S.C.C. Court File No. 41209

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

B E T W E E N:

PHARMASCIENCE INC.

Appellant

- and -

JANSSEN INC. and JANSSEN PHARMACEUTICA N.V.

Respondents

- and -

CANADIAN ORGANIZATION FOR RARE DISORDERS, INTERNATIONAL FEDERATION OF INTELLECTUAL PROPERTY ATTORNEYS, CANADIAN GENERIC PHARMACEUTICAL ASSOCIATION, DAVID HOMUTH, MARCO SOLMI, and PIERRE BLEAU, INNOVATIVE MEDICINES CANADA and BIOTECANADA

Interveners

FACTUM OF THE INTERVENERS INNOVATIVE MEDICINES CANADA and BIOTECANADA

(Pursuant to Rules 42 and 59 of the *Rules of the Supreme Court of Canada*)

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PART I - OVERVIEW

1. As the representatives of the innovative pharmaceutical and biotechnology industries, Innovative Medicines Canada (**IMC**) and BIOTECanada's members either own or license patents relating to medicines, including for dosage regimens, and commercialize them in Canada.

2. This Court has recognized that pharmaceutical innovation requires "the cost of massive research programs…to produce the few 'winners' from the many false starts and failed research projects that never came to market".[1] Pharmaceutical innovation is a high-risk economic activity, and a time-limited market monopoly is therefore necessary to coax pharmaceutical innovation into the public domain, whether it be new medicines or improved ways to use a known medicine like a dosage regimen.

3. While for years the *Patent Act* discriminated by field of invention and placed heavy restrictions on pharmaceutical patentability, that is no longer the case. To encourage pharmaceutical research and development, improve access to medicines for Canadians and comply with Canada's international treaty obligations, these restrictions were repealed starting in 1987. Pharmaceutical patentability is now governed by the same rules as other patents.

4. The Appellant, Pharmascience Inc. (**PMS**), relies on an out-dated judicial analysis to seek to impose discriminatory limits on pharmaceutical patentability. PMS encourages the Court to classify methods of medical treatment (including all pharmaceutical dosage regimens) as unpatentable subject-matter, in circumstances in which Parliament has deliberately removed restrictions on pharmaceutical patentability. There is no basis in statute to support PMS' submissions, and they ought to be rejected. No special test for methods of medical treatment is necessary or desirable.

5. PMS also argues that dosage regimens are not an "art" or "process" within the section 2 definition of "invention" under the *Patent Act*[2] but are non-economic discoveries that intrude on physician skill and judgment.

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[1] *Bristol-Myers Squibb Co. v. Canada (Attorney General)*, 2005 SCC 26 at para. 8 [***Biolyse***].
[2] *Patent Act*, R.S.C., 1985, c. P-4, s. 2 [***Patent Act***].

6. This is plainly incorrect. Dosage regimens, like all forms of pharmaceutical innovation, are economically motivated and require extensive clinical research and development. They are both an "art" and/or a "process". Further, dosage regimen patents do not intrude on physician skill; rather, they offer physicians new and novel treatment options for the benefit of patients.

7. It is a core premise of the *Patent Act* that all innovators be able to rely on patent rights "to generate profits and compensate themselves for the time, effort and risk associated with making the invention".[3] Dosage regimen innovation is not treated any differently under the *Patent Act* and ought not to be treated differently by the courts. Like all innovation, dosage regimens should be incentivized by the *Patent Act* for the benefit of Canadian patients.

PART II - QUESTIONS IN ISSUE

8. This appeal addresses whether methods of medical treatment, and dosage regimens specifically, are patentable in Canada.[4]

9. IMC and BIOTECanada submit that there is no basis, in patent law or policy, for treating method of medical treatment or dosage regimen innovation differently than other forms of patentable pharmaceutical innovation:

(a) Since the repeal of subsection 41(1) of the *Patent Act*, there is no prohibition against patenting methods of medical treatment. Subsection 41(1) was repealed as part of significant reforms to the *Patent Act* to end the discriminatory treatment of pharmaceutical patents that also provided a carefully constructed balance with Canada's overall pharmaceutical policy, and

(b) Dosage regimen innovation is patentable: (i) just like other forms of pharmaceutical innovation, dosage regimen innovation has economic and commercial value, and (ii) patenting and enforcing dosage regimens does not intrude on physician skill.

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[3] *Nova Chemicals Corp. v. Dow Chemical Co.*, 2022 SCC 43 at para. 43.
[4] Appellant's Memorandum of Fact and Law, dated December 16, 2024 at para. 2 [**PMS Factum**]. Respondent's Memorandum of Fact and Law, dated February 24, 2025 at para. 36 [**Janssen Factum**].

10. PMS' proposal that the courts create and impose a special test for determining the patentability of "therapeutic" or "medical" patent claims is unnecessary and unhelpful. Moreover, the consequences of PMS' new test on pharmaceutical patents are unknown. This Court should not open Pandora's box. Consistent with Canada's long-standing decision to treat pharmaceutical patents like other fields of inventions, methods of medical treatment, and specifically, dosage regimens ought to be patentable if they satisfy the section 2 definition of "invention" under the *Patent Act*.

PART III - ARGUMENT

A. No prohibition against patenting methods of medical treatment

11. There is no express prohibition against patenting methods of medical treatment or dosage regimens in the *Patent Act*. This reflects a deliberate legislative choice.

i. The *Patent Act* before 1987

12. In 1923, Parliament introduced section 41 of the *Patent Act* which provided for the compulsory license of pharmaceutical patents. Under that scheme, subsequent entrant applicants were entitled to work pharmaceutical patents in exchange for a nominal royalty.[5]

13. As part of that scheme, and until its repeal in 1987, subsection 41(1) of the *Patent Act* expressly prohibited patent claims to the medicine itself:

> **41.** (1) In the case of inventions relating to substances prepared or produced by chemical processes and intended for food or medicine, the specification shall not include claims for the substance itself, except when prepared or produced by the methods or processes of manufacture particularly described and claimed or by their obvious chemical equivalents.[6]

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[5] *An Act to amend and consolidate the Acts relating to Patents of Invention*, 13-14 George V, 14th Parliament, 2nd Session, June 30, 1923, s. 17 [numbering subsequently changed to 41], Book of Authorities of the Interveners, Innovative Medicines Canada and BIOTECanada, [**IMC and BIOTECanada BOA**], Tab 1.

[6] Patent Act, R.S., c. 203, s. 41(1).

14. Subsection 41(1) of the *Patent Act* restricted the patentability of medicines to only: (i) claims to the process of making the medicine, or (ii) claims to a product prepared by a particular process (*i.e.*, a product-by-process claim).

15. It is widely accepted that, as a result of section 41 and the compulsory license restrictions on pharmaceutical patentability, "the Canadian pharmaceutical industry very nearly died".[7]

16. In 1987, the Canadian government took action and repealed subsection 41(1) as part of a series of significant legislative reforms to Canada's *Patent Act*.[8] These reforms ended statutory constraints on the patentability of pharmaceuticals and brought Canada into compliance with its intellectual property treaty obligations by ensuring that patent rights for pharmaceuticals would be "…enjoyable without discrimination as to…the field of technology..."[9]

17. Under subsection 27(1) of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (**TRIPS**): "…patents shall be available for all inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application."[10]

18. While subsection 27(2) of TRIPS explicitly allows members to exclude from patentability "diagnostic, therapeutic and surgical methods for the treatment of humans", Canada did not enact any such exclusions. Instead, Canada introduced institutional protections in the form of:

(a) the Patented Medicine Prices Review Board with its authority to reduce any "excessive price" at which a patented medicine is sold in Canada;[11] and

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[7] Wilkes, Robert, "The New Canadian Patent Act" (1989) 71:3 Journal of Patent and Trademark Office Society 202 at p. 226, IMC and BIOTECanada BOA, Tab 5.
[8] *An Act to amend the Patent Act*, RSC 1985, c P-4; c.10 (2nd Supp), c 40, s. 14 [41(1) on chemical substances is repealed November 19, 1987] (Bill C-22), IMC and BIOTECanada BOA, Tab 2. See also the further reforms made by Bill C-91 in 1993, *Patent Act Amendment Act*, 1992, SC 1992, c 2, s. 4 in force February 27, 1993, IMC and BIOTECanada BOA, Tab 3.
[9] Department of Justice Canada, "Canada's Implementation of the TRIPS Agreement" (April 1996) at para. 8; *Biolyse*, *supra* at paras. 8-10.
[10] TRIPS, Article 27(1). See also: North American Free Trade Agreement, January 1, 1994, Article 1709 and Canada-United States-Mexico Agreement, July 1, 2020, Article 20.36.
[11] *Patent Act*, *supra*, s. 83.

(b) "early-working" rights for subsequent entrants to facilitate generic regulatory drug approval. This ensured the timely market entry of generic competition upon patent expiry, subject to protections against patent infringement.[12]

19. Since 1987, and consistent with TRIPS, the patentability of medicines is governed by the general provisions in section 2 of the *Patent Act* which defines an "invention" as "any new and useful art, process, machine, manufacture or composition of matter" and includes "any new and useful improvement" of same.[13]

ii. ***Tennessee Eastman* and its Legacy**

20. In 1974, this Court in *Tennessee Eastman*[14] addressed the question of whether the "proper doses" or the "methods of administration" could be claimed "themselves as a separate invention consisting in a method of treatment embodying the use of the new drug?"[15]

21. The Court determined that methods of medical treatment could not be patented because of subsection 41(1). The reasoning of the Court was that if a medicine could not be claimed as an invention, then the use of that medicine (including the "proper doses") could not be claimed:[16]

> 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 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.
>
> Section 41 was enacted for the purpose of restricting the scope of patents "relating to substances prepared or produced by chemical processes and intended for food or medicine". The first principle proclaimed is that in the case of such inventions, "the specification shall not include claims for the substance itself, except when prepared or

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[12] *Patent Act*, *supra*, s. 55.2(1); *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 [***PM(NOC) Regulations***]; *PM(NOC) Regulations*, Regulatory Impact Analysis Statement [**RIAS**] *Canada Gazette, Part II*, vol. 140, no. 21 (2006.10.18) at p. 1510 [**2006 RIAS**]; *PM(NOC) Regulations,* RIAS, *Canada Gazette, Part II*, Vol. 127, No. 6 (24.03.1993) at pp. 1387-1388.

[13] *Patent Act*, *supra*, s. 2. See also s. 27(8). A patent may not be granted for "any mere scientific principle or abstract theorem."

[14] *Tennessee Eastman v. Commissioner of Patents*, [1974] S.C.R. 111 [***Tennessee Eastman***].

[15] *Tennessee Eastman*, *supra* at p. 118.

[16] *Tennessee Eastman*, *supra* at pp. 118-119. Emphasis added.

> produced by the methods or processes of manufacture particularly described in the claim or by their obvious equivalents". In my view, this necessarily implies that, with respect to such substances, the therapeutic use cannot be claimed by a process claim apart from the substance itself. Otherwise, it would mean that while the substance could not be claimed except when prepared by the patented process, its use *however prepared* could be claimed as a method of treatment. In other words, if a method of treatment consisting in the application of a new drug could be claimed as a process apart from the drug itself, then the inventor, by making such a process claim, would have an easy way out of the restriction in s.41(1).

22. The entire basis for this Court's conclusion was that methods of medical treatment are not patentable by virtue of the now repealed subsection 41(1).[17] PMS' argument that the repeal of subsection 41(1) "does not impact the underlying *ratio* of the decision" is plainly incorrect.[18] Indeed, in *Apotex Inc. v. Wellcome Foundation*, this Court observed that *Tennessee Eastman* "was based on the former s. 41 of the *Patent Act*, now repealed."[19]

23. *Tennessee Eastman* is no longer binding on the question of whether a therapeutic use of a medicine is patentable. Its reasoning is no longer instructive. Rather, and given Parliament's decision to end patentability discrimination based on field of invention and on pharmaceuticals specifically, the question is one of general application: does the method of medical treatment meet the requirements of patentability under section 2 of the *Patent Act*? In short, is the new use of a known compound patentable? That question is governed by this Court's decision in *Shell Oil*.[20]

24. In its 1982 *Shell Oil* decision,[21] this Court held that a new use of a known compound can be patentable as any "new and useful art", finding that the word "art" should be "given its general connotation of 'learning' or 'knowledge' as commonly used in expressions such as 'the state of the art' or the 'prior art'."[22] In *Apotex Inc. v. Wellcome Foundation*, this Court followed the *Shell Oil* analysis in the pharmaceutical context and held that "'[h]itherto unrecognized properties' can

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[17] *Tennessee Eastman*, *supra* at p. 119; *Apotex Inc. v. Wellcome Foundation Ltd.*, [2002] 4 S.C.R. 153, 2002 SCC 77 at para. 49 [***AZT***].
[18] PMS Factum, *supra* at para. 62, footnote 79.
[19] *AZT*, *supra* at para. 49.
[20] *Shell Oil Co. v. Commissioner of Patents*, [1982] 2 S.C.R. 536 [***Shell Oil***].
[21] *Shell Oil*, *supra* at pp. 537-538, 547.
[22] *Shell Oil*, *supra* at p. 549. While *Shell Oil* discusses *Tennessee Eastman*, it focuses only on the decision of the lower Exchequer Court and not the decision of this Court.

constitute a patentable new use for an old substance".[23] This holding is consistent with section 2 of the *Patent Act,* which expressly allows for the patenting of "improvements".

25. In summary, while historically methods of medical treatment were not patentable under the *Patent Act*, that is no longer the case. There is no statutory basis to discriminate based on field of invention, and the *Patent Act* ought to be interpreted without discrimination and in a manner that is consistent with other fields of invention, according to Canada's international treaty commitments.[24]

B. Dosage Regimens are Patentable

26. There is no reason to single out dosage regimens for special treatment or a special test under the *Patent Act*: they have economic and commercial value and do not interfere with physician skill and judgment.

i. Dosage regimen innovation has economic value

27. Dosage regimens can satisfy the section 2 definition of "invention" as "any new and useful art, process" or an "improvement" of same. In the words of *Shell Oil,* a dosage regimen can contribute "new knowledge to effect a desired result which has an undisputed commercial value".[25] There can be no serious dispute that these inventions may have commercial value by: (i) improving the efficacy of a drug substance,[26] or (ii) decreasing negative side-effects, leading to improved patient compliance.[27]

28. Given the enormous cost and risk, it is well accepted that development of pharmaceutical advancement necessitates the reward of a patent to incentivize innovation.[28] The act of discovering and commercializing a dosage regimen shares the same characteristics as other pharmaceutical

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[23] *AZT*, *supra* at paras. 48-50.
[24] *Society of Composers, Authors and Music Publishers of Canada v. Entertainment Software Association*, 2022 SCC 30, [2022] 2 S.C.R. 303 at paras. 44-46.
[25] *Shell Oil*, *supra* at p. 549.
[26] See for *e.g.*, *AbbVie Biotechnology Ltd. v. AG of Canada*, 2014 FC 1251 at para. 51.
[27] See for *e.g.*, *Merck & Co. Inc. v. Apotex Inc.*, 2005 FC 755 at paras. 18, 27, 32, 133-137.
[28] DiMasi et al., "Innovation in the Pharmaceutical Industry" (2006) 47 Journal of Health Economics 20 at p. 26, IMC and BIOTECanada BOA, Tab 4. Estimated at $2.6 billion per medicine.

innovation in terms of the economic motivation and investment required to run extensive and costly clinical trials in patients, file drug submissions and obtain regulatory approval from Health Canada.

29. PMS raises issues of "evergreening" and so-called "second generation" patents – a refrain heard from generic manufacturers in many cases.[29] In the context of selection patents, this Court has previously held that "a generalized concern about evergreening" is no justification to attack a doctrine of patentability wholesale.[30] Similarly, these complaints cannot and do not disqualify dosage regimen patents as a group. Indeed, the *Patent Act* expressly provides for the patentability of "improvements".

30. Canada also recognizes "…the societal imperative of encouraging new and better medical therapies".[31] In particular, Canada has designated formulation, dosage form and use patents (which can encompass dosage regimens) – with claims that cover the marketed medicine – as categories of "second generation" patents eligible for listing on the Patent Register and subject to the protections of the *PM(NOC) Regulations*, including the 24-month statutory stay.

31. The patentability of a dosage regimen must be assessed on its own merits under section 2 of the *Patent Act* just like other forms of patentable pharmaceutical innovation.

32. Past attempts to establish a special test for the patentability of dosage regimens have proven entirely unsatisfactory. Some courts have suggested that "fixed" dosage regimens are "vendible" products with commercial value, whereas "variable" dosage regimens (*e.g.*, claiming a dosage range as opposed to a fixed amount) are unpatentable for claiming methods of medical treatment.[32] The Federal Court of Appeal has rightly doubted the soundness of this form-over-function distinction, describing it as having "a questionable underpinning."[33] Notably, both parties to this appeal agree that these distinctions have been unhelpful in determining the patentability of dosage

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[29] PMS Factum, *supra* at para. 102.
[30] *Apotex v. Sanofi-Synthelabo Canada*, [2008] 3 S.C.R. 265, 2008 SCC 61 at para. 98.
[31] *PM(NOC) Regulations*, 2006 RIAS, *supra* at p. 1511.
[32] *Pharmascience Inc. v. Janssen Inc.*, 2024 FCA 23 at paras. 27-37, 45 [***Janssen FCA***].
[33] *Janssen FCA*, *supra* at para. 28.

regimens and should be rejected.[34]

ii. Dosage regimen innovation does not monopolize professional skill

33. Finally, dosage regimen patents do not interfere with or monopolize any medical professional skill and judgment.

34. Concern has been expressed by certain lower courts that a dosage regimen patent (particularly a variable dosage regimen) could intrude on the ability of physicians to exercise their skill and judgment in determining an appropriate dosage.[35] These concerns are addressed by the ordinary requirements of patentability.

35. To be patentable a dosage regimen must be non-obvious, useful and not anticipated. If a dosage regimen meets the requirements of patentability, it is by definition not knowledge that would otherwise be available to a physician exercising ordinary skill and judgment.

36. Thus, dosage regimen innovation does not "fence in"[36] medical skill and judgment – but serves to enhance it. Much in the same way a new method of treatment for a disease offers physicians new insight into assisting their patients, a patentable dosage regimen will provide new treatment options and opportunities. Dosage regimen patents are the result of evidence-based clinical research on a drug, including extensive clinical trials. Physicians benefit from knowing that safe and effective patented dosage regimens have been determined in clinical research conducted by innovative drug manufacturers across multiple patients.

37. PMS seeks in this appeal to create a new test of patentability for "therapeutic" or "medical" patent claims that would have the courts assess whether such claims "relate to how and when a drug or treatment is to be administered". [37] PMS' proposal is fraught with both legal and practical issues: (i) it would codify patentability discrimination based on field of invention where the *Patent Act* has removed such restrictions, (ii) it would introduce significant uncertainty into the jurisprudence, particularly in circumstances where this Court has no evidence on the practical

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[34] PMS Factum, *supra* at paras. 109-113; Janssen Factum, *supra* at para. 90, footnote 189.
[35] See for *e.g.*, *Axcan Pharma Inc. v. Pharmascience Inc.*, 2006 FC 527 at paras. 45-51.
[36] *AZT*, *supra* at para. 50.
[37] PMS Factum, *supra* at paras. 6-8, 119.

impact of the test proposed in PMS' written argument, and (iii) it would significantly undermine patent rights for pharmaceuticals and discourage innovation with respect to existing medicines.

38. Ultimately, these attempts at judicial categorization of pharmaceutical patents *ex ante* ought to be rejected in favour of a careful application of the provisions of the *Patent Act* to each invention. Put otherwise, there is no need, nor any statutory grounds, for special judge-made rules to cover medical or dosage regimen patents.

C. Conclusion

39. IMC and BIOTECanada submit that there is no basis for adopting a special test that treats methods of medical treatment or dosage regimen patents any differently than other pharmaceutical patents. Discovering a novel dosage regimen has economic value that serves to advance (not hinder) professional medical skill, whether or not that dosage regimen is fixed, variable, or subsists as a vendible product. The dosage regimen itself contributes to the productive arts as part of the body of knowledge in relation to which a medicine is commercially sold. Methods of medical treatment, and dosage regimen innovation specifically, are patentable when they satisfy the section 2 definition of "invention" under the *Patent Act*.

PART IV - SUBMISSIONS ON COSTS AND PART V - ORDER SOUGHT

40. IMC and BIOTECanada will comply with the Order of this Court dated February 28, 2025.

41. Such further and other relief as this Court may deem just.

ALL OF WHICH IS RESPECTFULLY SUBMITTED this 11th day of April 2025.

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SECONDARY AUTHORITIES	
Department of Justice Canada, "Canada's Implementation of the TRIPS Agreement" (April 1996).	16
DiMasi et al., "Innovation in the Pharmaceutical Industry" (2006) 47 Journal of Health Economics 20.	28
PM(NOC) Regulations, Regulatory Impact Analysis Statement, *Canada Gazette, Part II*, vol. 140, no. 21 (2006.10.18) at p. 1510	18, 30
PM(NOC) Regulations, Regulatory Impact Analysis Statement, *Canada Gazette, Part II*, vol. 127, No. 6 (24.03.1993) at pp. 1387-88	18
Wilkes, Robert, "The New Canadian Patent Act" (1989) 71:3 Journal of Patent and Trademark Office Society 202.	15