SCC 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

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

REPLY
(JANSSEN INC. AND JANSSEN PHARMACEUTICA N.V., RESPONDENTS)
(Pursuant to the Order of Justice O'Bonsawin dated February 28, 2025)

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REPLY OF THE RESPONDENTS

A. Overview

1. In its factum, the Canadian Generic Pharmaceutical Association ("**CGPA**") makes no mention of Janssen's commercial offering—prefilled syringes of INVEGA SUSTENNA® together with instructions to treat schizophrenia through a novel and non-obvious dosing regimen. The CGPA argues that dosing regimens are methods of medical treatment ("**MMTs**") that interfere with physicians' professional skill and judgment.[1] The fatal flaw in its position, however, is that the CGPA's arguments apply equally to patent claims to a new use of a known drug, which have been held by this Court to qualify as inventions under the *Patent Act*.[2] Reading its factum and replacing "dosing regimen" with "new use" only reinforces that the CGPA is trying to relitigate issues this Court decided in favour of encouraging pharmaceutical innovation in the *AZT Case*.[3]

2. In particular, just as patent claims to the new use of a known drug do not stifle physicians' ability to treat their patients, patent claims to novel and non-obvious dosing regimens do not interfere with physicians acting in their patients' best interests. The new commercial offering gives the physician an additional evidence-based treatment option.

3. In characterizing the invention of dosing regimens as "merely methods for treating patients with a medicine,"[4] the CGPA ignores a crucial distinction between the role of a drug manufacturer in developing new commercial treatment options, and the role of a physician in providing individualized care to a patient. While they are interdependent, they are two separate spheres: one a commercial, industrial art, and the other a highly skilled professional. The fact that professionals use their clinical judgment to prescribe the most appropriate drug product (if any) to a patient, and to prescribe how and when the patient should use it, does not transform the manufacturer's invention (which is novel, non-obvious and useful) into unpatentable subject matter. In other words, the invention of a new commercial pharmaceutical treatment option by an industrial entity

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[1] Factum of the Intervener, Canadian Generic Pharmaceutical Association at para 18 [CGPA Factum].
[2] *Shell Oil Co v Commissioner of Patents*, [1982] 2 SCR 536 at 548-549, 1982 CanLII 207 (SCC).
[3] Capitalized terms not defined herein have the same meaning as in Janssen's primary factum.
[4] CGPA Factum at para 8.

(such as a series of pre-filled syringes that embody a new evidence-based approach to treating schizophrenia) does not cease to be a "useful art" merely because that commercial good is later prescribed to patients by professional healthcare providers.

4. When a drug manufacturer provides the market with the "hard coinage"[5] of a novel, non-obvious and useful commercial offering, such as the dosing regimens for INVEGA SUSTENNA, the result is squarely within the definition of "invention" in the *Patent Act*, and is separate and distinct from the professional skill and judgment of a physician in the practice of medicine.

B. Commercial medicines are "useful art"

5. The CGPA relies on an article by Durham, who in turn cites the 1950s writings of Coulter, for its assertion that "useful arts" do not include the practice of medicine[6] and therefore, according to the CGPA, do not include dosing regimens.[7] What is relevant here is the drug manufacturer's development of a commercial pharmaceutical treatment. This Court accepted in *AZT* (after both the Durham and Coulter articles, and after the repeal of s. 41 of the *Patent Act*) that a manufacturer's patent claim to a new, non-obvious use of a pharmaceutical product to treat a disease is a "commercial offering."[8] Indeed, the Durham article itself expresses concern that Coulter's approach "seems better suited to identifying the 'useful arts' of the eighteenth century than 'expanding outward' to identify the 'useful arts' of today."[9] The development of a new pharmaceutical treatment to be made commercially available, including the complex modelling and multiple phases of clinical trials conducted by Janssen in relation INVEGA SUSTENNA, is clearly an industrial art and not the exercise of individual, non-commercial professional skill.

C. Novel, non-obvious dosing regimens are not merely "further instructions"

6. The CGPA argues that "the 'hard coinage' of [dosing regimen] patents is not a new drug or commercial offering *per se* but simply further instructions on how and when to use the drug."[10]

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[5] *Apotex Inc. v Wellcome Foundation Ltd.,* 2002 SCC 77 at para 37 [*AZT*].
[6] CGPA Factum at para 24.
[7] CGPA Factum at para 26.
[8] *AZT* at para 50; Factum of the Respondent, Janssen at para 44 [Janssen Factum].
[9] Alan L Durham, "'Useful Arts' in the Information Age" (1999) BYU L Rev 1419 at 1439, online (pdf).
[10] CGPA Factum at para 39 [emphasis in original].

The multiple challenges overcome in inventing INVEGA SUSTENNA, and the abject need for the schizophrenia treatment option that this new dosing regimen provides, illustrate that dosing regimens that meet the *Patent Act* requirements for protection transcend the derogatory label of "further instructions." The dosing regimens at issue here, like other dosing regimens that meet the requirements for patentability under the *Patent Act* and are listed under the *PMNOC Regulations*, are novel and non-obvious commercial offerings. As such, the statutory and regulatory regime for patented medicines incentivizes the invention and entitles it to protection.

D. Patent-eligibility of dosing regimen patents has been uniformly recognized by peer jurisdictions

7. In its primary factum, Janssen explained that courts in comparable jurisdictions have uniformly found that novel, non-obvious dosing regimens are patentable, and that accepting Pharmascience's test—under which all dosing regimens would be *per se* unpatentable subject matter—would put Canada out of step with its peer jurisdictions. The CGPA suggests that Janssen has misrepresented the patentability of dosing regimens in peer jurisdictions.[11] It has not.

8. **USA:** Janssen explained in its primary factum that the US "has no exclusion of MMT from patentability" and that the patentability of dosing regimens is instead determined according to the ordinary patentability requirements as set out in the US *Patent Act*.[12] Citing *Mayo v Prometheus*,[13] Janssen notes that "[a] dosing regimen, like all patent claims, must not attempt to claim laws of nature, physical phenomena or abstract ideas."[14]

9. The CGPA argues that, because of *Mayo*, the exception to patentability for laws of nature "effectively deems many dosing regimens non-patent eligible subject matter" under US law.[15] This is incorrect. The claims in *Mayo* were not directed to dosing regimens but rather to methods for determining whether a certain dose of thiopurine drugs in the treatment of autoimmune diseases was too high based on its concentration in the bloodstream: "less than about 230 pmol per $8x10^8$

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[11] CGPA Factum at para 37.
[12] Janssen Factum at paras 73-74.
[13] *Mayo Collaborative Services v Prometheus Laboratories, Inc.* (2012), 566 US 66 (US Sup Ct) at 70, 72-73 [*Mayo*].
[14] Janssen Factum at para 73, footnote 153.
[15] CGPA Factum at para 33.

red blood cells indicates a need to increase the amount of said drug subsequently administered to said patient", while "greater than about 400 pmol per $8x10^8$ red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject."[16] The US Supreme Court held that this claim was unpatentable because it simply identified a law of nature.

10. Crucially, however, the US Supreme Court did not find that it was unpatentable because it instructed doctors to apply a medicament according to a particular dosage—or any other reason related to being a dosing regimen. To the contrary, the Court held the patent invalid as claiming a law of nature *despite* its instructions to a medical practitioner. As Breyer J explained:

> While it takes a human action (the administration of a thiopurine drug) to trigger a manifestation of this relation in a particular person, the relation itself exists in principle apart from any human action. The relation is a consequence of the ways in which thiopurine compounds are metabolized by the body — entirely natural processes. And so a patent that simply describes that relation sets forth a natural law.[17]

In short, the patent was not invalid due to a "concern about physicians having the requisite freedom to operate",[18] but rather because it claimed a patent over a natural phenomenon.

11. Since *Mayo* the US Federal Circuit has routinely upheld dosing regimen patents applying the ordinary criteria for patentability, without an MMT exception—as Janssen explained in its primary factum.[19]

12. Canada also prohibits patenting of a "mere scientific principle",[20] and yet dosing regimen patents for specific drugs have frequently been upheld. It is only patents that simply claim a method of verifying the efficacy of a dose based on natural phenomenon that risk unpatentability as a mere statement of a scientific principle. Pharmascience does not even contend, nor could it reasonably

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[16] *Mayo* at 74-75.
[17] *Mayo* at 77.
[18] CGPA Factum at para 34.
[19] See Janssen Factum at para 73, footnotes 152, 154, citing *Vanda Pharmaceuticals Inc v West-Ward Pharmaceuticals Int'l Ltd* (2018), 887 F3d 1117 (US Fed Cir); *Endo Pharmaceuticals Solutions, Inc v Custopharm Inc* (2018), 894 F3d 1374 (US Fed Cir); *AstraZeneca LP v Apotex, Inc* (2010), 633 F3d 1042 (US Fed Cir).
[20] *Patent Act*, RSC 1985, c P-4, s 27(8).

contend, that CA Patent No. 2,655,335 (the "**335 Patent**") is ineligible on this basis. The CGPA's reliance on *Mayo* is therefore entirely unfounded.

13. **Australia:** In the landmark judgment of *Apotex v Sanofi AUS*,[21] the High Court of Australia approved the patentability of MMT subject to the ordinary patentability criteria, while noting in *obiter* a possible distinction under those criteria "between a method of medical treatment which involves a hitherto unknown therapeutic use of a pharmaceutical (having prior therapeutic uses) *and the activities or procedures of doctors (and other medical staff) when physically treating patients*", the latter of which are typically unpatentable for lack of industrial application (i.e. the separate commercial and professional spheres noted in paragraph 3 above).[22]

14. The CGPA erroneously characterizes the High Court's distinction as "akin" to Pharmascience's proposed "how and when" test.[23] In fact, it is a distinction between (certainly patentable) methods of treatment involving the use of a pharmaceutical and (possibly unpatentable) methods of surgery.[24] *Apotex* did not approve the "how and when" test, or anything like it; to the contrary it upheld a patent teaching "[a] method of preventing or treating [psoriasis]" by "administering to a recipient an effective amount of a pharmaceutical composition containing as an active ingredient [leflunomide]".[25] Contrary to the CGPA and Pharmascience's position, the High Court even went out of its way to approve patents for the "hitherto unknown therapeutic use

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[21] *Apotex Pty Ltd v Sanofi-Aventis Australia Pty Ltd*, [2013] HCA 50 (Austl HC) [*Apotex v Sanofi AUS*].

[22] *Apotex v Sanofi AUS* at para 287 [emphasis added].

[23] CGPA Factum at para 35.

[24] See generally *Apotex v Sanofi AUS* at paras 237-242 (identifying the distinction in prior Australian case law). Notably, the CGPA's quotation of *Apotex* skips over (without ellipsis) the High Court's specific approval of method claims that involve the use of a pharmaceutical. Compare *Apotex v Sanofi AUS* at para 287 (acknowledging "a distinction […] between a method of medical treatment which involves a hitherto unknown therapeutic use of a pharmaceutical (having prior therapeutic uses) and the activities or procedures of doctors" (emphasis added)); with CGPA Factum at para 35 (suggesting that *Apotex* "held that here is 'a distinction […] between a MMT which involves a hitherto unknown therapeutic use and the activities or procedures of doctors'").

[25] *Apotex v Sanofi AUS* at para 3.

of a pharmaceutical (having prior therapeutic uses)".[26] Consistent with that instruction, Australian decisions since *Apotex* have upheld the patentability of dosing regimens without concern.[27]

15. **UK:** The CGPA criticizes Janssen's analysis of UK law for failing to discuss *Bristol-Myers Squibb Co. v Baker Norton Pharm. Inc. et al*, (the "*BMS Case*")[28] that, according to the CGPA, held that "claims for the administration of a patient-specific dosage were not capable of industrial application as they required several decisions be made by the physician."[29] Janssen did not address the *BMS Case* (beyond a footnote)[30] because it does not represent English law's approach to dosing regimen patents. Although the CGPA claims that *Actavis* later "distinguished" the *BMS Case*,[31] it actually concluded, first, that the *BMS Case* produced no clear holding on the patentability of dosing regimens as methods of medical treatment at all and, second, any holding should not be followed because it was inconsistent with settled case law from the EPO.[32] Under *Actavis*, as affirmed by the UK Supreme Court in 2019,[33] a new and non-obvious dosing regimen is patentable as long as it takes the form of a Swiss-type claim (now an EPC 2000 claim format).[34]

16. The bottom line is this: No comparator country considers dosing regimens *per se* unpatentable, and no comparator country would deem all claims of the 335 Patent unpatentable as MMT.

17. The CGPA has cited various multilateral agreements to which Canada is a party[35] to suggest that Canada took positive steps to retain the "flexibility" to exclude "diagnostic, therapeutic and surgical methods for the treatment of humans" from patentability. The CGPA has provided no support for this assertion, and the mere fact that Canada is a signatory to these

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[26] *Apotex v Sanofi AUS* at para 287.
[27] See e.g. *Neurim Pharmaceuticals (1991) Ltd v Generic Partners Pty Ltd (No 5)*, [2024] FCA 360 at para 474 (Austl FC).
[28] *Bristol-Myers Squibb Company v Baker Norton Pharmaceuticals Inc, Napro Biotherapeutics Inc.*, [1998] EWHC Patents 300, aff'd [2000] EWCA Civ 169.
[29] CGPA Factum at para 36.
[30] Janssen Factum at para 78, footnote 166.
[31] CGPA Factum at para 36.
[32] *Actavis UK Ltd v Merck & Co Inc*, [2008] EWCA Civ 444 at paras 71, 107-108, [2009] 1 WLR 1186 [*Actavis*].
[33] *Actavis Group PTC EHF v ICOS Corporation*, [2019] UKSC 15 at paras 74-77.
[34] *Actavis* at para 29.
[35] CGPA Factum at para 30.

multilateral agreements does not establish that Canada specifically sought such flexibility. On the other hand, it is uncontroverted that Canada has never amended the *Patent Act* to exclude MMT, despite expressly amending the *Patent Act* to bring it in line with Canada's treaty obligations and despite repealing former s. 41.[36]

E. The proposed "how and when" test is inconsistent with the outcome in *AZT*

18. The CGPA has also mischaracterized Janssen's reference to the *AZT* claim element "an amount effective to provide a unit dose."[37] Janssen's point is that Pharmascience's "how and when" test would render the claims upheld by this Court in *AZT* invalid.[38] The patent upheld in *AZT* included claims to a "pharmaceutical formulation for use in the treatment or prophylaxis of AIDS comprising an effective amount of 3'-azido-3'-deoxythymidine in association with a pharmaceutically acceptable carrier", with some claims further specifying "an amount effective to provide a unit dose of 10 to 1500 mg." The fact that the claims in *AZT* described how (i.e., using effective amounts, including the specified dose range) and when (i.e., when treating AIDS) to prescribe a previously known compound did not make them unpatentable. That some of the *AZT* claims referred to a "unit dose" does not change this point; indeed, certain challenged claims of the 335 Patent similarly refer to "pre-filled syringes."

F. It is entirely appropriate that innovative drug manufacturers do not sue physicians

19. The CGPA suggests that it is merely a strategic choice that physicians are not named as defendants when generic manufacturers are accused of infringing dosage regimen patents. However, as Janssen pointed out in its primary factum,[39] in litigation under the *PMNOC Regulations*, such as this appeal, the *Regulations* do not permit physicians to be named.

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[36] As noted by the intervener Fédération Internationale des Conseils en Propriété Intellectuelle ("FICPI") Canada has made legislative changes to be consistent with TRIPS, for example by Bill S-17, entitled "An Act to amend the Patent Act," which came into force on June 14, 2001 (see FICPI Factum at para 13).

[37] CGPA Factum at para 19.

[38] Janssen Factum at paras 12, 67.

[39] Janssen Factum at para 92.

20. Before any generic manufacturer receives market authorization from Health Canada, the *PMNOC Regulations* require that the generic must first address any patents listed on the patent register in respect of the relevant drug it seeks to copy. If the generic alleges that the innovator's listed patent will not be infringed by the generic product once approved, the innovator has a right of action (essentially, an action *quia timet*) against the generic manufacturer under the *Regulations* for a declaration that making, constructing, using or selling a drug in accordance with the generic manufacturer's regulatory submission or supplement would infringe a listed patent.[40] This right of action applies to listed patents under section 6(1) of the *Regulations* as well as eligible unlisted patents under section 8.2 of the *Regulations*. The language of section 6(1) limits the action as solely between the innovative and generic drug companies; it does not involve individual potential prescribers or users of the proposed generic drug.[41] In any event, as the generic drug is not yet on the market and no physician could have prescribed it, there could not be a cause of action against physicians.

21. Given the scheme provided by the PMNOC *Regulations* that allows for *quia timet* actions before generic approval, including for unlisted patents, there are very limited circumstances in which the hypothetical suggested by the CGPA[42] of a physician choosing to employ a patented dosing regimen with a generic product on the market could arise, such as a situation where the 24-month stay under the *PMNOC Regulations* expires before a decision on validity and/or infringement is released and the generic decides to launch "at risk" (i.e., at risk that the generic offering infringes a valid patent), and the patent in issue is ultimately upheld as valid. In any event, it is undisputed that innovative drug manufacturers only ever sue the copycat manufacturer and never their customers. The physicians who have intervened in this appeal confirm that patents do not negatively impact or limit how physicians treat patients.[43]

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[40] *Regulations Amending the Patented Medicines (Notice of Compliance) Regulations, 2017*, SOR/2017-166, *Canadian Gazette Part II*, Vol 151, No 1; see also *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133, s 6(1) [*PMNOC Regulations*].
[41] *PMNOC Regulations*, s 6, referring to the "first person" and "second person" expressly.
[42] CGPA Factum at para 28.
[43] Factum of the Interveners, David Homuth, *et al*. at paras 4, 28-34.

G. Contrary to the CGPA's claims, generic manufacturers have repeatedly been found to infringe valid dosing regimen patents

22. The CGPA asserts that the "MMT doctrine has been soundly-based settled law for 50 years";[44] however, it also had to acknowledge that the courts have "continually chipped away at the MMT doctrine" since 2002.[45] This reinforces the severity of the shortcomings of the supposed MMT doctrine, which was premised on a now-repealed provision of the *Patent Act*.

23. The CGPA's suggestion that at any time generic companies could "safely rely"[46] on the MMT doctrine as disqualifying dosing regimens from patent protection such that they could launch their products without waiting for the innovator to recoup its investments is plainly wrong and contradicted by the CGPA's own factum.[47] There are many cases in which dosing regimen claims were found to not constitute an unpatentable MMT.[48]

H. Dosage regimen patents do not have the alleged effects on generic manufacturers

24. In contrast with its "safe reliance" on MMT argument, the CGPA also asserts that "[e]ven if a generic drug approval is limited to unpatented uses, it may still induce infringement of a patented use, with the practical effect being a moratorium on generic approval for *any* use of the drug."[49] That concern does not apply to this case, where paliperidone palmitate did not exist as a commercial offering in any form prior to the invention of the dosing regimens at issue. In any event, CGPA's argument does not warrant eliminating dosing regimen patents.

25. The test for inducement to infringe in Canada requires that the inducer (the generic manufacturer) knowingly influence the doctor to the point where without this inducement, infringement would not occur. It is obvious from the jurisprudence that a generic company that

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[44] CGPA Factum at para 12.
[45] CGPA Factum at para 4.
[46] CGPA Factum at para 17.
[47] CGPA Factum at para 4.
[48] *Merck & Co. v Apotex Inc.*, 2005 FC 755 at paras 27, 137; *Pfizer Canada Inc. v Apotex Inc.*, 2005 FC 1421 at paras 8, 144, 149; *Merck & Co. v Pharmascience Inc.*, 2010 FC 510 at paras 4-6, 109, 111, 114; *Abbott Laboratories (Bermuda) Ltd., Re*, 2014 FC 1251 at paras 13, 108, 111, 113-115, 121-122, 127; *Biogen Canada Inc. v Taro Pharmaceuticals Inc.*, 2020 FC 621 at paras 22, 209, 211-214; *Janssen Inc. v Apotex Inc.*, 2021 FC 7 at paras 17, 222-223; *AbbVie Corporation v Jamp Pharma Corporation*, 2023 FC 1520 at paras 57, 61, 333-334, 339, 413-415.
[49] CGPA Factum at para 40 [emphasis in original].

properly limits its offering to unpatented uses can obtain approval for such uses. There have been ample cases where a generic or biosimilar that has properly carved out the patented use from its marketing material (including product monograph and labelling) has been held not to infringe the innovator's patent.[50]

26. In any event, any generic or biosimilar manufacturer is free to develop its own new dosing regimen for an existing drug, so long as it is willing to make the investment to do so. Even before the expiry of the patent to the drug itself, a generic/biosimilar can rely on the experimental use exemption[51] of the *Patent Act* to develop a new dosing regimen and the regulatory submission exemption[52] for any required clinical trials and to prepare a new drug submission for Health Canada. The generic or biosimilar manufacturer could also avoid the *PMNOC Regulations* altogether by filing a new drug submission that makes no comparison to the innovator's product. However, the CGPA's members are likely unwilling to invest the "hard coinage" themselves, and instead prefer to benefit from the innovator's investment to bring new and innovative dosing regimens to the market, as is the case with INVEGA SUSTENNA. Regardless, the CGPA's unfounded arguments about "perpetuating monopolies" is addressed by the *Patent Act*'s exclusion of "evergreening" and is not justification to disentitle from patentability an entire category of new, non-obvious, and useful inventions that provide meaningful benefits for Canadian patients and the healthcare system.[53]

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[50] See e.g. *Allergan Inc. v Apotex Inc*., 2022 FC 260 at paras 921-922, 927-928; *Novopharm Limited v Sanofi-Aventis Canada Inc.*, 2007 FCA 167 at para 13; *Sanofi-Aventis Canada Inc. v Laboratoire Riva Inc*., 2008 FC 291 at paras 27-29; *Aventis Pharma Inc. v Apotex Inc*., 2005 FC 1461 at paras 33-36, aff'd 2006 FCA 357; *Pfizer Canada Inc. v Apotex Inc*., 2005 FC 1421 at paras 162-168; see also *Bristol-Myers Squibb Canada v Apotex Inc*., 2017 FC 1061 at paras 25-26, 46.
[51] *Patent Act*, s 55.3(1).
[52] *Patent Act*, s 55.2(1).
[53] *Apotex Inc v Sanofi-Synthelabo Canada Inc*, 2008 SCC 61 at para 98.

ALL OF WHICH IS RESPECTFULLY SUBMITTED this 25th day of April, 2025.

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