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

Interveners

FACTUM OF THE INTERVENER THE CANADIAN ORGANIZATION FOR RARE DISORDERS

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

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PART I – OVERVIEW OF POSITION

1. The objective of the *Patent Act* is to encourage innovation and economic development by coaxing new and useful inventions into the world.[1] It is difficult to conceive of an area of research where the need for innovation is greater than the treatment of rare disorders.[2] Many rare disorders—which disproportionately affect children—are genetically-based, severe, chronic, and progressive, with high mortality rates.[3] Prescription medicines are often the only form of treatment for Canadians with rare disorders. However, many medicines impose a significant burden on the lives of patients which can, in turn, reduce patient compliance and desired outcomes. [4]

2. New treatments, including improvements to existing medicines, frequently come in the form of novel dosing regimens that reduce treatment burden, improve compliance, and enhance patients' and their caregivers' quality of life. While at first it may seem that differences in dosing regimens only represent small or incremental improvements, such innovations can have profoundly positive impacts on patients with rare disorders and their caregivers. For example, a medicine which only requires administration of a drug once or twice daily to a child, as opposed to several times a day, including in the middle of the night, can allow that child to lead a more normal life.[5]

3. At the core of this appeal is whether the *Patent Act* prohibits, or ought to prohibit, patent claims to so-called "methods of medical treatment" in respect of which

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[1] *Free World Trust v Électro Santé Inc.*, 2000 SCC 66, ¶42.

[2] Rare disorders are sometimes referred to as rare diseases or "orphan" diseases. Medicines used to treat rare disorders are sometimes referred to as "orphan drugs".

[3] Canadian Agency for Drugs and Technology in Health, "Environmental Scan: Drugs for Rare Diseases", October 2013 (Updated February 2016) at 3-4.

[4] See for example, van Stein C, *et al*. A comparison of immediate release and delayed release cysteamine in 17 patients with nephropathic cystinosis. *Orphanet J Rare Dis*. 2021 Sep 14;16(1):387 at 6.

[5] See for example, van Stein C, *et al*. A comparison of immediate release and delayed release cysteamine in 17 patients with nephropathic cystinosis. *Orphanet J Rare Dis*. 2021 Sep 14;16(1):387.

the Appellant proposes an unworkable and dangerously broad "how and when" test[6] and which the Appellant contends includes claims to novel dosing regimens.

4. The Canadian Organization for Rare Disorders (**CORD**) is Canada's national network for patients with rare disorders, representing nearly 100 patient groups, foundations, and societies. CORD is concerned that prohibiting or restricting patent claims to "methods of medical treatment" will disproportionately and negatively affect patients with rare disorders by disincentivizing the introduction of new and necessary treatment innovations in Canada.

5. Whether the *Patent Act* prohibits, or ought to prohibit, claims to "methods of medical treatment" is a matter of statutory interpretation. Reading the words of the *Patent Act* in their entire context and grammatical and ordinary sense harmoniously with the *Patent Act*'s scheme and object and Parliament's intention[7] leads to one conclusion: no prohibition to claims for "methods of medical treatment" exists.

6. The *Patent Act* is structured such that "invention" is defined broadly in section 2 with express restrictions constraining patentability provided elsewhere in the statute. The *Patent Act* contains no express bar to claims for "methods of medical treatment" or dosing regimens. To the contrary, a previous prohibition (section 41) was repealed by Parliament in 1991 and then, subsequently, regulations were enacted to expressly contemplate use claims including dosing regimens.[8]

7. The spectre of a prohibition on claims to "methods of medical treatment" arises from *Tennessee Eastman*, a case decided when then section 41 of the *Patent Act* was in force. Despite the repeal of section 41, lower courts have followed *Tennessee*

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[6] The Appellant's ill-conceived "how and when" test may also capture other innovative use claims, such as novel dosage forms for use in the treatment of rare disorders. These innovations are likewise important to, and can positively impact, the lives of patients with rare disorders and CORD's submissions herein would apply to those as well.

[7] *Bell ExpressVu Limited Partnership v Rex*, 2002 SCC 42, ¶26.

[8] *Patent Act*, RSC 1985, c P-4, s. 55.2; *Patented Medicines (Notice of Compliance) Regulations,* SOR/93-133 (March 12, 1993).

Eastman and its progeny, thereby causing confusion as to the scope of the so-called prohibition on claims to "methods of medical treatment", including whether such a prohibition includes novel uses and dosing regimens.[9]

8. The solution to this confusion is plain: the *Patent Act* does not prohibit the claiming of "methods of medical treatment". "Methods of medical treatment" constitute patentable subject-matter and the patentability of claims to these inventions ought to be evaluated in the same way as all others. There is no basis to differentially treat innovations in the pharmaceutical space—in fact, the reverse is true—there is good reason not to do so, including protecting and supporting vulnerable Canadians with rare disorders. Provided that the requirements of the *Patent Act* are met, "methods of medical treatment" are entitled to patent protection.

PART II – POSITION ON QUESTIONS IN ISSUE

9. CORD's submissions are directed to whether the *Patent Act*—as it presently exists—prohibits or ought to prohibit patent claims for "methods of medical treatment". This is the key issue underlying the appeal as framed by the parties.[10] CORD's position is that the *Patent Act*, when read purposively, provides no basis for prohibiting patent claims to "methods of medical treatment". Further, CORD submits that prohibiting such claims will negatively impact Canadians with rare disorders by disincentivizing the introduction in Canada of needed new treatments, including novel dosing regimens that materially improve patient compliance, quality of life, and outcomes.

PART III – STATEMENT OF ARGUMENT

10. Canadian patent law is a creature of statute—not common law. Patent rights, including the scope of what is patentable and what is not, must be grounded in the

[9] See: *Cobalt Pharmaceuticals Company v Bayer Inc.*, 2015 FCA 116, ¶101; *Hospira Healthcare Corporation v Kennedy Trust for Rheumatology Research*, 2020 FCA 30, ¶53; *Janssen Inc. v Teva Canada Ltd.*, 2020 FC 593, ¶143.
[10] Pharmascience Factum, ¶52(a); Janssen Factum, ¶9.

Patent Act.[11] Fundamentally, the question of whether claims to "methods of medical treatment" are prohibited is one of statutory interpretation.

A. The Definition of "Invention" Presumptively Includes "Methods of Medical Treatment"

11. Generally, the *Patent Act* is structured such that (i) section 2 defines "invention" and broadly characterizes the subject-matter entitled to patent protection, and (ii) the remainder of the *Patent Act* sets out how an invention may be patented,[12] provides restrictions on what may be patented[13] and on the scope of the monopoly granted.[14] The evaluation of whether specific subject-matter is patentable must therefore have regard to the definition of "invention" in section 2 and consider any express restrictions provided elsewhere in the *Patent Act*.[15]

12. Section 2 of the *Patent Act* provides that an "invention" is 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.[16] Canadian courts have held that "invention" must be interpreted broadly since inventions inherently encompass "unforeseen and unanticipated technology."[17]

13. The term "art", for example, has been construed to have "the general

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[11] *Apotex Inc. v Sanofi-Synthelabo Canada Inc.*, 2008 SCC 61, ¶12; *Commissioner of Patents v Farbwerke Hoechst Aktiengesellschaft Vormals Meister Lucius & Bruning*, 1963 CanLII 2 (SCC) at 57.

[12] For example, section 27(1) to (5.2) describes application requirements.

[13] For example, section 27(8) provides that no patent shall be granted for any mere scientific principle or abstract theorem.

[14] For example, sections 21.02 to 21.2 allow for use of claimed subject-matter during the monopoly to further public health problems in developing and least-developed countries.

[15] *Schlumberger v Commissioner of Patents* (1981), [1982] 1 FC 845 (FCA) at 847; *Tennessee Eastman v Commissioner of Patents* (1972), [1974] SCR 111 (SCC) at 117-120.

[16] *Patent Act,* RSC 1985, c. P-4, s. 2.

[17] See: JA Rothstein's (as he was) findings in *Harvard College v Canada (Commissioner of Patents)* (2000), [2000] 4 FC 528 (FCA), ¶116-117.

connotation of 'learning' or 'knowledge' as commonly used in expressions such as 'the state of the art' or 'the prior art.'" This Court in *Shell Oil* interpreted "art" to include new uses for known compounds:[18]

> The appellant's discovery in this case has added to the cumulative wisdom on the subject of these compounds by a recognition of their hitherto unrecognized properties and it has established the method whereby these properties may be realized through practical application. In my view, this constitutes a "new and useful art" and the compositions are the practical embodiment of the new knowledge.

"Process" has similarly been interpreted broadly.[19] The definition of "invention" plainly includes so-called "methods of medical treatment" and novel dosing regimens.

B. No Prohibition to "Methods of Medical Treatment" in the *Patent Act*

14. Any exclusion from the broad definition of an "invention" must be derived from an explicit provision in the *Patent Act*.[20] For example, section 27(8) of the *Act* provides that "no patent shall be granted for any mere scientific principle or abstract theorem." The Federal Court of Appeal in *Schlumberger* relied on this express exclusion in construing "invention" to not include mathematical formulae to facilitate the exploration for oil and gas.[21]

15. The *Patent Act* does not contain any similar prohibitions or exclusions for claims to "methods of medical treatment" or novel dosing regimens. To the contrary, an express prohibition against patent claims "relating to substances prepared or

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[18] *Shell Oil v Commissioner of Patents* (1982), [1982] 2 SCR 536 (SCC) at 549.
[19] *Commissioner of Patents v Ciba Ltd.* (1959), [1959] SCR 378 (SCC) at 383.
[20] *Harvard College v Canada (Commissioner of Patents)*, 2002 SCC 76, ¶145.
[21] *Schlumberger Canada Ltd. v Commissioner of Patents* (1981), [1982] 1 FC 845 (FCA) at 847. *Schlumberger* was decided in view of then section 28(3) which included the same prohibition against "mere scientific principle or abstract theorem" now found in section 27(8) in the current *Patent Act*. See: *Patent Act*, RSC 1985, c P-4, s. 27(8); *Patent Act*, RSC 1970, c P-4, s. 28(3).

produced by chemical processes and intended for food or medicine"[22] (then section 41) was repealed from the *Patent Act* in 1991.[23]

16. The notion of a prohibition against "methods of medical treatment" arises from *Tennessee Eastman*,[24] old jurisprudence decided when section 41 was still in force. In *Tennessee Eastman*, a novel surgical method using a known adhesive for joining a wound—which the Court characterized as a "method of medical treatment"—was found to not be an "art" or "process" under section 2 of the *Act* in view of then section 41.[25]

17. The existence of then section 41 was paramount in this Court's analysis in *Tennessee Eastman*. As noted by a majority of this Court in the subsequently decided *Harvard College*:[26]

> [145] Some commentators remark that the Canadian courts have in the past excluded certain subject matter from patentability on moral, ethical or policy grounds ... While it is true that certain categories of invention were excluded from patentability with these policy concerns in mind, these exclusions were justified by reference to explicit provisions of the Patent Act. … In *Tennessee Eastman*, however, the determination that a method for bonding incisions and wounds was not an "art" or a "process" was based primarily on the fact that the bonding material itself when prepared for medical purposes would not be patentable under what was then s. 41 of the *Patent* Act. Section 41, since removed from the

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[22] *Tennessee Eastman v Commissioner of Patents* (1972), [1974] SCR 111 (SCC) at 115.

[23] Section 41 of the *Patent Act* later became section 39 of the *Patent Act*, which, in 1987 was amended to cease to have effect in 4 years. See: *Patent Act*, RSC 1985, c P-4, s. 39; Bill C-22, *An Act to amend the Patent Act and to provide for certain matters in relation thereto*, 2nd Sess, 33rd Parl, 1987, cl 14.

[24] *Tennessee Eastman v Commissioner of Patents* (1972), [1974] SCR 111 (SCC).

[25] *Tennessee Eastman v Commissioner of Patents* (1972), [1974] SCR 111 (SCC) at 118-119.

[26] *Harvard College v Canada (Commissioner of Patents)*, 2002 SCC 76, ¶145. See also: *Apotex v Wellcome Foundation*, 2002 SCC 77, ¶49, though in *Wellcome*, there was no "serious challenge" to subject-matter patentability.

> *Act,* restricted the scope of patents on substances prepared or produced by chemical processes and intended for food or medicine. [*Emphasis added*]

18. The findings of *Tennessee Eastman* have continued to be cited by some lower courts despite the repeal of section 41, causing confusion as to the scope of the so-called prohibition on claims to "methods of medical treatment".[27] Continued reliance on *Tennessee Eastman* and its progeny is wrong and contrary to settled principles of statutory interpretation as it (i) improperly imports a limitation found only in the now repealed section 41 and (ii) fails to consider the proper scope of the definition of "invention" in section 2 of the *Patent Act* in light of the repeal of section 41.[28]

19. Further support for the patentability of purported "methods of medical treatment" and dosing regimens in the current *Patent Act* is found in the *Patented Medicines (Notice of Compliance) Regulations* (the ***Regulations***).[29] The *Regulations* were promulgated under section 55.2 of the *Patent Act* to help ensure, *inter alia*, that the early working exception to patent infringement provided by section 55.2 of the *Act* is not abused.[30]

20. The first iteration of the *Regulations* came into force in 1993 *after* the repeal of section 41. Section 4 of the *Regulations* expressly provides that patents containing claims to a medicine or its "use" may be eligible for listing on Health Canada's Patent Register.[31] The *Regulations* thus presume that "uses", including dosing regimens are

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[27] See: *Cobalt Pharmaceuticals Company v Bayer Inc.*, 2015 FCA 116, ¶101; *Hospira Healthcare Corporation v Kennedy Trust for Rheumatology Research*, 2020 FCA 30, ¶53; *Janssen Inc. v Teva Canada Ltd.*, 2020 FC 593, ¶143.

[28] *R v Wolfe*, 2024 SCC 34, ¶39; *Ontario (Finance) v Echelon General Insurance Company*, 2019 ONCA 629, ¶49.

[29] *Patent Act*, RSC 1985, c P-4, s. 55.2; *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133, s. 2.

[30] See: Regulatory Impact Analysis Statement, Canada Gazette Part II, Vol. 127, No. 6 at 1388. The exception is intended to allow generic manufacturers to "early work" patented inventions so that they are prepared to enter the Canadian market upon patent expiry.

[31] *Patented Medicines (Notice of Compliance) Regulations,* SOR/93-133 (March 12, 1993), s.4.

patentable subject-matter. The express inclusion of these claim types in the *Regulations* reinforces that Parliament intended for such subject-matter to be patentable following the repeal of section 41 of the *Act*. [32]

C. "Evergreening" Concerns are Misguided and Do Not Justify a Prohibition

21. The Appellant submits that a prohibition against "methods of medical treatments" is needed to prevent "evergreening" and that there is "nothing to coax" in respect of claims to "methods of medical treatment."[33] This argument is flawed and presumes, wrongly, that all patents claiming so-called "methods of medical treatment" are not inventive.

22. Moreover, such assertions fail to recognize existing mechanisms in the *Patent Act* that are applicable to all patents and which guard against "evergreening". For example, the *Patent Act* requires that the subject-matter of a patent claim be new (s.28.2), non-obvious (s.28.3), and fully described (s.27(3)).[34] If a patentee sought to claim subject-matter that was not new or was obvious in light of existing art and knowledge, such claims could be held invalid for anticipation or obviousness. Similar concerns were raised and aptly dismissed by this Court in *AstraZeneca v Apotex* when finding, as the Court should similarly find here, that the common law "Promise Doctrine" had no grounding in the *Patent Act*.[35]

D. A Prohibition is Contrary to Policy and Will Cause Prejudice to Disadvantaged Groups

23. Contrary to the Appellant's assertions, a prohibition on claims for "methods of medical treatment" or dosing regimens would not accord with the overarching policy objective of the *Patent Act*: advancing research and development.[36] Rather, such a prohibition would stifle innovation and disproportionately impact disadvantaged

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[32] *Reference re Impact Assessment Act*, 2023 SCC 23, ¶59; *Canada (Attorney General) v Mavi*, 2011 SCC 30, ¶57; *Monsanto Canada Inc. v Ontario (Superintendent of Financial Services)*, 2004 SCC 54, ¶35;
[33] Pharmascience Factum, ¶82-84 & 100.
[34] *Patent Act*, RSC 1985, c P-5, s.27(3), 28.2 and 28.3.
[35] *AstraZeneca Inc. v Apotex Inc.*, 2017 SCC 36, ¶36 & 46.
[36] *Free World Trust v Électro Santé Inc.*, 2000 SCC 66, ¶42.

groups, such as Canadians with rare disorders.

24. Improvements in dosing regimens have profound impacts on the lives of patients and their caregivers by decreasing the frequency in which a patient may need to take a drug. Not only do these innovations improve the lives of patients by improving patient adherence and quality of life, but they can also provide substantial economic benefits, lowering healthcare costs.[37] For example, nephrotic cystinosis, a rare infantile disease that can be fatal, was historically treated with cysteamine bitartrate which required administration four times daily with strict timing—including through the night—inevitably interrupting a child's sleep pattern. The development of delayed release cysteamine permits twice daily administration, allowing children and their families to lead more normal lives.[38]

25. In CORD's experience, when it is perceived that Canada does not offer sufficient protections for an innovative medicine for a rare disorder, the innovative companies involved are more reluctant, and in fact may not, seek to bring the innovative medicine to market in Canada. Further, without the introduction of new innovative products, and novel dosing regimens, generic manufacturers are unlikely to fill this gap, resulting in fewer treatment options for patients with rare disorders being introduced in Canada. Given Canada represents a small portion of the global drug market, and Canadian patients with rare disorders an even smaller portion, CORD fears

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[37] Srivastava K, *et al*. Impact of reducing dosing frequency on adherence to oral therapies: a literature review and meta-analysis. *Patient Prefer Adherence*. 2013 May 20;7:419-34.

[38] van Stein C, *et al*. A comparison of immediate release and delayed release cysteamine in 17 patients with nephropathic cystinosis. *Orphanet J Rare Dis*. 2021 Sep 14;16(1):387. Similarly, improvements that significantly decrease the time for administration of a medicine (e.g., moving from intravenous to subcutaneous administration) improve patient satisfaction, convenience, and quality of life: Lugtenburg P, *et al*. Efficacy and safety of subcutaneous and intravenous rituximab plus cyclophosphamide, doxorubicin, vincristine, and prednisone in first-line diffuse large B-cell lymphoma: the randomized MabEase study. *Haematologica*. 2017 Nov;102(11):1913-1922.

that a prohibition or restriction on patent claims to "methods of medical treatment" as proposed by the Appellant will disincentivize innovative companies from introducing new products with improved dosing regimens in Canada. This will result in Canadians being unable to access needed therapies that can be obtained by rare disorder patients in other countries.

E. Conclusion

26. Only one conclusion can be arrived at by reading the words of the *Patent Act* in its entire context and grammatical and ordinary sense harmoniously with the scheme and object of the *Patent Act* and the intention of Parliament:[39] there is no prohibition against patent claims for "methods of medical treatments" or novel dosing regimens. To the contrary, such innovations can have profound impacts on the lives of Canadian with rare disorders and their caregivers. These innovations should be incentivized, not deterred, by the *Patent Act*.

PART IV – SUBMISSIONS ON COSTS

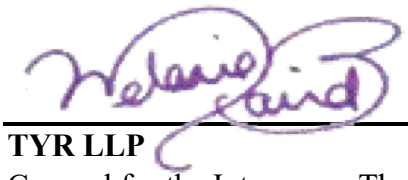
27. CORD proposes that there be no additional costs or disbursements against it on this appeal save for those ordered by the Court in the Order of the Honourable Madam Justice O'Bonsawin dated February 28, 2025.

PART V – ORDER SOUGHT

28. CORD takes no position in respect of the specific outcome of this appeal.

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

[39] *Bell ExpressVu Limited Partnership v Rex*, 2002 SCC 42, ¶26



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PART VI – TABLE OF AUTHORITIES

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