The Supreme Court clarifies Canada's methods of medical treatment doctrine

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On July 17, 2026, the Supreme Court of Canada released its long-awaited decision in *Pharmascience Inc. v. Janssen Inc.*, 2026 SCC 26, providing the most significant guidance in decades on the patentability of methods of medical treatment in Canada. While the Court ultimately upheld Janssen's patent, which the Court characterized as being for dosing regimens for formulations used to treat schizophrenia, the broader significance of the decision lies in its clarification of how subject matter should be assessed to determine if it defines non-patentable methods of medical treatment.

Background

The evolution of the method of medical treatment doctrine

Unlike many exclusions from patentability, the prohibition of patenting methods of medical treatment (MMT) does not appear anywhere in the *Patent Act*. Instead, it emerged through the common law, most notably from the Supreme Court's decision in *Tennessee Eastman*.

In *Tennessee Eastman*, the Court held that a surgical method did not constitute patentable subject matter because it related to the exercise of professional skill rather than an "art" within the meaning of the *Patent Act*.

Over the decades that followed, that reasoning expanded beyond surgical procedures, and Courts were increasingly asked whether therapeutic methods involving pharmaceuticals likewise crossed the line into unpatentable subject matter. While a new drug could constitute patentable subject matter, greater difficulty arose where patents claimed how a drug should be administered, particularly where treatment depended on dosage adjustments, treatment schedules, or patient-specific considerations.

In attempting to distinguish patentable pharmaceutical inventions from unpatentable methods of medical treatment, the Canadian Courts considered a variety of recurring factors when attempting to assess if a claim required the exercise of professional skill and judgement, including:

- whether the claim recited a fixed dosage regimen or a range requiring adjustment;
- whether treatment required ongoing individualized clinical decision-making; and
- whether the claimed invention more closely resembled a vendible product than the exercise of a professional medical skill.

The difficulty was that professional skill and judgement is not referred to in the *Patent Act* itself and no single factor led to a comprehensive legal framework.

The dispute before the Supreme Court

The present dispute arose with respect to Janssen's Canadian Patent No. 2,655,335, whose claims recite specific dosage regimens for paliperidone used in the treatment of schizophrenia. The patent teaches a dosing schedule involving the administration of particular loading and maintenance doses.

The Federal Court in *Janssen Inc. v. Pharmascience Inc.*, 2022 FC 1218 recognized that the existing jurisprudence related to methods of medical treatment had largely developed around a distinction between fixed and variable dosing regimens. Under that line of inquiry, claims directed to specific dosage amounts and fixed administration schedules were generally considered patentable subject matter, whereas claims requiring a physician to select a dose or treatment schedule from within a range were more likely to be characterized as unpatentable methods of medical treatment. Although the Federal Court questioned the theoretical foundation of this dichotomy, it acknowledged that this remained the prevailing state of the law.[1]

The Federal Court of Appeal (FCA) in *Pharmascience Inc. v Janssen Inc.*, 2024 FCA 23 held, and what ultimately became the guiding rule until now, was that the fixed versus variable dosage distinction was not the correct test. Rather, the proper inquiry was whether use of the invention (not whether to use it) required the exercise of skill and judgement. Importantly, the Court of Appeal acknowledged that this assessment inherently turned on the particular claims and evidence in each case.[2]

At the heart of Pharmascience's appeals was the contention that Janssen's patented dosing regimen crossed the line from a patentable pharmaceutical innovation into an unpatentable method of medical treatment that attempted to monopolize a physician's judgement on "how" and "when" to administer the drugs.

The Supreme Court's analysis

Before turning to Janssen's patent itself, the Supreme Court addressed the broader question: Are methods of medical treatment non-patentable subject matter under Canadian law?

The Court's answer was unequivocal.

From the opening paragraphs of the decision, the Court repeatedly characterized the doctrine as settled Canadian law. For more than fifty years, Canadian courts have consistently treated methods of medical treatment as unpatentable subject matter, and the Court emphasized that no Canadian court has held otherwise. In language rarely

seen on a question of patent doctrine, the Court noted that it was being asked to "disrupt this settled law" and declined to do so.[3]

Importantly, the Court rejected Janssen's submission that the MMT doctrine disappeared with the repeal of former section 41(1) of the *Patent Act*. The Court concluded that the doctrine has been reaffirmed repeatedly by subsequent jurisprudence, is rooted in the broader principle that professional skills are not patentable and has become an established part of Canadian patent law independent of the former statutory provision.

In doing so, the Court effectively closed the door on arguments that the prohibition on methods of medical treatment ceased to exist as a distinct exclusion following the repeal of former section 41(1) of the *Patent Act*.

Adopting the Federal Court of Appeal's framework for methods of medical treatment

Neither Pharmascience nor Janssen succeeded with their competing positions. Instead, the Court expressly endorsed the framework previously articulated by the Federal Court of Appeal, describing it as a "balanced approach" grounded in the purpose of the doctrine itself.

Under that approach, the ultimate question remains whether the claimed subject matter amounts to professional medical skill and judgment. Put differently, the inquiry is whether the claim seeks to "fence in" an area of medical practice.[4]

The Court emphasized that this assessment begins with purposive claim construction and focuses on the “real subject matter of the claim.”[5] Citing the Federal Court of Appeal, the Supreme Court emphasized that what matters in this part of the analysis is substance, not form.[6]

Professional skill and judgement

Perhaps the most significant aspect of the decision appears in the Court's discussion of professional skill and judgment.[7]

The Court drew a distinction between whether a claimed invention amounts to professional medical skill and judgement, or whether professional medical skill and judgement would be used in *selecting* the invention for a particular use.

By way of example, the Court stated that a medical professional prescribing a drug to a patient exercised clinical judgement in deciding *whether* it was appropriate, but that does not itself make the drug unpatentable. Rather, it is the prescribing decision that is the unpatentable subject matter. Further, once selected, a medical professional may still need to monitor a patient and decide whether to continue, stop or alter treatment. The Court affirmed that the mere existence of those decisions does not render the treatment unpatentable subject matter.[8]

The test for methods of medical treatment[9]

The most significant contribution of the decision may be the Supreme Court's clarification of how the methods of medical treatment doctrine is to be applied. Although the Court declined to draw a bright line between patentable medical innovations and unpatentable methods of medical treatment, it endorsed the Federal Court of Appeal's approach and identified three key considerations to guide the analysis.

> **First**, the need for professional skill and judgement in determining whether a treatment is appropriate for a patient will generally not affect its patentability. The decision to prescribe a treatment is distinct from the invention itself.
>
> **Second**, the more a claimed invention requires tailoring to the circumstances of individual patients, the more likely it is to amount to a method of medical treatment. Conversely, inventions capable of broad application without individualized adjustment are less likely to constitute methods of medical treatment.[10]
>
> **Third**, the analysis must remain connected to the rationale underlying the doctrine. The more a medical professional would naturally develop, refine, or improve the subject matter through ordinary professional practice, the more likely it is that the subject matter is a non-patentable method of medical treatment.[11]

Importantly, the Court emphasized that these are not bright-line rules. Rather, they are guideposts in what the Court repeatedly described as a "factually suffused" inquiry.

Moving beyond the fixed-versus-variable dosage debate

Endorsing the Federal Court of Appeal's approach, the Court held that the fixed-versus-variable dosage distinction "skirts the ultimate issue" and is, at best, an evidentiary proxy for the real inquiry of whether the claimed invention amounts to professional medical skill and judgment.[12] A variable dosage regime is therefore not inherently unpatentable, nor is a fixed dosage regimen automatically patentable, subject matter.

Application to Janssen’s Patent

Applying these principles, the Court concluded that the subject matter of Janssen's claimed invention did not amount to professional medical skill and judgment. The claimed subject matter did not require the kind of individualized clinical decision-making that characterizes an unpatentable method of medical treatment. The claims therefore remained patentable subject matter, and the appeal was dismissed.

Implications

The Supreme Court’s decision confirms that methods of medical treatment remain excluded from patentable subject matter in Canada. At the same time, the Court held that a claim is not unpatentable merely because it concerns variable dosages or timing. The analysis remains fact-specific and turns on the substance of the claim, including whether implementing the claimed subject matter requires a physician or other health professional to exercise individualized skill and judgment. Claim form may be relevant to that assessment, but the decision does not suggest that form alone is determinative.

Footnotes

[1] *Janssen Inc. v. Pharmascience Inc.*, 2022 FC 1218 at paras 164-166.

[2] *Pharmascience Inc v Janssen Inc.*, 2024 FCA 23, at para 37.

[3] *Pharmascience Inc. v. Janssen Inc.*, 2026 SCC 26, at paras 1-5.

[4] *Pharmascience Inc. v. Janssen Inc.*, 2026 SCC 26, at para 89.

[5] *Pharmascience Inc. v. Janssen Inc.*, 2026 SCC 26, at para 91.

[6] *Ibid*.

[7] *Pharmascience Inc. v. Janssen Inc.*, 2026 SCC 26, at para 93-94.

[8] *Pharmascience Inc. v. Janssen Inc.*, 2026 SCC 26, at para 94.

[9] *Pharmascience Inc. v. Janssen Inc.*, 2026 SCC 26, at para 100.

[10] *Pharmascience Inc. v. Janssen Inc.*, 2026 SCC 26, para 95.

[11] *Pharmascience Inc. v. Janssen Inc.*, 2026 SCC 26, at para 97.

[12] *Pharmascience Inc. v. Janssen Inc.*, 2026 SCC 26, at para 105.

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