Supreme Court of Canada Maintains Dosing-Regimen Patent and Clarifies Patentability of Therapeutic Methods

July 22, 2026

Author

Serge Shahinian

Partner, Patent Agent

On July 17, 2026, the Supreme Court of Canada (SCC) issued its decision in *Pharmascience Inc. v. Janssen Inc.,* (2026 SCC 26), dismissing Pharmascience's invalidity challenge to Janssen's paliperidone palmitate dosing-regimen patent. While the majority of the SCC confirmed that a doctrine still exists in Canadian patent law under which a method of a medical treatment (MMT) is non-patentable subject matter, they affirmed the analysis and conclusions of the lower Courts that the claims of Janssen's patent are **not** directed to a non-patentable MMT.

Background

Treatment of Schizophrenia entails lifelong management with antipsychotic medications, and the effectiveness of such treatment relies significantly on adherence to treatment regimens. A successful approach to improve treatment adherence has been the development of long-acting formulations, known as "depot formulations" or "long-acting injectables", which gradually release the medication from the injection site and thus entail less frequent administration. Janssen developed such a long-acting injectable type of dosing regimen for the drug paliperidone palmitate for the treatment of Schizophrenia, marketed under **INVEGA SUSTENNA**.

Janssen's Canadian Patent No. 2,655,335 (the '335 Patent) relates to such a dosing regimen, under which the drug is administered as follows:

> **Day 1**: A first dose via deltoid injection;
> **Day 8 ± 2 days**: A second dose via deltoid injection;
> **Monthly ± 7 days thereafter**: Maintenance doses via deltoid or gluteal injection;
> **Two regimens** are defined depending on renal impairment status, with specified mg-eq doses.

Pharmascience sought to invalidate the patent, arguing that the claims were invalid as impermissible methods of medical treatment.

Procedural History

Federal Court

Pharmascience sought to obtain marketing approval or a “Notice of Compliance” to market a generic version of **INVEGA SUSTENNA**. Under Canada’s pharmaceutical patent linkage regime, this led to proceedings before the Federal Court in which Pharmascience alleged invalidity of the patent. In its decision of August 23, 2022 (2022 FC 1218), the Federal Court (FC) upheld the validity of the ‘335 Patent.

Federal Court of Appeal

On February 1, 2024 (2024 FCA 23), the Federal Court of Appeal (FCA) affirmed the FC’s decision and again upheld the validity of the ‘335 Patent. In its analysis, the FCA established that in order to determine whether a claim is directed to an unpatentable MMT, the key inquiry is whether practising the invention calls for the exercise of professional skill and judgment. The FCA drew a distinction between:

> skill and judgment applied in deciding **how** to use a treatment, which points to an unpatentable MMT; and
> skill and judgment applied in deciding **whether** to use a treatment, which **does not**, **on its own**, **indicate** an unpatentable MMT.

Each case turns on its specific facts and the onus remains on the party attacking the patent to establish that the claim encompasses an unpatentable MMT.

Pharmascience then sought leave to appeal to the SCC, where the sole issue being assessed was patentable subject matter - whether the claims impermissibly claim a MMT and do not comply with section 2 (definition of “invention”) of the *Patent Act*.

Supreme Court

The SCC maintained that a doctrine still exists in Canadian patent law under which MMTs are non-patentable subject matter. This doctrine is primarily attributable to the 1972 decision of the SCC in the *Tennessee Eastman*[1] case, at which time it was only possible to patent a drug based on its method of manufacture, not as a pharmaceutical substance *per se*, as per former section 41(1) of the *Patent Act*. Following the repeal of former section 41(1), it has been argued that the rationale of *Tennessee Eastman* hinged on this repealed section and therefore the principles established in *Tennessee Eastman* should no longer apply. The majority of the SCC now confirms that the rule against patenting MMTs does not rest on former section 41(1) alone and continues to apply, grounded in the long-standing broader principle that “professional skills” are not patentable.

The SCC also affirmed that the ‘335 Patent’s dosing regimen claims do not monopolize professional medical skill and judgment in their implementation and thus do not relate to an unpatentable MMT. The appeal was therefore dismissed and the patent upheld on this ground.

The majority’s test: when does a claim cross the line into an MMT?

A patent impermissibly claims an MMT only if it seeks to monopolize professional medical skill and judgment - i.e., if it “fences in” an area of medical treatment. The analysis
is purposive and substance-over-form; it turns on the claims and the evidentiary record.

The majority offered three non-exhaustive guideposts:

Focus on the claimed subject matter, not on the fact that doctors exercise judgment in choosing whether to use it for a particular patient. Clinical judgment in selecting/monitoring treatment generally does **not** make the invention unpatentable.
Individualization increases risk: the more the claim requires tailoring to individual patient characteristics, the more likely it is an MMT.
Ordinary-course professional development: the more the claimed subject matter is the kind of thing physicians would be expected to develop/improve as part of practice (without patent incentives), the more likely it is an MMT.

Fixed vs. variable dosage is not dispositive. While past Court decisions focused on fixed vs. variable dosages or timing of administration to be determinative factors, the SCC rejected such a categorical bright line; at most, variability may be an evidentiary proxy tied to the central "skill and judgment" question.

Application to Janssen's dosing regimens

The majority affirmed the lower Courts' key findings that:

Once the regimen is selected, no professional skill/judgment is required to *implement* it as claimed.
The renal-impairment split reflects an **objective distinction** and does not meaningfully constrain professional judgment.
The ± dosing windows and alternate injection sites were supported by evidence as **clinically interchangeable** / operational flexibility **without clinical implications**.

Result: the claims were not framed (in substance) as fencing in physicians' clinical decision-making; they were treated as **patentable subject matter**.

Concurring reasons

While all of the Justices agreed on the result, two of the Justices disagreed on the doctrine and would have gone further. They:

Disagreed that MMTs are *inherently* non-patentable subject matter;
Would **re-examine/overrule *Tennessee Eastman*** and assess MMT claims like any other invention as defined in the *Patent Act*, with many failing instead under utility/operability/reproducibility/control concepts (rather than under a subject-matter exclusion).

Despite that doctrinal divergence, they agreed that the **'335 Patent is valid**.

Practical Takeaways

MMT exclusion remains the majority rule: claims that effectively fence in **clinical decision-making** remain vulnerable on subject-matter grounds.
Dosing regimen patents remain viable: evidentiary record and claim substance will be critical - particularly around whether implementation requires individualized clinical judgment.
No bright-line "fixed vs. range" rule: Rather, the **actual role of medical skill/judgment** in practicing the claimed regimen is key.

Overall, the SCC's decision appears to fall in a middle ground between the positions advanced by the parties: confirming a doctrine of non-patentability of MMTs while at the same time confirming the patentability of dosing-regimen-based inventions depending on the facts of a given case, and as a result upholding the validity of the '335 Patent.

---

1. *Tennessee Eastman Co. et al. v. Commissioner of Patents*, [1974] SCR 111.