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 REPLY TO THE INTERVENERS, THE CANADIAN ORGANIZATION FOR RARE DISORDERS; THE INTERNATIONAL FEDERATION OF INTELLECTUAL PROPERTY ATTORNEYS; CANADIAN GENERIC PHARMACEUTICAL ASSOCIATION; INNOVATIVE MEDICINES AND BIOTECANADA; AND DRS DAVID HOMUTH, MARCO SOLMI AND PIERRE BLEAU

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PART I - OVERVIEW

1. Fédération Internationale Des Conseils En Propriété Intellectuelle ("FICPI"), Innovative Medicines Canada and BIOTECanada ("IMC/BTC"), Canadian Organization for Rare Disorders ("CORD") and Drs. Homuth, Solmi and Bleau (the "Doctors") (collectively, the "patentee-side interveners") ask this Court to abolish Canada's clear and settled law, which holds that methods of medical treatment ("MMT") are not patentable.

2. The patentee-side interveners ground this request in a mixture of law and policy.

3. As a matter of law, the patentee-side interveners argue that: (a) MMTs fall within the definition of an "invention" in section 2 of the *Patent Act*[1]; (b) the repeal of section 41 of the *Patent Act* removed the basis for the previous prohibition on MMT patents[2]; and (c) there is no basis for treating therapeutic or medical patents differently than other fields of inventions.[3]

4. As a matter of policy, FICPI advocates for the patentability of MMT in order "to harmonize the types of inventions that should be afforded patent protection under Canadian patent law with those of its peer jurisdictions and to bring [Canadian] law in line with Canada's treaty obligations." IMC/BTC, CORD and the Doctors aver that MMT patents are necessary to ensure that new dosing regimens are developed and that such patents will not impact how doctors prescribe medicines.[4] Finally, without elaboration, the patentee-side interveners assert that the "how and when" test proposed by the Appellant ("Pharmascience") is unworkable and uncertain.[5]

5. Pharmascience respectfully submits that each of these arguments is without merit. The legal positions advanced are incorrect and the policy considerations that are invoked are either inapposite or unsubstantiated.

PART II – APPELLANT'S POSITION ON THE QUESTIONS IN ISSUE

6. Pharmascience's position on the points raised by the patentee-interveners is that:

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[1] CORD Factum at paras. 11-13; IMC/BTC Factum at para. 27
[2] IMC/BTC Factum at paras. 9, 13, 20-25; CORD Factum at para. 7
[3] Doctors Factum at para. 34
[4] IMC/BTC Factum at para. 28; CORD Factum at paras. 23-25; Doctors Factum at paras. 22-27
[5] IMC/BTC Factum at para. 37

(a) the *Patent Act* does not authorize the patenting of MMTs;

(b) the repeal of section 41 of the *Patent Act* did not remove the basis for the prohibition on the patents to MMTs;

(c) the position of the Doctors and CORD regarding the need for MMT patents is manifestly incorrect, unreliable and, in any event, speculative;

(d) FICPI's suggestion that Canada should abolish its prohibition on patents to MMTs to align with international norms is without merit; and

(e) the proposed "how and when" test is structured to enable it to be applied in a straightforward manner.

PART III - STATEMENT OF ARGUMENT

1. *The Patent Act* does not authorize patents over MMTs

7. The patentee-side interveners assert that the MMTs are patentable because they are not explicitly excluded as patentable subject-matter by the *Patent Act*.[6] This position is plainly incorrect. This Honourable Court has held that subject matter may be specifically precluded from patent protection **either** explicitly by subsection 27(8) **or** by judicial interpretation.[7] The patentee-side interveners ignore the second basis.

8. In so doing, the patentee-side interveners strip the Court of its role as interpreter of the *Patent Act* in favour of rigid literalism.[8] A *Patent Act* devoid of judicial interpretation would result in a very different legal landscape. Phrases like "essential elements"[9], "enablement"[10], "inventive

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[6] CORD Factum at para. 14; See also: IMC/BIOTEC Factum at paras. 18(b) and 25
[7] *Monsanto v. Schmeiser*, 2004 SCC 34 at para. 133
[8] The complaint that Canada did not amend the *Patent Act* to exclude same despite being invited to do so by subsection 27(3)(a) of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) suffers the same flaw. An amendment to the *Patent Act* explicitly excluding MMTs is unnecessary in view of the governing interpretation of section 2 of the *Patent Act*. See: FICPI Factum at para. 13

[9] *Whirlpool Corp. v. Camco Inc.*, [2000] 2 S.C.R. 1067, para. 49(e)
[10] *Apotex Inc. v. Sanofi-Synthelabo Canada Inc.*, 2008 SCC 61 at para. 26

concept"[11], and "sound prediction"[12], which underlie approaches to claim construction, anticipation, obviousness and utility, are not explicitly found in the *Patent Act* but are grounded in an interpretation of it.

9. The words of section 2 of the *Patent Act*, like the words of all statutes, are given a textual, contextual and purposive analysis.[13] For instance, employing such an analysis, this Court held that higher life forms were not patentable inventions. As explained in the decision:

> Based on the language and the scheme of the Act, both of which are not well accommodated to higher life forms, it is reasonable to assume that Parliament did not intend the monopoly right inherent in the grant of a patent to extend to inventions of this nature. It simply does not follow from the objective of promoting ingenuity that all inventions must be patentable, regardless of the fact that other indicators of legislative intention point to the contrary conclusion.[14]

10. Employing this same approach (and not a rigid literalism), this Court found that MMTs are also not patentable inventions. MMTs do not "lay in the field of the manual or productive arts, nor when applied to the human body, [do they] produce a result in relation to trade, commerce or industry or a result that is essentially economic. . . [they] lie essentially in the professional field of surgery and medical treatment of the human body."[15] This interpretation remains valid.

11. Despite the soundness of the approach, the patentee-side interveners ask this Court to overturn itself on the basis that dosing regimens are "economic". To that end, it is asserted that they "improv[e] the efficacy of a drug substance, decreas[e] negative side effects, "[lead] to improved patient compliance"[16] or "decrease the frequency in which a patient may need to take a drug or lower healthcare costs".[17] These assertions are no more than a simple rebranding of "improved health outcomes" as "essentially economic". In a country like Canada that extolls the virtues of its public healthcare system, the framing of medical rights and benefits as "economic" ought to be rejected.

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[11] *Apotex Inc. v. Sanofi-Synthelabo Canada Inc.*, 2008 SCC 61 at para. 67
[12] *Apotex Inc. v. Wellcome Foundation Ltd.*, 2002 SCC 77, at paras. 51-56
[13] *Canada Trustco Mortgage Co. v. Canada*, 2005 SCC 54 at para. 10
[14] *Harvard College v. Commissioner of Patents.* 2002 SCC 76 at paras. 166, 183 and 187
[15] *Tennessee Eastman Co. et al. v. Commissioner of Patents* (1970), 62 C.P.R. 117 (Ex. Ct.) at p. 154-155
[16] See, *e.g.* IMC/BTC Factum at para. 27
[17] See, *e.g.* CORD Factum at para. 24

12. The frailty of this rebranding exercise is apparent from the fact that the patentee-side interveners and even the Respondent ("Janssen") equivocate as to whether MMTs are best categorized as "arts", "processes" or "improvements".[18] Their inability to properly situate MMTs in the language of section 2 is instructive: it highlights that MMTs generally and dosing regimens specifically fall outside of the ambit of the sort of activities ordinarily targeted by the *Patent Act*.

2. The repeal of section 41 of the Patent Act did not change the "context" of Section 2

13. The patentee-side interveners assert that the repeal section 41 of the *Patent Act* in 1987 removed the basis for the existing prohibition on MMTs. This too is incorrect.

14. Courts have already considered and rejected this argument. In *Imperial Chemical Industries Ltd. v. Commissioner of Patents*, the Court considered a patent that related to a method of cleaning teeth by applying an aqueous composition. The Patent Appeal Board rejected the method claims on the basis that the applicant's process constituted a treatment of the human body and was "not a process in the economic sense which the *Patent Act* was created to protect."[19] On appeal, the patentee asserted that "only methods of medical treatment that invoke the use of compositions governed by subsection 41(1) of the *Patent Act* were unpatentable.[20] The Court rejected this assertion, holding:

> In my opinion, this is a clear and unequivocal statement that "methods of medical treatment are not contemplated in the definition of `invention' as a kind of `process' ...". That was the sole issue before the Court, and it is here answered in unmistakable and unambiguous language. Accordingly, in my view, the force of that pronouncement cannot be restricted merely to factual situations where subsection 41(1) of the Act applies.[21]

15. In a similar vein, in *Shell Oil*, this Court, rather than focusing on section 41, observed that the ratio in *Tennessee Eastman* was grounded in an interpretation of the phrase "invention" and noted that MMTs were not patentable because the method at issue "was not the kind of discovery which fell within the definition of "invention" in the Act.[22]

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[18] See, *e.g.* Janssen Factum at para. 49
[19] *Imperial Chemical Industries Ltd. v. Commissioner of Patents*, [1986] 3 FC 40 at p. 44
[20] *Imperial Chemical Industries Ltd. v. Commissioner of Patents*, [1986] 3 FC 40 at p. 47
[21] *Imperial Chemical Industries Ltd. v. Commissioner of Patents*, [1986] 3 FC 40 at p. 50
[22] *Shell Oil Co. v. Commissioner of Patents*, [1982] 2 S.C.R. 536 at p. 549

16. Finally, although this Court in *Apotex v. Wellcome* observed that *Tennessee Eastman* was based on the now repealed section 41, it also affirmed that the policy rationale for the prohibition was "that the claims were essentially non-economic and unrelated to trade, industry or commerce, [but rather] the area of professional skill"[23] – a rationale divorced from section 41. Significantly, the Court, when considering this issue, did not hold that the repeal of section 41 rendered MMTs patentable; rather, they simply clarified the scope of the prohibition – *i.e.* that it is not appropriate to "fence in" how and when" a drug is to be employed – precisely the position Pharmascience urges at bar.

17. It follows that the suggestion that the repeal of section 41 somehow changed the "context" germane to the MMT analysis is without foundation. The prohibition on patenting MMTs has already been grounded in the fact that subject matter of this sort is outside the ambit of the *Patent Act* because it is not the sort of subject matter at which the *Patent Act* is directed.

3. Context supports the ongoing prohibition

18. The patentee-side interveners assert that the repeal of section 41 removed any statutory basis "to discriminate based on field of invention" and assert that there is nothing in the *Patent Act* that suggests that medical or therapeutic patents should be treated differently than patents directed at other types of technology. This view, too, is incorrect.

19. The repeal of section 41 and related compulsory licence provisions was ultimately replaced with an entire regime – the *Patented Medicines (Notice of Compliance) Regulations* (the "*Regulations*") that drives and directs the enforcement of patents related to pharmaceuticals pursuant to section 55.2 of the *Patent Act*. The *Regulations*, described by this Court as draconian[24], affords a patentee drug manufacturer the ability to obtain an automatic 24 month injunction against a potential infringer even before the generic has made a single sale; it affords the patentee with the ability to be notified of the intention of a competitor to sell a competing product and grants the patentee an early preview of arguments that may be advanced at Court.

20. This regime, as found by this Court, was intended to balance patentee rights with the need

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[23] *Apotex Inc. v. Wellcome Foundation Ltd.,* 2002 SCC 77 at para. 50
[24] *Merck Frosst Canada Inc. v. Canada (Minister of National Health and Welfare)*, [1998] 2 S.C.R. 193 at para. 33

for timely access to generic medicines[25] and has been interpreted to preclude attempts by patentees to evergreen their products.[26] Purveyors of patented washing machines, telephones or canola seeds are not afforded the same rights.

21. In a similar vein, sections 79 to 103 of the *Patent Act* also created the Patented Medicine Price Review Board with a similar aim to balance the monopoly power held by a patentee of a medicine with the interests of purchasers of those medicines.[27] Again, the *Patent Act* does not create a similar board to limit the price of patented computer chips.

22. The existence of these regimes highlights why the suggestion that the *Patent Act* is agnostic as to the type of technology being patented is manifestly incorrect. They instead highlight why it is appropriate to be circumspect about the sorts of patents given the putative impact that such patents may have on the public healthcare system. As stated by this Court some 60 years ago (and as still holds true today), "in the particular class of case with which we are here concerned dealing with drugs and medicines, there is considerable public interest at stake, and the Commissioner should most carefully scrutinize the application to see if it merits the grant of monopoly privileges and to determine the scope of the monopoly available."[28]

23. All that said, the finding that MMTs are not patentable is not wholly unique to the medical sphere; patents that are directed to matters of professional skill and judgment rather than trade or commerce are not patentable employing the same logic.[29]

4. Speculative medical arguments

a. Preliminary remark about the Doctors

24. The Doctors devote much of their written argument purporting to describe what physicians

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[25] *Bristol-Myers Squibb Co. v. Canada (Attorney General)*, 2005 SCC 26 at para. 47
[26] *AstraZeneca Canada Inc. v. Canada (Minister of Health)*, 2006 SCC 49 at para. 39
[27] *Celgene Corp. v. Canada (Attorney General),* 2011 SCC 1 at paras. 28-29
[28] *Commissioner of Patents v Farbwerke Hoechst Aktiengesellschaft Vormals Meister Lucius & Bruning,* [1964] S.C.R. 49 at p. 56
[29] See e.g.: *Lawson v. The Commissioner of Patents* (1970), 62 C.P.R 101 at 110 and CD 1245, 1999 CanLII 33028 (CA CP). In the latter case, a patent relating to a personal financial system was found to be unpatentable subject matter because it was based on the professional skill and judgment of financial experts.

and pharmaceutical companies do. This is improper as such statements are in the nature of evidence not argument. The Doctors were not qualified as experts in the within proceeding, subjected to cross-examination or shown to be free of bias. On the latter point, Pharmascience observes that, in a 2025 article, Dr. Solmi indicated that he has previously received honoraria, been a consultant, provided expert testimony and received grant support from Janssen[30], casting at least *prima facie* doubt on the reliability of his evidence.

25. Further, the Doctors were not put forth as the representative of any organization or association and there is no basis for this Court to infer that what they assert represents any view other than their own. For instance, whereas the Doctors assert that: (a) the pharmaceutical industry develops treatment options while physicians employ them; (b) patents are necessary to incentivize the development of these options and (c) physicians would never withhold or refuse treatment for fear of violating patent rights[31], the World Medical Association ("WMA"), an international organization with some 10 million members, put out a policy statement that articulates the opposite view.

26. In particular, the "WMA Statement on Patenting Medical Procedures" provides that: (a) physicians have a myriad of incentives to improve their skills, including professional reputation and the ethical and legal obligations to provide competent medical care, such that medical procedure patents are unnecessary to spur invention; and (b) medical procedure patents can negatively affect patient care by causing physicians to refrain from carrying out their professional skills because they did not obtain the necessary licence, or by deterring physicians from introducing new or modified procedures as they may be uncertain whether they are patented or not. This same logic applies to patents for dosing regimens and other MMT patents and tells against the Doctors' assertion that such patents will not impact their practice.

b. The need to incentivize the development of new dosing regimens

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[30] See, *e.g.* Chan, JK and Solmi et al. "Predicting 10-year risk of chronic kidney disease in lithium-treated patients with bipolar disorder: A risk model development and internal cross-validation study". 2025 Apr. 11; 95:24-30

[31] See Factum of the Doctors at paras. 1525, and 28; WMA Statement on Patent Medical Procedures, adopted by the 51st (October 1999) and 6th WMA General Assembly (October 2009) and reaffirmed by the 212th WMA Council Session (April 2019).

27. IMC/BTC, CORD and the Doctors each assert that appropriate dosage regimens are identified by pharmaceutical companies rather than practising physicians and that prohibiting patents for MMTs would remove a key incentive necessary to the ongoing development of new dosing regimens.[32] This position is flawed for the following reasons.

28. First, these arguments are made without any evidence. To the extent that articles are cited that discuss the costs of developing drugs, these interveners do not set out which of those costs are attributable to the development new dosing regimens or why MMT patents are somehow necessary to allow the recovery of any development costs that may have been incurred.

29. Second, the argument ignores that the exclusion for patents on MMTs does not cover new drugs, new uses, new products, new formulations, new salts, new polymorphs, or new medical equipment. Given that the scope of the exclusion is narrowly directed at the *actual methods* of medical treatment of patients by physicians (*i.e.,* how and when a drug is administered), the suggestion that it will disincentivize pharmaceutical research is specious at best.

30. Third, the position ignores that Canada *already* prohibits the patenting of MMTs, including prohibiting many dosing regimen patents. If the prohibition on MMT patents really disincentivizes innovation, *quaere* why the patentee-side innovators do not suggest that this has *already* occurred. Pharmascience is only asking this Court to simplify the legal test for this longstanding prohibition; it is not seeking a fundamental change to the Canadian legal landscape.[33]

31. Fourth, this position ignores the fact that pharmaceutical regulators require drug manufacturers to provide dosing information and clinical and/or non-clinical data justifying same. It follows that, insofar as pharmaceutical companies are *already* motivated to develop new drugs (of which there can be no doubt), it is dubious whether there is an additional need to incentivize them to do so with the promise of the patent.[34]

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[32] See *e.g.*: Doctors Factum at paras. 7, 25; IMC/BTC Factum at para. 28; CORD Factum at paras. 24-25

[33] The absence of patents on MMTs may also explain, if correct, the Doctors suggestion that pharmaceutical patent owners have not been known to pursue physicians in Canada. The caveat ("if correct") is used as the Doctors refer to a lack of lawsuits without noting what efforts were made to justify this assertion (e.g., identification of Statements of Claim).

[34] These requirements flow from Section C.08.002 or C.08.003 of the *Food and Drug Regulations.*

32. Last, the blanket suggestion that doctors do not develop dosing regimens does not withstand scrutiny. It is widely recognized that off-label drug use –prescribing of a medication for an indication, age group, dosage or route of administration that has not been approved by a regulator -– is very common across all medical specialties. [35] Indeed, medications for psychiatric disorders are frequently used for unapproved indications and it is estimated that the cost of off-label anti-psychotic drug use in 2006 was $6.0 billion.[36] *Contra* CORD's position, off-label use is particularly common for rare "orphan diseases" where it is not sufficiently profitable for a drug company to seek approval for a narrow indication.[37]

33. Further, despite acknowledging that physicians often deviate from recommended dosing regimens[38], the Doctors fail to acknowledge that many physicians must design a drug dosing regimen for a significant portion of real-world patients not evaluated in clinical trials including neonate patients, elderly patients, morbidly obese patients or those with other specific conditions.[39]

5. Improper Recourse to International Law

34. The patentee-side interveners' arguments[40] that Canada's law is discordant with international consensus ought to be ignored. Foreign law is a question of fact that must be pleaded, proven and explained in the evidence, circumstances that are absent at bar. Had foreign law been at issue at trial, Pharmascience would have led evidence to establish the fact that there is no consensus on patent laws and Canada is not an outlier.

35. In any event, FICPI's position is without merit. It improperly portages control of Canadian innovation policy from Canada into the international sphere. Canada's approach to the patentability of MMTs such as dosing regimens is properly based on Canadian law and policy, not international standards. It also demands harmonization where there is none; some countries allow MMTs, many do not. And, it ignores that comparative law analyses must be undertaken on a holistic basis rather

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[35] In 2012, off-label prescriptions account for 20% of all prescriptions. See: Wittich, C.M. et al. "Ten Common Questions (and Their Answers) About Off-label Drug Use". *Mayo Clinic Proc.* October 2012; 87(10):982-990 at 983
[36] *Ibid* at 985
[37] *Ibid* at 989
[38] Doctors Factum at para. 32
[39] See, e.g. Powell, J. *et al*, "Drug Dosing Recommendations for All Patients: A Roadmap for Change". *Clinical Pharmacology & Therapeutics*, Vol. 109, No. 1, January 2021 at p. 65
[40] FICPI Factum at paras. 27-30.

than by considering a single doctrine in isolation from the legal and policy matrix in which it is embedded. For instance, while dosing regimens are theoretically patentable in the UK, the Court in *Actavis v ICOS* acknowledged that, due to their routine nature, "nearly always such dosage regimes will be obvious."[41] One can only speculate as to whether a different approach to obviousness may have entailed a different view as to patentability.

36. Finally, as to the suggestion that "no peer jurisdiction approaches MMT or dosing regimens [using] a complex judge made test,"[42] Pharmascience knows of no authority for the proposition that judges from different countries must employ the same legal tests even if they share the same policy goals. Moreover, there is nothing inherently complex about assessing whether a patent claim is directed at "how" (*e.g.* by injection into the deltoid) and "when" (*e.g.* once a week) a medicine is to be employed.

PART IV - SUBMISSIONS ON COSTS

37. Pharmascience requests that it be awarded its costs in responding to the intervention of the patentee-interveners.

PART V – ORDER SOUGHT

38. Pharmascience respectfully asks that the arguments of the patentee-side interveners be rejected by this Court and the appeal allowed.

April 25, 2025

ALL OF WHICH IS RESPECTFULLY SUBMITTED

GOODMANS LLP
Lawyers for the Appellant

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[41] *Actavis v. ICOS*, [2019] UKSC 15 at paras. 74-77
[42] FICPI Factum at para. 29

PART VI - TABLE OF AUTHORITIES

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10.	*CD 1245*, 1999 CanLII 33028 (CA CP)	23
11.	*Celgene Corp. v. Canada (Attorney General),* 2011 SCC 1	21
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16.	*Merck Frosst Canada Inc. v. Canada (Minister of National Health and Welfare),* [1998] 2 S.C.R. 193	19
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20.	*Whirlpool Corp. v. Camco Inc.*, [2000] 2 S.C.R. 1067	8

TAB NO.	DESCRIPTION	PARA.
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21.	Chan, JK and Solmi et al. "Predicting 10-year risk of chronic kidney disease in lithium-treated patients with bipolar disorder: A risk model development and internal cross-validation study". 2025 Apr. 11; 95:24-30	24
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23.	Wittich, C.M. et al. "Ten Common Questions (and Their Answers) About Off-label Drug Use". Mayo Clinic Proc. October 2012; 87(10):982-990	31, 32
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