ It does not expire until December 17, 2028.¹⁰ Janssen has marketed its 335 Patent under the brand name INVEGA SUSTENNA®.

15. At its core, the 335 Patent relates to dosing regimens of a paliperidone depot formulation for treatment of schizophrenia and related disorders.¹¹ The 335 Patent does not purport to claim the invention of paliperidone, its use to treat schizophrenia or psychiatric disorders, or even depot formulations containing paliperidone. To the contrary, the 335 Patent acknowledges that it was already known that extended-release tablets of paliperidone were marketed in the United States for the treatment of schizophrenia, and that depot formulations of paliperidone palmitate for injection had been made and evaluated.¹²

16. The 335 Patent also does not purport to reflect the first time *how* and *when* paliperidone should be administered had been investigated. To the contrary, as the record establishes, this was something that physicians were *already* exploring, including multiple clinical trials evaluating the performance of fixed doses (*i.e.* the same dose given each day) and flexible doses (*i.e.* determined by physicians rather than in pre-set amounts) of paliperidone depot formulations given according to a specified schedule.¹³

17. The 335 Patent states that its claimed invention has different “aspects”. Common to all these aspects, however, is one of two dosing regimens. The first dosing regimen specifies:

- (a) a first loading dose of 150 mg-eq. of paliperidone administered into the deltoid on day 1 of treatment;
- (b) a second loading dose of 100 mg-eq. of paliperidone administered into the deltoid on day 8 ± 2 days; and

⁹ Trial Decision at paras. [28-30](#), AR, Tab 3.

¹⁰ The 7-year period from filing to issuance was due to the fact that the application was repeatedly rejected for patenting a method of medical treatment. Janssen was only able to overcome these objections by repeatedly revising the claims and characterizing them in a certain way to the Patent Examiner. See: Trial Exhibit (“TX”) 40, AR, Tab 17.

¹¹ Trial Decision at paras. [28](#) and [31](#), AR, Tab 3.

¹² Trial Decision at paras. [115](#) and [132](#), AR, Tab 3.

¹³ Trial Decision at para. [133](#), AR, Tab 3.

- (c) maintenance doses of 75 mg-eq. of paliperidone administered into the deltoid or gluteal monthly \pm 7 days.¹⁴

18. The second dosing regimen is identical to the first, except it contemplates that patients with renal impairment would be given lower amounts (*i.e.* 100 mg-eq. loading dose, a 75 mg-eq. second dose and a 50 mg-eq. maintenance dose).

19. The different “aspects” of the invention, in essence, refer to different ways of describing the claimed dosing regimens: (i) “pre-filled syringes” of paliperidone adapted for administration according to the claimed dosing regimen; (ii) the “use of a dosage form” of paliperidone according to the claimed dosing regimen; (iii) the use of paliperidone in the manufacture of a medicament adapted for administration according to the claimed dosing regimen; and (iv) a “dosage form” of paliperidone adapted for administration according to the claimed dosing regimen.¹⁵

20. The 335 Patent then provides further details about its invention. These details confirm that the 335 Patent is directed at *how* and *when* paliperidone is to be administered by physicians in an effort to ensure an appropriate response to the drug:

[T]he recommended dosing regimen for patients to attain a therapeutic plasma level of paliperidone is for patients to receive the first dose of paliperidone palmitate on day 1 of treatment, followed by a second dose between days 6 to 10 of treatment and then a third dose between days 34 to 38 of treatment or monthly \pm 7 days after the second dose. ... The first two doses will preferably be injected in the deltoid muscle. ... Preferably the first two doses will be loading dose [sic] from about 100 mg-eq to about 150 mg-eq... The subsequent dose thereafter will drop to a therapeutic maintenance dose from about 25 mg to 150mg-eq. per month (\pm 7 days). ... Those of ordinary skill in the art will understand that the maintenance dose may be titrated up or down in view of the patients [sic] condition (response to the medication and renal function). [emphasis added]

[...]

Those of skill in the treatment of diseases could easily determine the effective amount of paliperidone to administer for the treatment of the disease listed above. [emphasis added]¹⁶

¹⁴ Trial Decision at paras. 33, 35 and 36, AR, Tab 3.

¹⁵ 335 Patent, p. 2, l. 18 – p. 7, l. 8, AR, Tab 7A.

¹⁶ 335 Patent at p. 12, ln. 3-25; p. 25, ln. 1-2, AR, Tab 7A.

21. Finally, the 335 Patent contains examples, which highlight that the 335 Patent is directed at *how* and *when* paliperidone is to be administered for the treatment of schizophrenia. For instance, Examples 2, 3 and 4 of the 335 Patent compare the pharmacokinetics¹⁷ profile of paliperidone based on whether it was administered in the deltoid or gluteal muscle; Example 6 identifies the target exposure ranges for paliperidone following injection; and Example 7 focuses on optimal dosing strategies in terms of when and how much drug should be given.¹⁸

ii. The claims of the 335 Patent

22. The claims of the 335 Patent are also directed at *how* and *when* paliperidone is to be administered. These claims fall into four sets.¹⁹ The construction of each of these claims (*i.e.* the understanding of each claim to a person of skill in the art to which the patent is directed) is not in dispute.

23. **Claim Set #1 (claims 1 to 16):** The trial judge, Justice Manson, found that the essential elements of claim 1 were:

- (a) Prefilled syringes²⁰ containing a depot formulation²¹ of paliperidone;
- (b) For administration by intramuscular injection²² to a psychiatric patient in need of

¹⁷ Pharmacokinetics refers to the study of how the body processes a drug. It looks at how a drug is absorbed, metabolized and distributed throughout the body.

¹⁸ 335 Patent, p. 29, ln. 15-p. 30, ln. 16; p. 35, ln. 18-25; p. 36, ln. 12-p. 37, ln. 18, AR, Tab 7A.

¹⁹ Trial Decision at para. 34, AR, Tab 3, AR, Tab 3.

²⁰ “Prefilled syringes” are syringes that come from the manufacturer already filled with the drug formulation; *Teva v. Janssen*, [2020 FC 593](#) at paras. [126](#) and [145](#); Trial Decision, at para. [9](#), AR, Tab 3.

²¹ “Depot formulation” is a type of sustained release dosage form that allows for the release and subsequent absorption of the active drug ingredient over an extended period of time; *Teva v. Janssen*, [2020 FC 593](#) at paras. [126](#) and [145](#); Trial Decision, at para. [9](#), AR, Tab 3.

²² “For administration by intramuscular injection” means that the formulation is to be injected into muscle tissue; *Teva v. Janssen*, [2020 FC 593](#) at paras. [126](#) and [145](#); Trial Decision, at para. [9](#), AR, Tab 3.

treatment for schizophrenia, schizoaffective disorder, or schizophreniform disorder;

- (c) A “loading dose regimen” wherein the prefilled syringes are adapted for administration in accordance with the following dosing regimen:
- (i) A first loading dose²³ of about 150 mg-eq.²⁴ of paliperidone injected into the deltoid on treatment Day 1;
 - (ii) A second loading dose of about 100 mg-eq. of paliperidone injected into the deltoid on treatment Day 8 ± 2 days; and
 - (iii) Continuous maintenance doses²⁵ of about 75 mg-eq. of paliperidone injected into the deltoid or gluteal monthly ± 7 days thereafter.²⁶

24. The essential elements of claim 2 are the same, except that the patient in need of treatment must have renal impairment and the claimed dose amounts are about 100 mg-eq, 75 mg-eq, and 50 mg-eq, respectively.²⁷

25. Claims 3 through 16 incorporate the dose amounts, dosing windows and injection sites from claims 1 and 2 but include specific limitations regarding the composition or components of the depot formulation (claims 3 to 14) or specify the disease to be treated (schizophrenia in claim 15 and schizoaffective disorder in claim 16).²⁸

²³ “Loading dose” is a dose used to quickly bring the blood plasma concentration of the drug into the desired therapeutic range; *Teva v. Janssen*, [2020 FC 593](#) at paras. [126](#) and [145](#); Trial Decision, at para. [9](#), AR, Tab 3.

²⁴ “About (150/100/75) mg-eq.” means the amount of paliperidone palmitate required to provide the stated dose of paliperidone. “About” means some variability in the amount is allowable; *Teva v. Janssen*, [2020 FC 593](#) at paras. [126](#) and [145](#); Trial Decision, at para. [9](#), AR, Tab 3.

²⁵ “Maintenance dose” is a dose used to maintain the steady state plasma concentration of the drug within the therapeutic range; *Teva v. Janssen*, [2020 FC 593](#) at paras. [126](#) and [145](#); Trial Decision, at para. [9](#), AR, Tab 3.

²⁶ Trial Decision at para. [94](#), AR, Tab 3.

²⁷ Trial Decision at para. [95](#), AR, Tab 3.

²⁸ Trial Decision at paras. [97-99](#), AR, Tab 3.

26. The trial judge emphasized that these “claims are conjunctive ... the claimed invention is a dosing regimen, not simply dosage forms.”²⁹

27. **Claim Set #2 (claims 17 to 32):** These claims effectively mirror claims 1 to 16, except that they are directed towards “use of a dosage form of paliperidone” *in the claimed dosing regimen*, rather than prefilled syringes. The trial judge interpreted “dosage form” to mean a paliperidone formulation, and a delivery system to administer the formulation to the patient, in a manner suitable for administration by intramuscular injection (*i.e.* a syringe).³⁰

28. **Claim Set #3 (claims 33 to 48):** These claims are directed towards the use of paliperidone palmitate for the preparation or manufacture of a medicament, again for use *in the claimed dosing regimen*. In this case, the trial judge observed that “medicament” means medicine and is distinguished from “dosage form” only insofar as “medicament” does not require a delivery means for the formulation. He also observed that “these claims’ essential features go beyond simple manufacture of a depot formulation and additionally prescribe a specific dosing schedule, specific dose amounts, and specific injection sites.”³¹

29. **Claims Set #4 (claims 49 to 63):** These claims were found to be identical to the earlier claims, referring to a dosage form adapted for administration of the claimed dosing regimen.³²

30. It is important to note what the 335 Patent did *not* claim. It did not claim:

- (a) pre-filled syringes of paliperidone *independent* of the dosing regimen in which they were to be employed;
- (b) dosage forms of paliperidone *independent* of the dosing regimen in which they were to be employed;
- (c) the use of paliperidone for the preparation of a medicament *independent* of the dosing regime in which it was to be employed; or
- (d) the use of paliperidone *independent* of how or when it was to be administered.

²⁹ *Teva v. Janssen*, [2020 FC 593](#) at para. [147](#); Trial Decision, at para. [96](#), AR, Tab 3.

³⁰ *Teva v. Janssen*, [2020 FC 593](#) at paras. [147-151](#); Trial Decision, at paras. [100-104](#), AR, Tab 3.

³¹ *Teva v. Janssen*, [2020 FC 593](#) at paras. [161-162](#); Trial Decision at para. [108](#), AR, Tab 3.

³² Trial Decision at para. [110](#), AR, Tab 3.

31. The reason for this is that, presumably, claims of this sort would not satisfy the novelty and non-obviousness requirements of the *Patent Act*, given the trial judge's findings that it was already known that: paliperidone could be used to treat schizophrenia; paliperidone product had been marketed as an extended-release oral tablet;³³ and paliperidone depot formulations had been developed.³⁴

3. The allegations below

32. Under the statutory scheme of the *Patented Medicines (Notice of Compliance) Regulations* (the "*Regulations*"), Janssen had listed the 335 Patent on the Patent Register maintained by the Minister of Health in connection with their INVEGA SUSTENNA product. INVEGA SUSTENNA is a paliperidone depot formulation sold in dosage strengths of 50 mg/0.5 mL (*i.e.*, 50 mg-eq.), 75 mg/0.75 mL, 100 mg/1 mL, and 150 mg/1.5 mL. The product monograph³⁵ for INVEGA SUSTENNA sets out dosing regimens that mirror those described in the 335 Patent, including the direction to physicians that the monthly maintenance dose (the third prong of the three-prong dosing regimen) "can be higher or lower within the recommended range of 25 to 150 mg based on individual patient tolerability and/or efficacy".³⁶

33. Because of Janssen's listing of the 335 Patent on the Patent Register and the scheme of the *Regulations*, any drug company that wished to market a generic version of INVEGA SUSTENNA in Canada before patent expiry first had to establish in a court proceeding that the 335 Patent is invalid and/or would not be infringed by the generic version.³⁷

34. Pharmascience sought approval from Health Canada to market a generic version of INVEGA SUSTENNA. In accordance with the framework established by the *Regulations*,

³³ The tablet contains paliperidone, not the related paliperidone palmitate.

³⁴ Trial Decision at paras. [115-116](#) and [132](#), AR, Tab 3.

³⁵ A product monograph is a document that contains scientific information and instructions on the safety and efficacy of a drug. It goes through extensive regulatory review and is ultimately approved and issued by Health Canada as part of the marketing authorization (known as a Notice of Compliance) to be issued. See: *Food and Drug Regulations*, para. [C.08.002.1\(1\)](#).

³⁶ Trial Decision at paras. [37-38](#), AR, Tab 3. INVEGA SUSTENNA Product Monograph, TX-30, AR, Tab 15.

³⁷) *Regulations*, ss. [4\(1\)](#), [6\(1\)](#) and [7\(1\)](#).

Pharmascience asserted that its proposed paliperidone product would not infringe the 335 Patent for several reasons, one being that the 335 Patent was invalid for monopolizing a method of medical treatment.

35. On this issue, Pharmascience's argument was straightforward. The evidence established that, in practice, physicians typically exercise their discretion to provide a maintenance dose that ranges from 50 to 150 mg-eq. These doses are indicated as available in the INVEGA SUSTENNA Product Monograph and it was accepted that the selection of a specific dose depends upon a patient's individual characteristics. Indeed, all the experts agreed that a particular maintenance dose may not work for every patient and that the physician, alongside the patient, would need to determine the most safe and effective dose based on the assessment of the patient's tolerance of other medications, comorbidities, and related factors.³⁸

36. It follows that, insofar as the claimed maintenance doses (*i.e.* 75 mg-eq and 50 mg-eq.) fall within this range, they operate to circumscribe the skill and judgment of the physician and thereby impermissibly monopolize a method of medical treatment. Indeed, in other proceedings involving the 335 Patent, the Federal Court and FCA acknowledged that the prescription of the claimed dosing regimen would require the exercise of skill and judgment.³⁹ Similarly, the Federal Court and FCA recognized that, in a large number of cases, patients would receive a maintenance dose greater than 75 mg-eq. such that "acts of infringement may be few and far between".⁴⁰

4. The trial decision⁴¹

37. The trial judge rejected Pharmascience's allegations. Although he acknowledged that methods of medical treatments are not patentable in Canada, he found that the 335 Patent did not

³⁸ Trial Decision at para. [162](#), AR, Tab 3. See, *e.g.*: Expert Report of Dr. Joel Jeffries, TX-38, at paras. 52-82, AR, Tab 16; Transcript, Cross-Examination of Dr. Ereshefsky, pp. 557:6-20; 657:26-658:24 and 662:21-25, AR, Tab 13; and Transcript, Cross-Examination of Dr. Chue, pp.706: 19-26; 710:26-711:14; 722:24-723:11; 724:3-21; 729:7-731:25, 733:28-734:14; 736:21-26; 737:3-738:19; 748:12-20; 749: 7-19; 763:14-764: 15 and 805:1-806:5, AR, Tab 14.

³⁹ See, *e.g.*: *Janssen v. Apotex*, [2022 FC 107](#) at para. [147](#), *aff'd* [2024 FCA 9](#); *Teva v. Janssen* [2023 FCA 68](#) at para. [110](#).

⁴⁰ *Janssen v. Teva*, [2020 FC 593](#) at paras. [271-272](#) and [290](#), *rev'd*, [2023 FCA 68](#).

⁴¹ The Trial Decision also considered whether the 335 Patent was obvious. The findings of the trial judge on obviousness are not at issue on this appeal.

monopolize a method of medical treatment.⁴²

38. The decision is striking in that it highlights the “patchwork” approach to the method of medical treatment analysis. Indeed, as noted below, the decision is grounded in a number of seemingly formal distinctions and acknowledges the existing inconsistency in the jurisprudence.

39. The trial judge asserted that a common starting point for a method of medical treatment analysis was to look at the language and substance of the claims.⁴³ He then found that claim sets #1, #3 and #4 (*i.e.* claims 1 to 16 and 33 to 63) did not monopolize a method of medical treatment because they are directed at vendible products.⁴⁴ In his view, “there appears to be no question in the case law that claims to a vendible product are patentable as not being methods of medical treatment” (hereinafter, the “vendible product restriction”).⁴⁵ The trial judge arrived at this conclusion despite the fact that these so-called product claims each had as an essential element that the product be “adapted for administration” of the dosing regimen to patients, as noted above.

40. The trial judge found that claim set #2 (claims 17 to 22) also did not monopolize a method of medical treatment because the claimed dosing regimens were said to be “fixed”. According to the trial judge, a patent claim does not patent a method of medical treatment “if it includes a specific dosage amount and/or specific administration interval”; it does so only if it monopolizes dosages or schedules “with ranges within which the physician must exercise skill and judgment” (hereinafter, the “fixed-variable dichotomy”).⁴⁶ The trial judge further explained that the claimed dosing regimens were fixed because: (i) the claims only provide for two possible dosing regimens, one for non-renally impaired patients and one for renally impaired patients with specified dosage amounts; and (ii) where there is variability (*e.g.* the choice of dosing windows (*e.g.* +/- 7 days) and injection sites (*e.g.* the deltoid or gluteal muscle)), the variability was not of clinical importance.⁴⁷

41. Based on the foregoing, the trial judge held that the claimed subject matter does not “require the exercise of skill and judgment”, despite holding that the claims are a “guide for the treatment of schizophrenia”, “[provide a] specific dosing regimen expected to produce a plasma

⁴² Trial Decision at para. [160](#), AR, Tab 3.

⁴³ Trial Decision at para. [161](#), AR, Tab 3.

⁴⁴ Trial Decision at para. [163](#), AR, Tab 3.

⁴⁵ Trial Decision at para. [163](#), AR, Tab 3.

⁴⁶ Trial Decision at para. [164](#), AR, Tab 3.

⁴⁷ Trial Decision at paras. [167-170](#), AR, Tab 3.

concentration of paliperidone within the therapeutic range necessary for safe and effective treatment of patients”, and is a regimen that “a physician can choose to implement ... or not”.⁴⁸

5. The appeal

42. Pharmascience appealed the trial judge’s decision. It asserted that, by ascribing a convenient label of “vendible product”, and applying the vendible product restriction to three of the four claim sets, the trial judge lost sight of their substance. Although those claims were ostensibly to a product, the product had to be “adapted for administration” to the claimed dosing regimen, and thus did not simply comprise dosage forms. Contrary to his reliance on the vendible product restriction, the trial judge had construed *all* of the claims as being to “a dosage regimen, not simply dosage forms”.⁴⁹

43. Pharmascience also asserted that the trial judge erred by basing his finding for the second claim set, *i.e.* the use claims, on the fixed-variable dichotomy. Contrary to the view expressed by the trial judge, Pharmascience maintained that patent claims for fixed dosages and schedules are not *per se* patentable; rather, they are methods of medical treatment if the evidence establishes that physicians must still exercise their skill and judgment when prescribing the medicine.⁵⁰ It contended that the fixed-variable dichotomy is not the operative dichotomy; rather, the dichotomy is between “one size fits all” dosing regimens that require no skill or judgment to implement (patentable), and dosing regimens that require the ongoing exercise of skill and judgment (unpatentable).⁵¹ Pharmascience further submitted that claims 17 to 32 were not properly characterized as relating to a fixed dosing regimen.⁵²

44. The FCA dismissed the appeal. In so doing, Justice Locke, writing on behalf of the Court, held that:

- (a) Methods of medical treatment do not meet the definition of “invention” in section 2 of the *Patent Act*, as established by *Tennessee Eastman*,⁵³ as approved by this Court

⁴⁸ Trial Decision at para. [171](#), AR, Tab 3.

⁴⁹ FCA Decision at para. [40](#), AR, Tab 5.

⁵⁰ FCA Decision at para. [13](#), AR, Tab 5.

⁵¹ FCA Decision at para. [33](#), AR, Tab 5.

⁵² FCA Decision at para. [44](#), AR, Tab 5.

⁵³ FCA Decision at para. [19](#), AR, Tab 5, citing *Tennessee Eastman* at p. [118](#).

in both *Shell Oil*⁵⁴ and *Apotex v. Wellcome*;⁵⁵

- (b) Claims to methods of medical treatment are unpatentable because they are “essentially non-economic and unrelated to trade, industry or commerce and related rather to the area of professional skill”;⁵⁶
- (c) A patent should not seek to fence in the exercise of such skills (including how and when a drug is administered) but it may cover a commercial offering”;⁵⁷
- (d) Vendible products have economic value and are thus distinguishable from the skilled work of a physician and hence outside the realm of methods of medical treatment;⁵⁸
- (e) The fixed-variable dichotomy has a “questionable underpinning” and had been rejected in four Federal Court cases, each of which found that fixed dosing regimens were held to constitute unpatentable methods of medical treatment;⁵⁹
- (f) Rather than focusing on the fixed-variable dichotomy, the proper inquiry is to ask “whether use of the invention (i.e., how to use it, not whether to use it) requires the exercise of skill and judgment” [emphasis in original]⁶⁰; and
- (g) Seemingly in recognition of the generality of this holding, the Court stated that “it is difficult to provide more detailed guidance than this.”⁶¹

45. Following these legal determinations, the FCA turned to the arguments directed at the 335 Patent.

46. As regards Claim Sets #1, #3 and #4 (claims 1 to 16 and 33 to 63), the FCA held that the trial judge was correct in holding that each of these claims was directed at a patentable, vendible

⁵⁴ *Shell Oil* at [554](#).

⁵⁵ *Apotex v. Wellcome* at para. [49](#).

⁵⁶ FCA Decision at para. [22-23](#), AR, Tab 5.

⁵⁷ FCA Decision at para. [23](#), AR, Tab 5, citing *Apotex v. Wellcome* at para. [50](#).

⁵⁸ FCA Decision at para. [26](#), AR, Tab 5.

⁵⁹ FCA Decision at paras. [29-37](#), AR, Tab 5.

⁶⁰ FCA Decision at para. [37](#), AR, Tab 5.

⁶¹ FCA Decision at para. [37](#), AR, Tab 5.

product, namely, pre-filled syringes (*i.e.*, claims 1 to 16), paliperidone for use in the “preparation of a medicament” (*i.e.* claims 33 to 48) and a dosage form (*i.e.* claims 49 to 63).⁶² Despite acknowledging Pharmascience’s argument that this put “form over substance”⁶³, given that each claim set required that the invention be “adapted for administration” in accordance with the claimed dosing regimens, the FCA held that “a claim may concern a vendible product even if it includes a dosing regimen as an essential element.”⁶⁴

47. Turning to Claim Set #2 (claims 17 to 32), the FCA acknowledged that the trial judge’s analysis was “incomplete”, insofar as it focused on the fixed-variable dichotomy rather than the skill and judgment test.⁶⁵ Nonetheless, the FCA was not satisfied that this “incomplete” finding constituted a reviewable error, because it was convinced that, elsewhere in his reasons, the trial judge had adverted to the question of skill and judgment and had “properly recognized the distinction between ... deciding whether to use the invention ... and how to use the invention.”⁶⁶

48. Finally, the FCA rejected a number of arguments advanced by Pharmascience, borne out by the evidence, that practising the claimed invention of the 335 Patent involved the skill and judgment of a physician. In particular, it held it did not matter that:

- (a) “different dosages may be required for different patients”, since “the fact that a fixed dosage may not work for some patients [is not] sufficient to conclude that the invention is an unpatentable method of medical treatment”;
- (b) the claims had dosing and scheduling windows as these windows were not “clinically relevant”;
- (c) the claims contemplated different injection points in the deltoid or gluteal muscles as this choice did not have “clinical implications”;
- (d) the patent contemplated that the maintenance dose may be “titrated up or down in view of patients [*sic*] condition”, as this titration did not imply that the claimed

⁶² FCA Decision at para. [42](#), AR, Tab 5.

⁶³ FCA Decision at para. [42](#), AR, Tab 5.

⁶⁴ FCA Decision at para. [41](#), AR, Tab 5.

⁶⁵ FCA Decision at para. [45](#), AR, Tab 5.

⁶⁶ FCA Decision at para. [49](#), AR, Tab 5.

invention demands the exercise of skill and judgment; and

- (e) the 335 Patent contemplated different dosages for patients with renal impairment and those without, as this difference was merely an “objective distinction that does not involve the exercise of physician’s skill and judgment”.⁶⁷

6. The effects of the decisions below

49. The effects of the FCA decision are significant. Although the Court acknowledged that a large number of patients on INVEGA SUSTENNA receive 100 mg-eq or 150 mg-eq as their maintenance dose (*i.e.* not the 75 mg-eq maintenance dose contemplated by the claims) and that instances of infringement may be “few and far between”⁶⁸ by operation of the *Regulations*, the Minister of Health is enjoined from granting Pharmascience the necessary authorization to market its paliperidone product in Canada until the expiry of the 335 Patent in December 2028.

50. Until December 2028, Pharmascience is prevented from selling any paliperidone product regardless of how it is used. Physicians and patients likewise are prevented from using Pharmascience’s paliperidone product for any treatment protocol and not merely the patented regime. Given that generic drugs are required by statute to be sold at a fraction of the cost of their corresponding brand name drug, the cost to provincial and federal (and private) health care plans is significant.

PART II – ISSUES

51. The sole issue on this appeal is whether the 335 Patent is invalid in that it claims an unpatentable method of medical treatment.

52. In support of its position that the courts below erred in concluding otherwise,

⁶⁷ FCA Decision at paras [50-56](#), AR, Tab 5.

⁶⁸ *Janssen v. Teva*, [2020 FC 593](#) at paras. [271-272](#). The evidence established that maintenance doses of 150 mg-eq and 100 mg-eq constituted 80% of refill prescriptions, whereas 75 mg-eq, the ostensible “continuous monthly maintenance dose”, represented only 13% of refill prescriptions (with the remainder being 50 mg-eq.). Expert Report of Dr. Joel Jefferies, TX-38, at paras. 79-80, AR, Tab 16.

Pharmascience proceeds as follows:

- (a) outlining why methods of medical treatment are not patentable under Canadian law;
- (b) situating the approach to patentability described in subparagraph (a) above within the broader scheme of the *Patent Act* as a whole;
- (c) delineating the problems associated with the existing approaches to determining what constitutes an unpatentable method of medical treatment;
- (d) describing an appropriate test for defining whether a patent claims a method of medical treatment; and
- (e) using this test to show that the 335 Patent is invalid for claiming a method of medical treatment.

PART III – ARGUMENT

A. Why Methods of Medical Treatment are Not Patentable in Canada

1. Section 2 of the *Patent Act*

53. At common law, market monopolies and restraints of trade are treated as being inherently evil and they are sanctioned under the criminal law.⁶⁹ The *Patent Act* and the jurisprudence associated with it create exceptions to the common law. Both define circumstances in which the public's right to free trade ought to be restricted and on specific terms.⁷⁰ There exists no such thing as an inherent right to a patent. Patent monopolies are valid only to the extent that they arise from compliance with all of the preconditions of the *Patent Act*. If they do not, the patent is invalid.⁷¹

54. One of these preconditions is that a patent can only be granted for an "invention". Section 2 of the *Patent Act* defines an invention as "any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement in any art, process, machine, manufacture or composition of matter."⁷² This definition, while broad, does not allow anything and

⁶⁹ *Reference re Validity of the Combines Investigation Act and of s. 498 of the Criminal Code*, [1929] S.C.R. 409 at 416; *The Case of Monopolies* (1603) 11 Co. Rep. 84b at 86a *et seq.*

⁷⁰ *Free World Trust v. Electro Santé Inc.*, 2000 SCC 66 ("Free World") at para. 13.

⁷¹ *Patent Act*, ss. 59, 62.

⁷² *Patent Act*, s. 2.

everything to be patented. As explained by this Court in *Harvard Mouse* case:

I cannot however agree with the suggestion that the definition is unlimited in the sense that it includes “anything under the sun that is made by man”. In drafting the *Patent Act*, Parliament chose to adopt an exhaustive definition that limits invention to any “art, process, machine, manufacture or composition of matter”. Parliament did not define “invention” as “anything new and useful made by man”. By choosing to define invention in this way, Parliament signalled a clear intention to include certain subject matter as patentable and to exclude other subject matter as being outside the confines of the Act [emphasis added].⁷³

55. Judicial interpretations of the definition of “invention” in section 2 have resulted in certain subject matter being excluded from the definition. As explained by this Court in *Monsanto*:

Subject matters that are specifically precluded by statute from patent protection are natural phenomena, laws of nature, and scientific principles: s. 27(8). Other subject matter has been excluded by judicial interpretation of s. 2 definitions of “invention” and “process” and s. 27(8). For example . . . methods of medical treatment ... [I]t is not unusual for courts and the Patent Office to interpret provisions of the Patent Act so as to exclude subject matter from patentability. If a claim encompasses subject matter that is precluded from patentability, it is invalid [emphasis added]⁷⁴

56. In short, it is well established that “methods of medical treatment” are not included in the “exhaustive list” for inventions described in section 2 of the *Patent Act*. They are thus not patentable.

2. Interpretations of Section 2 of the *Patent Act*

57. The analysis, however, does not end there. There is significant and controlling jurisprudence that interprets the meaning of various terms found in the *Patent Act*. Courts have properly taken up their role to clarify the abstract generalities that exist within the *Patent Act*.⁷⁵ In the case of methods of medical treatment, this Court and lower courts have consistently interpreted section 2 of the *Patent Act* as excluding methods of medical treatment.

ii. The source of the prohibition: *Tennessee Eastman*

58. The source of the prohibition on the patenting of methods of medical treatment in Canada

⁷³ *Harvard College v. Canada*, [2002 SCC 76](#) at para. 158.

⁷⁴ *Monsanto v. Schmeiser*, [2004 SCC 34](#) at paras. 133-134.

⁷⁵ Barrigar, Robert H, et. al., “Canadian Patent Act Annotated”, 2016 Thompson Reuter Canada Ltd., at 1:20.

is this Court's seminal decision in *Tennessee Eastman*. A careful review of the case is warranted, as it has not been overruled and remains good law.

59. In *Tennessee Eastman*, the applicant sought a patent on a method of closing incisions following surgery, by the use of a particular adhesive substance. The Commissioner of Patents refused the patent on the basis that this was not the kind of discovery (the adhesive itself not being new) that fell within the definition of "invention" in the *Patent Act*. As medical methods were not matters related to "trade, industry or commerce", they were not processes within the meaning of section 2 of the *Patent Act*. The Commissioner held:

Inasmuch as applicants claims are directed to a process limited solely to a medical or surgical treatment of animals including humans, and inasmuch as it is held such medical or surgical processes are not involved in commerce, trade and industry and are therefore outside the scope of a process which fall under Section 2(d) of the Patent Act, it is held that the claims are outside the scope of a process which falls under Section 2(d) of the *Patent Act* and that therefore, even if the arguments presented by applicant are accepted as proof of novelty, utility and unobviousness, the claims must fail for lack of subject matter [emphasis added].⁷⁶

60. On a follow-up review, the Commissioner's holding was upheld by the Acting Commissioner of Patents. He concluded that methods of medical treatment could not be said to be an "art" within the meaning of section 2 of the *Patent Act*:

[W]e are concerned with a process of medical or surgical treatment of living tissues. ... However, not all methods or processes fall within the meaning of "art" under Section 2(d) of the Patent Act. The word "art" cannot be taken in its broadest meaning for there are arts which are excluded by statutes for instance by Section 28(3), others by well known and accepted court rulings such as business system, method of teaching, etc. [emphasis added]⁷⁷

61. The decision of the Commissioner was judicially reviewed by Justice Kerr of the (then) Exchequer Court. After an exhaustive review of the authorities, he confirmed that medical methods were neither arts nor processes for the purposes of section 2 of the *Patent Act*. He explained that the reason for this exclusion was tied to the nature of the activity in question. That is, medical methods were essentially non-economic and related to professional fields. As Kerr J. explained:

⁷⁶ *Tennessee Eastman* at p. 114.

⁷⁷ *Tennessee Eastman* at p. 114.

In my view the method here does not lay in the field of manual or productive arts nor, when applied to the human body, does it produce a result in relation to trade, commerce or industry or a result that is essentially economic. The adhesive itself may enter into commerce, and the patent for the process, if granted, may also be sold and its use licensed for financial considerations, but it does not follow that the method and its result are related to commerce or are essentially economic in the sense that those expressions have been used in patent case judgments. The method lies essentially in the professional field of surgery and medical treatment of the human body, even although it may be applied at times by persons not in that field. Consequently, it is my conclusion that in the present state of the patent law of Canada and the scope of subject matter for patent, as indicated by authoritative judgments that I have cited, the method is not an art or process or an improvement of an art or process within the meaning of subsection (d) of section 2 of the *Patent Act* [emphasis added].⁷⁸

62. Kerr J.'s decision was upheld. Writing for the Court, Pigeon J. held that the medical method described in the application was neither an art nor a process within the meaning of "invention" under section 2 of the *Patent Act*. The Court, however, augmented its decision by recourse to then section 41 of the *Patent Act*. That section (now repealed)⁷⁹ held that a patentee could only claim a medicine when made by a specified process (*i.e.* and not *per se* as is presently the norm). As Pigeon, J. observed:

It is clear that a new substance that is useful in the medical or surgical treatment of humans or of animals is an "invention". It is equally clear that a process for making such a substance also is an "invention". In fact, the substance can be claimed as an invention only "when prepared or produced by" such a process. But what of the method of medical or surgical treatment using the new substance? Can it too be claimed as an invention? In order to establish the utility of the substance this has to be defined to a certain extent. In the case of a drug, the desirable effects must be ascertained as well as the undesirable side effects. The proper doses have to be found as well as methods of administration and any counter-indications. May these therapeutic data be claimed in themselves as a separate invention consisting in a

⁷⁸ *Tennessee Eastman v. Commissioner of Patents* (1970), 62 C.P.R. 117 (Ex. Ct.) at p. 154-155.

⁷⁹ The repeal of section 41 of the *Patent Act* does not impact the underlying *ratio* of the decision which, in a more fundamental way, is directed at the interpretation of section 2. This was first confirmed by the Federal Court of Appeal, which held that that "methods of medical treatment are not contemplated by the definition of invention [in section 2 of the *Patent Act*] as a kind of a process" and that "[t]he force of that pronouncement cannot be restricted to factual situations where subsection 41(1) of the Patent Act applies." See: *Imperial Chemical* at p. 50.

method of treatment embodying the use of the new drug? I do not think so, and it appears to me that s.41 definitely indicates that it is not so. ... [emphasis added]⁸⁰,

63. The principles arising out of *Tennessee Eastman* may be summarized as follows:
- (a) methods of medical treatment are not inventions for the purposes of the *Patent Act*, being neither “arts” nor “processes” as set out in section 2;
 - (b) methods of medical treatment are not inventions because they are essentially “non-economic” – the method and result are not related to trade, commerce and industry; and
 - (c) methods of medical treatment are not inventions because they are essentially directed to matters of “professional skill and judgment.”.

64. These themes had arisen in the lower courts even before *Tennessee Eastman*. The case of *Lawson v. Canada* is instructive. Although the specific patent at issue in that case did not directly relate to the medical arts, the Exchequer Court highlighted why methods of medical treatment were non-economic and that professional skills are not patentable:

The exclusion of methods of surgery and other processes for treating the human body may well lie outside the concept of invention because the whole subject is conceived as essentially non-economic

[...]

If a surgeon were to devise a method of performing a certain type 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 [emphasis added].⁸¹

65. This case law provides the foundation for why methods of medical treatment are not patentable. However beneficial or instructive such methods might be, they are not the sort of “inventions” contemplated by the *Patent Act*. In the words of one commentator, “a fundamental trait of patent law is its reliance on economic motivation and reward ... [it] is this trait which

⁸⁰ *Tennessee Eastman* at p. 119.

⁸¹ *Lawson v. Canada* (1970), 62 C.P.R. 101 (Can. Ex. Ct.).

distinguishes patent law from medical law most”.⁸²

iii. Later Supreme Court of Canada jurisprudence

66. As indicated above, this Court considered and applied the holding in *Tennessee Eastman*.

67. In *Shell Oil*, the Court held that a new use (the regulation of plant growth) for an old compound was an invention for the purposes of section 2 of the *Patent Act*. In so doing, the Court held that the word “art” could be interpreted as referring to “learning or knowledge” and that an invention of a new and useful and art applied “knowledge to effect a desired result which has an undisputed commercial value”.⁸³ Despite articulating this broad conception of “art,” Wilson J. cited *Tennessee Eastman* with approval, noting that the method of medical treatment described therein was not an “art” and thus not patentable: “[I]t was essentially non-economic and unrelated to trade, industry or commerce. It was related rather to the area of professional skills.”⁸⁴

68. In *Apotex v. Wellcome*, this Court considered a patent that, in a manner akin to *Shell Oil*, claimed a new use for an old compound, namely, the use of the drug AZT (previously known to be an anti-cancer agent) to treat HIV. Justice Binnie applied *Tennessee Eastman*, explaining:

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 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.⁸⁵

69. Pharmascience submits that *Apotex v. Wellcome* is instructive, as it provides for a ready way of distinguishing between that which is patentable (*i.e.* new uses or new compounds) and that which is not (*i.e.* medical methods that cover “how” and “when” AZT is to be used) in a way that maps onto the logic for the exclusion. Indeed, this distinction explains why claims structured as

⁸² [Martin, T. “Patentability of Methods of Medical Treatment: A Comparative Study”, *J Pat Trademark Off Soc.* 2000 Jun; 82\(6\):381-423.](#)

⁸³ *Shell Oil* at p. 549.

⁸⁴ *Shell Oil* at p. 554.

⁸⁵ *Apotex v. Wellcome* at paras. 49-50.

“the use of compound X to treat disease Y” are patent-eligible, while 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. Stated differently, what is patentable is a drug and its uses; what is an unpatentable method of medical treatment are matters such as dose selection, duration of therapy, medical decisions that are grounded on the patient’s age and condition, possible interactions with other drugs, and related assessments of how and when a medicine should be used.

iv. Lower court jurisprudence

70. Lower court jurisprudence has also consistently maintained that methods of medical treatment are not patentable. Although courts have vacillated about what constitutes a method of medical treatment, they have consistently recognized that they are not patentable. Following *Tennessee Eastman*, lower courts have framed the unpatentability of methods of medical treatment on the grounds that they are “non-economic” and/or improperly monopolize the exercise of professional skill and judgment.

71. As regards the former, the courts have, at once, accepted that methods of medical treatments are non-patentable because they are non-economic, while also relying on this fact to maintain the validity of patents whose claims are directed at vendible products. As explained in the FCA decision under review:

The references to “trade, industry or commerce” and “commercial offering” by the Supreme Court appear to be the basis for the focus of many decisions on whether the invention concerns a “vendible product” ... The idea, with which I agree, is 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 as contemplated by the Supreme Court of Canada.⁸⁶

72. As regards the latter, the finding that patents are not intended to monopolize the skill and judgment of a physician has resulted in a line of cases that:

⁸⁶ FCA Decision at para. [26](#), AR, Tab 5, citing: *Merck v. Apotex*, [2005 FC 755](#) at paras. [136–137](#); *Merck v. Pharmascience*, [2010 FC 510](#) at paras. [110, 114](#); *Janssen v. Mylan*, [2010 FC 1123](#) (“*Mylan*”) at para. [53](#); *Novartis v. Cobalt*, [2013 FC 985](#) (“*Novartis*”) at paras. [78, 91, 98](#), aff’d [2014 FCA 17](#); *Bayer v. Cobalt*, [2013 FC 1061](#) (“*Bayer*”) at para. [162](#); *Abbvie v. Canada*, [2014 FC 1251](#) at paras. [115, 125](#); *Biogen v. Taro*, [2020 FC 621](#) at para. [211](#) and *Visx v. Nidek* (1999), [3 C.P.R. \(4th\) 417](#) at para. [173](#), aff’d ([2001 FCA 215](#)).

| TAB NO. | DESCRIPTION | PARAGRAPH |
|--------------------------|--|------------------------|
| 38. | <i>Teva v. Janssen</i> , 2020 FC 593 , rev'd on other grounds, 2023 FCA 68 | 23, 26, 27, 28, 36, 49 |
| 39. | <i>The Case of Monopolies</i> (1603) 11 Co. Rep. 84b | 53 |
| 40. | <i>The Wellcome Foundation Ltd. v. Plantex Ltd.</i> 1974 R.P.C. 514 | 94 |
| 41. | <i>Visx Inc. v. Nidek Co.</i> (1999), 3 C.P.R. (4th) 417 , aff'd 2001 FCA 215 | 71 |
| SECONDARY SOURCES | | |
| 42. | "New uses for existing drugs". <i>Pharmacology</i>. September 17, 2024 | 83 |
| 43. | Barrigar, Robert H, et. al., "Canadian Patent Act Annotated", 2016 Thompson Reuter Canada Ltd., at 1:2 | 57 |
| 44. | CIPO, Practice Notice PN2020-04 | 115 |
| 45. | CIPO, Practice Notice, PN2015-01 | 115 |
| 46. | CMA Code of Ethics and Professionalism, 2018 | 87 |
| 47. | Cornish, Llewelyn and Aplin, <i>Intellectual Property</i> | 94 |
| 48. | Hippocratic Oath (modern version) (Written in 1964 by Louis Lasagna, Academic Dean of the School of Medicine at Tufts University) | 87 |
| 49. | Logothetis, D. "Rewarding Pharmaceutical Innovation for being Innovative: A Summary of the Pharmaceutical Patent System and Amendment to the Patent Act to Negate 'Evergreening' and 'Patent Thickets'". <i>Appeal</i>, Vol. 29 pp. 1-24 | 104 |
| 50. | <i>Manual of Patent Office Practice</i> , sections 16.10.02 , 17.03.02 and 23.01 | 3 |
| 51. | Martin, T. "Patentability of Methods of Medical Treatment: A Comparative Study", <i>J Pat Trademark Off Soc.</i> 2000 Jun;82(6):381-423 | 65 |
| 52. | Mitnovetski et al., "Are patents for methods of medical treatment contrary to ordre public and morality or 'generally inconvenient'?" (2004) 30 <i>J. Med. Ethics</i> 470 | 74 |
| 53. | Vaver, D. "Defining and rewarding invention: a review and a modest proposal for patent law" in Mirfield and Smith (eds.) <i>Essays for Colin Tapper</i> (Butterworths, London, 2003). | 82 |
| 54. | Vaver, <i>Intellectual Property Law</i> , 2 nd Ed. (Concord, Ont: Irwin Law, 2011) at p. 316 | 87 |

- (a) distinguish between patents to fixed-dosage regimens (patentable) and variable-dosage regimens (unpatentable) on the supposed basis that a physician does not exercise discretion when applying a fixed dosing regimen but does when applying a variable dosing regimen; and
- (b) assess whether the subject matter of a claim is patentable by asking whether, in point of fact, it interferes with the skill and judgment of a physician.⁸⁷

73. As regards (b), courts have emphasized that physicians need a sphere of autonomy in which to treat patients without worrying about whether they are infringing a patent. As explained by the Federal Court:

[A] patent claim over a method of medical treatment that, by its nature, covers an area for which a physician's skill or judgment is expected to be exercised is not patentable in Canada. This would include the administration of a drug whereby the physician, while relying upon the dosage advice of the patentee, would still be expected to be alert and responsive to a patient's profile and to the patient's reaction to the compound.

[...]

[A]ttempting to monopolize a [method of medical treatment] interferes with the ability of physicians to exercise their judgment in the administration of generic versions of the drug. This is because, absent a license [from the patentee], any physician attempting to administer a generic version to treat [the disease in question] by the method claimed [by the patent in question] would infringe.⁸⁸

v. Revisiting the concepts

74. The idea that claims to methods of medical treatment embrace “non-economic” subject matter may, at times, seem difficult to grasp. It need not be. In reality, this idea merely recognizes that what medical practitioners do falls outside the “normal” commercial marketplace, and is related, instead, to the more fundamental values of health and well-being. A physician does not affix a cast to a broken arm to ensure that his patient can earn more money as a crane operator; a physician does so because it is their job to heal. A psychiatrist does not administer a dosing regimen

⁸⁷ *Mylan* at paras. [26](#) and [51](#); *Hoffmann v. Sandoz*, [2021 FC 384](#) (“*Hoffman*”) at paras. [194-208](#); and *Novartis* at para. [101](#).

⁸⁸ *Mylan* at paras. [50](#) and [52](#).

to a schizophrenic patient so that the patient can make more sound investment decisions; a psychiatrist does so because it is their job to treat the mentally ill. While physicians are paid and oftentimes employ patented articles in the course of doing their job, this does not mean that what they do is properly parsed in economic terms. Selling a widget is different than healing the sick. The principal societal value of these methods is medical not economic.⁸⁹

75. The non-economic nature of practising medicine is especially true in Canada where our healthcare system is publicly administered and funded, and is comprehensive and universally available to all. It is one of “the hallmarks of Canadian identity”⁹⁰ and, in Canada, interference with timely access to healthcare has been framed not just as a violation of an economic entitlement, but, more fundamentally, as a deprivation of life and security of the person.⁹¹

76. The idea that methods of medical treatment are unpatentable because they are directed at matters of professional skill and judgment may seem equally difficult to reconcile with the many patents that exist over pharmaceuticals and their uses. There is no question that such patents, unlike methods of medical treatment, comprise patentable subject matter. Again, recourse to common sense is useful. The validity of these patents simply recognizes that they fall outside the sphere of therapeutic activities that physicians engage in when practising medicine – administering therapies, monitoring patient response and tailoring treatments to the needs of patients.

B. Situating the Doctrine

77. The prohibition on patenting methods of medical treatment also accords with the purpose and scheme of the *Patent Act* as a whole.

2. The patent bargain and methods of medical treatment

i. Legal framework

78. The *Patent Act* encourages the public disclosure of new, inventive and useful solutions to

⁸⁹ See, e.g.: Mitnovetski et al., “Are patents for methods of medical treatment contrary to *ordre public* and morality or ‘generally inconvenient’?” (2004) 30 J. Med. Ethics 470 at [470](#).

⁹⁰ See, e.g. *Chaoulli v. Quebec*, [2005 SCC 35](#) at para. [16](#).

⁹¹ *Cambie Surgeries v. British Columbia*, [2022 BCCA 245](#) at paras. [232](#) and [260](#). These deprivations were, however, in accordance with the principles of fundamental justice and so did not constitute a breach of section [7](#) of the *Charter of Rights and Freedoms*.

practical problems. To do so, the *Act* provides for an inventor and the public to enter a bargain in which consideration is exchanged. The inventor pays “hard coinage” by providing a patent application containing the correct and full disclosure of new, useful and non-obvious subject matter. In return, the inventor receives “the promise of a limited monopoly” if this and all of the other requirements of the *Patent Act* are met. Once this bargain is struck, it cannot be reopened.⁹² As a general rule, if the patent holder obtains a monopoly for something that does not fulfil the statutory requirements of novelty, ingenuity and utility, then the public is short-changed.⁹³

79. This bargain functions to hasten the availability of technological advances into the marketplace so that society can benefit from this knowledge. Patent applications are published and available at a publicly accessible repository maintained by the Patent Office. Members of the public can study the teachings in the applications and, standing on the ‘shoulders’ of such disclosures, go further. Researchers can rely on the published applications to detail what has already been accomplished, and where best to focus new efforts. The public can also use the teaching to practise the invention when the patent expires.⁹⁴

80. On the other side of the bargain, prospective inventors are incentivized to invent new, non-obvious and useful inventions, knowing that they will be financially rewarded by a state-sanctioned 20-year monopoly. Inventors are granted the statutory ability to exclude others from making, using or selling their invention, which in turn gives them the ability to sell their invention at monopolistic prices and/or receive licence fees for others to make, use and sell their invention.

81. This bargain is embodied by subsections 27(4) and 27(3) of the *Patent Act*. The grant of the patent claim required by subsection 27(4) is provided in return for the description of the invention required by subsection 27(3).⁹⁵

ii. Application: there is nothing to coax (it is already there)

82. Pharmascience respectfully submits that a logical extension of the bargain is that the *Patent Act* should be directed at the sorts of things that require coaxing into the marketplace. The idea that

⁹² *Teva v. Pfizer*, [2012 SCC 60](#) at paras. [32-33](#); *Apotex v. Wellcome* at para. [37](#).

⁹³ *Bristol-Myers Squibb v. Canada*, [2005 SCC 26](#) at paras. [1](#), [14](#).

⁹⁴ *Patent Act*, R.S.C. 1985, C. P-4, as amended, s. [10](#); *Cadbury Schweppes v. FBI Foods*, [\[1999\] 1 SCR 142](#) at para. [46](#); *Teva v. Pfizer*, [2012 SCC 60](#) at paras. [32](#), [69](#), [70](#), [74](#).

⁹⁵ *Patent Act*, R.S.C. 1985, C. P-4, as amended, ss. [27\(3\)](#).

“non-economic” matters related to “professional skill” are *not* inventions contemplated by the *Patent Act* can be seen as a means of giving effect to this idea. As explained by Professor Vaver, “[p]rofessionals do not need the spur of the patent to do the best for their client; professional codes of conduct require that of them in any event.”⁹⁶ Patent-ineligible subject-matter of this sort cannot satisfy the demands of the bargain.

83. The holding of this Court in *Apotex v. Wellcome* provides a useful illustration of this point. Absent the inventive work required to discover that the drug AZT was useful to treat HIV, it would never have existed as an option for HIV treatment. Thus, it was appropriate to have it “coaxed” into the market by the promise of a statutory monopoly. Because drug repurposing – finding new uses for existing drugs – can represent a less expensive approach to new medicines, various government programs (beyond patent grants) have been implemented to encourage such research.⁹⁷

84. Conversely, “how and when” drugs are to be administered does not require coaxing into the marketplace. Once AZT had been found useful to treat HIV, physicians and other clinicians were motivated to develop and investigate how best to administer it in a way that maximizes its efficacy while minimizing unwanted side effects, in order to best serve their patients. Likewise, the patentee (in the case of AZT, Wellcome) was incentivized to develop and investigate how best to administer the drug to increase sales at monopolistic prices.

85. More generally, it is well known that any pharmaceutical company wishing to obtain regulatory approval to market a drug must submit a drug label or product monograph describing how the drug should be used. As noted in *Tennessee Eastman*, identifying a new drug is expected to result in the identification of its desirable and undesirable effects, proper doses, methods of administration and contraindications. This is not to say that it does not require effort or work to do so, only that this work does not amount to an invention.

86. The point can also be analogized beyond the drug context – *any* new product comes with a how-to guide. The invention of a revolutionary new television remote control warrants patent protection, lest the remote control be the immediate subject of copycats. However, the monopoly grant from the patent is useless if consumers are not told by the manufacturer or vendor, and cannot

⁹⁶ Vaver, D. “Defining and rewarding invention: a review and a modest proposal for patent law” in Mirfield and Smith (eds.) *Essays for Colin Tapper* (Butterworths, London, 2003).

⁹⁷ See, e.g. [“New uses for existing drugs”](#), *Pharmacology*, September 17, 2024.

figure out on their own, how to use it to change the channel. No one will buy the product, defeating the benefit of having a monopoly. Thus, the patentee is incentivized to determine the optimal use of the remote control irrespective of whether such use is protected by patent.

87. This point is more cogent if one recognizes that physicians are ethically bound both to ensure that patients are treated in the most optimal way and to share what they have learned.⁹⁸ The modern version of the Hippocratic Oath requires physicians to attest: “I will respect the hard-won scientific gains of those physicians in whose steps I walk, and gladly share such knowledge as is mine with those who are to follow.”⁹⁹ Likewise, the Canadian Medical Association Code of Medical Ethics instructs physicians “to contribute to the development and innovation in medicine through clinical practice, research, teaching, mentorship, leadership, quality improvement, administration, or advocacy on behalf of the profession or public.”¹⁰⁰

88. In view of these pre-existing norms of sharing information, it is not surprising that the medical literature is replete with information about new treatment strategies and post-market information gleaned about how best to use a drug. The patenting of medical methods may not only fail to satisfy the terms of the bargain, it may have the opposite effect. In a world where the existing norm is to share information, the possibility of obtaining patent protection may have the unwanted effect of delaying the dissemination of information; a medical practitioner who establishes a new treatment protocol may withhold sharing this information until they are able to obtain patent protection.

3. Patent claims and methods of medical treatment

i. Legal framework

89. Subsection 27(4) of the *Patent Act* requires that the specification of a patent application end with “a claim or claims defining distinctly and in explicit terms the subject matter of the invention for which an exclusive privilege or property is claimed.” The “invention” made and disclosed in accordance with subsections 27(1)-(3) of the *Patent Act* defines the unitary invention of the patent; the claims under subsection 27(4) represent various expressions of those aspects of the invention

⁹⁸ See, e.g.: Vaver, *Intellectual Property Law*, 2nd Ed. (Concord, Ont: Irwin Law, 2011) at p. 316.

⁹⁹ *Hippocratic Oath* (modern version) (Written in 1964 by Louis Lasagna, Academic Dean of the School of Medicine at Tufts University).

¹⁰⁰ *CMA Code of Ethics and Professionalism*, 2018 at p. 3.

that the inventor has chosen to fence off from others.¹⁰¹ Within the bounds of the claims, the patentee is granted “the exclusive right, privilege and liberty of making, constructing and using the invention and selling it to others to be used”.¹⁰²

90. This Court has developed a careful approach for delineating the metes and bounds of the exclusive rights of the patentee over what has been coaxed into the public. The Court has emphasized both the obligation of an applicant to make clear in the claims the ambit of the monopoly sought and the requirement that the terms used in the claims be clear and precise. As observed by this Court in *Free World Trust*:

By his claims the inventor puts fences around the fields of his monopoly and warns the public against trespassing on his property. His fences must be clearly placed in order to give the necessary warning and he must not fence in any property that is not his own. The terms of a claim must be free from avoidable ambiguity or obscurity and must not be flexible; they must be clear and precise so that the public will be able to know not only where it must not trespass but also where it may safely go.¹⁰³

91. This Court, similarly, held that the patent system is designed to advance research and development and to encourage broader economic activity. Achievement of these objectives is undermined, however, if competitors fear to tread in the vicinity of the patent because its scope lacks a reasonable measure of precision and certainty. A patent of uncertain scope becomes “a public nuisance”.¹⁰⁴ As this Court also explained in *Free World Trust*:

Potential competitors are deterred from working in areas that are not in fact covered by the patent even though costly and protracted litigation (which in the case of patent disputes can be very costly and protracted indeed) might confirm that what the competitors propose to do is entirely lawful. Potential investment is lost or otherwise directed. Competition is “chilled”. The patent owner is getting more of a monopoly than the public bargained for. There is a high economic cost attached to uncertainty and it is the proper policy of patent law to keep it to a minimum.¹⁰⁵

92. Significantly, infringement of a patent claim requires appropriation of all of the essential

¹⁰¹ *Teva v. Pfizer*, [2012 SCC 60](#) at paras. [45](#), [54-58](#), [63-64](#).

¹⁰² *Patent Act*, s. [42](#).

¹⁰³ *Minerals Separation v Noranda Mines*, [\[1947\] Ex CR 306](#) at [352](#); *Free World*, [2000 SCC 66](#) at para. [14](#).

¹⁰⁴ *Free World*, [2000 SCC 66](#) at para. [42](#).

¹⁰⁵ *Free World*, [2000 SCC 66](#) at para. [42](#).

elements of a claim. If a claim has ten essential elements and someone appropriates only nine of them, they do not infringe.¹⁰⁶

ii. Application: methods of medical treatment and the risk of a public nuisance (i.e. let me do my job)

93. In the case of patents over methods of medical treatment, the concerns over monopolies' "chilling" behaviour – in this case, of physicians – are heightened.

94. Patents for methods of medical treatment directly affect the *actions* of physicians because physicians perform medical procedures and administer drugs. A physician may refrain from administering a dosing regimen or modifying a treatment schedule for fear of infringing a patent. Patients will suffer as doctors refrain from providing optimal treatment. At the same time, other physicians may be able to profit by having a monopoly over or licence to a method of medical treatment, to the invariable detriment of many. This concern has been identified by Canadian courts, international courts and academics alike:

The concern with the patenting of a dosage regimen is that the physician may be prevented from exercising skill and judgment in using a known compound for an established purpose absent a license from the patentee. It is surprising to me that the Janssen witnesses failed to address the problem of imposing a monopoly over the prescribing practices of the medical profession.¹⁰⁷

[...]

The spectre of a single doctor reserving the performance of the most satisfactory, possibly life-saving, operation to his or her own team and extracting therefrom monopoly profits on the scale of a successful pop-star seemed to put the matter beyond argument.¹⁰⁸

[...]

There exist grave reasons against the creation of a monopoly by a patent in respect of medical treatment. We are confronted here with saving human life or alleviating human suffering and one should take care lest a restriction on the freedom of action of those who treat, caused by patents, should affect human life or health.¹⁰⁹

¹⁰⁶ *Free World*, [2000 SCC 66](#) at para. [20](#), [31\(f\)](#), [68](#) and [75](#).

¹⁰⁷ *Mylan* at paras. [51](#) and [52](#).

¹⁰⁸ Cornish, Llewelyn and Aplin, *Intellectual Property*, pp. 231.

¹⁰⁹ *Wellcome v. Plantex* [1974 R.P.C. 514](#), p.

95. On this point, two related matters merit mention. First, as noted above, certain courts have held that patents to “fixed” dosing regimens do not interfere with the skill and judgment of physicians, whereas “variable” dosing regimens do. In this case, despite having rejected the fixed-variable dichotomy, the FCA appeared to rely on the (supposedly) fixed nature of the dosing regimen claimed in the 335 Patent to conclude that skill and judgment was not required to use the invention, and thus it did not monopolize a method of medical treatment.

96. Respectfully, that courts have so found shows a misapprehension of the issue. Whether a patent monopolizes one, five or ten possible dosing regimens is of no moment. A patent that monopolizes a method of medical treatment *removes a treatment option* regardless of whether it is specifically defined (fixed) or amorphous (variable).

97. Second, focusing on what a patent monopolizes highlights why framing a patent as being directed at a “vendible product” also ignores the critical issue. A patent that is stylized as relating to a vendible product can still interfere with the ability of a physician to practise medicine if it limits how that physician can administer the drug in question. The issue is not whether a physician is restricted from using or prescribing a particular product (*e.g.* a pre-filled syringe), it is whether they are free to use or prescribe the syringe to administer a drug in the best way they see fit.

98. In *Novartis v. Cobalt*, the Federal Court and FCA appeared to recognize this idea:

In argument, Novartis’s Counsel says that the patent claims a vendible product; namely, a bottle containing 5 mg of zoledronic acid, the use of the bottle’s contents is a once-a-year injection to treat osteoporosis.

... However, because each claim of the '201 patent, directly or by incorporation by reference, includes as well treatment by intermittent dosages with some claims specifying a dosage range and others specifying specific dosages; and some claims claiming more frequent intervals of dosing, and others less; that the claims include that which lies within the skill of the medical practitioner and are thus invalid. [emphasis added]¹¹⁰

4. The need for balance

99. Admittedly, the problem of interfering with the skill and judgment of would-be infringers can arise in the cases of patents that are not directed at methods of medical treatment. For instance,

¹¹⁰ *Novartis* at paras. [98-99](#), aff’d [2014 FCA 17](#) at paras. [1-4](#).

a patent to a vendible drug product theoretically precludes a physician from using that vendible drug product for all purposes. Nevertheless, where the patent explicitly claims one method and not all, its impact on how physicians treat patients is expected to be more pronounced; the uncertainty occasioned by a physician being able to employ *some* methods but not *all* of them creates the very “uncertainty” against which the patent system endeavours to guard. In this way, Pharmascience submits that prohibiting patents on medical treatments represents an appropriate balance between the need to encourage innovation, on the one hand, and the importance of promoting health on the other.

5. The concern of evergreening

100. Finally, Pharmascience submits that foreclosing patents on methods of medical treatment also serves an additional purpose: tempering the problem of evergreening, which is endemic to the pharmaceutical industry.

101. To explain, a patent over a pharmaceutical drug confers a 20-year monopoly over that drug from the date when the patent is filed. Patents for medicines are typically filed early in the process of developing a new drug and can be consumed by a combination of the preclinical and clinical testing and regulatory review process required for market approval. The role that such patents serve is, as explained above, to incentivize: as it is costly to bring a drug to market, the promise of market exclusivity serves as a “carrot” to reward the investment required to do so.

102. In reality, however, pharmaceutical companies take out numerous patents that relate to a product they intend to bring, or have already brought, to market. These patents are filed for after the initial patent for a product has been obtained, and therefore expire on a later date. Frequently, these so-called “second generation” patents, relate to alternative forms for existing drugs (e.g. “crystal forms” or “polymorphs”) or specific dosage forms for existing drugs (e.g. tablets or capsules). The practice of obtaining additional patents over an already-patented product for the purpose of extending the monopoly in the market for that product is known as “evergreening”.

103. This practice is commonplace. In the words of Justice Binnie: “it is an evident (and entirely understandable) commercial strategy ... to evergreen their products by adding bells and whistles to

a pioneering product even after the original patent for that pioneering product has expired.”¹¹¹

104. The adverse effects of this practice are many. By blocking generic competitors from entering a pharmaceutical market, patentees maintain high drug prices for their branded products, which prices the public must shoulder. By foreclosing multiple avenues related to the use of a drug, the strategy deters follow-on innovation by discouraging others from improving on the product. By providing a facile way for pharmaceutical companies to profit from an extended monopoly over a given drug, they encourage pharmaceutical companies to devote efforts towards acquiring patents rather than socially beneficial innovation.¹¹²

105. The role that methods of medical treatment patents play in this scheme is readily apparent. Although patents typically relate to a specific treatment protocol or administration method for an already known product with an already known use, they are almost invariably tools used to extend a monopoly in an existing pharmaceutical market. In the present instance, for example, the 335 Patent is but one of many patents filed and obtained by Janssen related to paliperidone. Most problematically, the 335 Patent has operated to foreclose competition in the paliperidone market long after the expiry of Janssen’s patent for paliperidone itself, even though many, if not most, physicians do not actually employ the claimed dosing regimens.¹¹³

¹¹¹ *AstraZeneca v. Canada*, [2006 SCC 49](#) at para. 39.

¹¹² The problem is not only theoretical. For example, for the drug Humira, used to treat rheumatoid arthritis, Abbvie filed and obtained some 250 patents, some of which will not expire until 2037. The vast majority of these patents were filed for after Humira was already on the market and designed to shield Humira from generic competition. See, e.g.: Logothetis, D. “Rewarding Pharmaceutical Innovation for being Innovative: A Summary of the Pharmaceutical Patent System and Amendment to the *Patent Act* to Negate “Evergreening” and “Patent Thickets””. *Appeal*, Vol. 29 pp. 1-24 at p. 9.

¹¹³ For instance, Canadian Letters Patent Nos. 2,309,629 and 2,236,691 describe and claim depot paliperidone palmitate formulations and expired many years before the 335 Patent will expire. See: Expert Report of Dr. Gupta, TX-42 at paras. 57-58, 66-68 and Schedules “9” and “10”, AR, Tab 19.

C. The existing approaches

106. The foregoing establishes that the prohibition on patents over methods of medical treatment is grounded in both the language of the *Patent Act* and the policy objectives that underlie the patent regime more generally. The analysis has, however, side-stepped a critical issue, namely, how one should identify whether a patent claims a method of medical treatment.

107. Pharmascience submits that most decisions take as a starting point: (a) that the subject matter need be medical in nature (*i.e.* relating to therapeutic or surgical methods that would be understood as being related to health); (b) that claims to new medical uses (*i.e.* the use of drug X to treat Y) are patentable; and (c) that claims to new medicines and pharmaceutical formulations are patentable.

108. However, from this starting point, courts have taken three different approaches, which are more technical in nature and often yield inconsistent results. These approaches may be summarized as follows.

109. **The formalist approaches.** In some cases, rather than articulating a principled basis for identifying whether something constitutes a method of medical treatment, courts employ formal categories to discern the propriety of the claim. As noted above, these decisions have categorically held that vendible products or fixed dosage regimens are not tantamount to methods of medical treatment but accepted that variable dosage regimens do monopolize methods of medical treatment.¹¹⁴

110. The difficulty with the formalist approaches is that they disregard what is claimed. The “vendible product” restriction simply ignores that an essential element of the monopoly is the method. This method is part of the exclusive monopoly claimed and granted pursuant to subsection 27(4) and section 42 of the *Patent Act*; the claim is not infringed unless the element comprising the method of medical treatment (*e.g.* the dosing regimen) is appropriated.

111. To hold that the invention can be parsed by reference only to the product element of the claim is to distort what was invented. As explained by the Federal Court in *Axcan*, a claim to a “[p]harmaceutical composition for the treatment of primary biliary cirrhosis ... being processed in

¹¹⁴ See, *e.g.*: *Merck v Apotex*, [2005 FC 755](#) at paras. [133-137](#); *Bayer* at para. [162](#).

a form allowing for ... treatment of primary biliary cirrhosis based on a dose of 13 to 15 mg/kg/day” is an unpatentable method of medical treatment because “the claimed dosage is an essential element”.¹¹⁵

112. To the extent courts have held otherwise, their holdings represent an improper triumph of form over substance. At bar, the only way in which the three “product” claim sets could be construed as pure product claims immune from a method of medical treatment analysis is if the requirement that the product be “adapted for administration in accordance with the claimed dosing regimens” was read out of the claims entirely, despite the trial judge’s finding that the invention *is* the dosing regimen.

113. The “fixed” versus “variable” dosage restriction test suffers from the same defect of failing to focus on the effect of what was monopolized. As explained above, claims to fixed dosage regimens and variable dosing regimens both interfere with the skill and judgment of physicians. The difference is but one of degree.

114. **The skill and judgment test.** In other cases, such as the case at bar, courts have suggested that whether a claim is to a method of medical treatment can be ascertained by asking whether the claim *monopolizes* an area for which a physician’s skill or judgment is expected to be exercised. As stated in the FCA decision, the “proper inquiry remains whether use of the invention (*i.e.* how to use it, not whether to use it) requires the exercise of skill and judgment.” [emphasis in original]¹¹⁶

115. Regardless if the dosing regimen is fixed or variable, if the claims interfere with the skill and judgment of the physician, they are not patentable.¹¹⁷ These include claims that cover various dose ranges, instances where a physician would be expected to be alert and responsive to a patient’s profile (*e.g.* weight, lifestyle or hormonal status) and responses to a treatment¹¹⁸, or where the evidence establishes “that the [claimed] default dose escalation regimen is not appropriate for all

¹¹⁵ *Axcan* at paras. [32-35](#).

¹¹⁶ FCA Decision at para. [37](#), AR, Tab 5.

¹¹⁷ See, *e.g.* *Mylan* at para. [26](#); *AbbVie v. Canada*, [2014 FC 1251](#) at paras. [112-114](#); *Novartis* at para. [101](#), *aff’d* [2014 FCA 17](#).

¹¹⁸ *Novartis* at paras. [93-95](#) and [99](#).

patients”.^{119 120}

116. The problem with the skill and judgment test is one of practicality. The test requires the court to assess whether a patent claims a method of medical treatment by an examination of its putative effect. Its scope is not based on what is set out in the patent but rather an evaluation of whether what is in the patent, in fact, interferes with the skill and judgment of a physician. It is impossible to apply with any measure of certainty and ultimately involves the invocation of arbitrary judgments as to what does and does not constitute interference.

117. For instance, on its face, the claimed dosing regimen of the 335 Patent monopolizes and interferes with the exercise of a physician’s skill and judgment. The FCA held that it did not matter that: (a) “different dosages may be required for different patients”; (b) the claims had dosing and scheduling windows; (c) the claims contemplated different injection points in the deltoid or gluteal muscles; (d) the maintenance dose may be “titrated up or down in view of patients [*sic*] condition”; or that (e) the 335 Patent contemplated different dosages for patients with renal impairment and those without.¹²¹ Respectfully, it is difficult to conceptualize why those matters *do not* involve the exercise of professional skill and judgment whereas choosing between three doses in a range *do*.

118. **The AZT test.** In *Apotex v. Wellcome*, this Court suggested that whether a claim monopolizes a method of medical treatment could be ascertained by asking whether it claims “how and when” a drug should be employed. This test, rather than embarking on an inquiry of whether the skill and judgment of a physician is impacted, elegantly identifies that methods of medical treatment can be conceived of as subject matter directed to “how and when” a drug should be

¹¹⁹ *Hoffman* at para. [205](#).

¹²⁰ CIPO has taken an analogous approach. See, e.g. CIPO [Practice Notice PN2020-04](#), which requires the patent examiner to assess whether one or more of the essential elements of the claim “restrict, prevent, interfere with, or require the exercise of the professional skill and judgment of a medical professional.” The previous [Practice Notice, PN2015-01](#) also provided that, “where an essential element only serves to instruct a medical professional ‘how’ to treat a patient..., it must be determined whether the essential element prevents, interferes with or requires the professional skill of a physician”.

¹²¹ FCA Decision at paras [50-56](#), AR, Tab 5.

administered.¹²²

D. The Proposed Legal Test

119. Instead of the varying existing approaches, Pharmascience proposes the patentability question be assessed by formalizing the essential teaching of the *AZT Test*, namely, that a claim can be said to monopolize a method of medical treatment where it monopolizes “how and when” a drug should be offered. Specifically, Pharmascience proposes that, in assessing whether a patent monopolizes a method of medical treatment, courts proceed by:

- (a) construing the claims of the patent according to the existing canons of patent claim construction;
- (b) identifying whether any of the essential elements so identified can properly be said to be “therapeutic” or “medical”; and
- (c) identifying whether any of those essential elements relate to how and when a drug or treatment is to be administered by a medical practitioner.¹²³

120. If both steps (b) and (c) are satisfied, then presumptively the claims can be determined to

¹²² The lower courts have also, from time to time, had recourse to “how and when”. In *Merck v. Apotex*, [2005 FC 755](#) at para. [136](#), the Federal Court appeared to recognize the soundness of the approach when observing that the patent at issue did not monopolize a method of medical treatment because “the how and when of administration” were not part of the patent. Likewise, in *Hoffmann* at para. [194](#), the patentee contended that the patent did not monopolize a method of medical treatment because “how and when” was left to the physician’s discretion. The Court, however, ultimately, based its decision on the “skill and judgment” test.

¹²³ “How” generally refers to the manner in which the drug is administered, such as injection into a certain location or a specific dosing instruction (e.g. to take with or without food), whereas “when” refers to the frequency of a given dose. The distinction, however, need not always be rigid. For instance, an instruction to take a “tablet on an empty stomach every other day” can be parsed as either “how” or a “when”. Depending on the claims at issue, the courts may choose to focus on one or other branch of the test.

be directed at a method of medical treatment and unpatentable.

121. With respect to (a), the test ensures that the analysis is properly oriented at the invention as claimed. This orientation is appropriate since the concerns about patenting medical methods are intimately connected to the idea that it is not proper to claim an exclusive right over certain subject matter. In addition, proceeding with a construction of all the claims ensures that reference is made to *all* of the essential elements therein, thereby avoiding the pitfalls of the vendible product analyses that are predicated on only part of the claims being considered.

122. With respect to (b), whether the claim is directed at “medical or therapeutic” subject matter, Pharmascience submits that the definition used in the European Patent Convention is instructive, namely, “any treatment which is designed to cure, alleviate, remove or lessen the symptom of, or prevent or reduce the possibility of contracting any malfunction in the human body”.¹²⁴ This definition is sufficiently broad to ensure that different therapeutic enterprises are covered, but sufficiently narrow to exclude disciplines such as cosmetic or veterinary treatments that do not attract the same policy concerns identified above.

123. With respect to (c), the test only requires consideration of what the claims say, not their impact on what physicians do. This approach gives effect to the idea that certain subject matter is not an invention for purposes of section 2 of the *Patent Act*, regardless of whether, in point of fact, it interferes with the discretion of physicians. While one can *assume* that claims to dosing regimens (fixed and variable) or claims that require a medicine to be titrated based on how a patient is responding will impact how physicians practise medicine, the patentability question need not turn on such extrinsic considerations.

124. This test also allows the distinction between that which is patentable and that which is not to be parsed in more general terms. New medicines or new medical uses for old compounds are patentable because, at their core, they are related to new “things” that have to be coaxed into the world.¹²⁵ What is not patentable is how a subject is to behave – in other words, conduct. Decisions

¹²⁴ See: e.g. [SALMINEN/Pigs III \(T 58/97\)](#).

¹²⁵ A new use for an old compound in effect introduces that compound into a new public domain. Prior to being investigated for its ability to treat HIV, AZT was only known in the cancer world; it did not exist in the universe of HIV therapies.

regarding what dose to administer, how long a therapy is to be applied, or how a patient's response is to be assessed, regulate the conduct of medical practitioners in a way that oversteps the limits of the *Patent Act*.¹²⁶

125. Though the distinction between claims to new uses and claims to methods of medical treatment can appear subtle, focusing on whether they are directed at the “how and when” obviates this difficulty. In truth, oftentimes, less nuance than might be expected is required. For instance, in *Bristol-Myers Squibb v. Baker Norton Pharmaceuticals*, the UK Enlarged Board of Appeal considered a patent covering the administration of taxol (a known anti-cancer agent) via a short infusion over a three-hour period, which allowed administration of the drug on an out-patient basis. In rejecting the argument that these were claims to a “new use”, Lord Jacob colourfully opined:

All you have is more information about the old use. [These claims] must be confined to true new uses not mere discoveries about old uses. ... It must be assumed that there is not a single expert/doctor in the present field of science who would believe that what is involved here is a second medical indication in the sense of an application of a substance for a different therapeutic purpose (for example, to fight another illness or for prevention instead of as cure.).¹²⁷

126. Indeed, common sense allows us to differentiate the “tricks of the trade”, know-how and methods employed by physicians from the invention of a new product for the treatment of a given disease or the determination that a drug known to treat one disease can also be used to treat another.

E. Application to the Case at Bar

127. The application to the case at bar is straightforward.

¹²⁶ In *Hospira v. Kennedy Trust*, [2018 FC 259](#) at para. [147](#), aff'd [2020 FCA 30](#), the Federal Court held that focusing on “how and when a drug” is to be administered, “[t]aken to its logical end...prevent[s] an inventor from patenting any subsequent use for a known compound, as this would monopolize the ‘how and when’”. This is incorrect. A claim to a subsequent use is directed at “for what”, not how and when. Notably, the patent in the case did not claim a dosing regimen but rather, the combined use of two drugs to treat rheumatoid arthritis (RA) in a certain patients.

¹²⁷ *Bristol-Myers Squibb/Yew Tree*, [\[1999\] RPC 253](#) at [272](#).

128. With respect to branch (a), there is no dispute over the construction of the claims.

129. With respect to branch (b) of the test, the subject matter of these claims is plainly medical/therapeutic in nature, namely, the amelioration of a psychiatric disorder.

130. With respect to branch (c), each of these claim sets is fundamentally directed at “how and when” paliperidone is to be administered, namely, by way of the administration of the dosing regimen described. This is true for all of the claim sets, including the purported “product” claims, which contain as an essential element that the product be “adapted for administration” in accordance with the claimed dosing regimen. That the disclosure of the 335 Patent provides various treatment ranges and advises that “the maintenance dose may be titrated up or down in view of the patients [sic] condition (response to the medication and renal function)” is corroborating.

131. Parsed as such, there can be no doubt that the 335 Patent monopolizes a method of medical treatment. The 335 Patent, on its face, restricts how and when psychiatrists may administer paliperidone for the treatment of schizophrenia.

PART IV – SUBMISSIONS CONCERNING COSTS

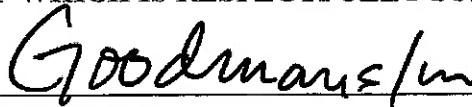
132. Pharmascience respectfully submits that the costs of this appeal should follow the event.

PART V – ORDER SOUGHT

133. For the reasons described above, Pharmascience requests that this Honourable Court: (a) set aside the FCA Decision below; (b) dismiss the action; and (c) award it its costs of this appeal, and the appeal and trial below.

December 16, 2024

ALL OF WHICH IS RESPECTFULLY SUBMITTED,



GOODMANS LLP

Solicitors for the Appellant, Pharmascience Inc.

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