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Status Quo, With a Twist: The SCC Reaffirms, and Reframes, the Medical Method Exclusion

The most hotly anticipated IP decision in 2026 has arrived. The Supreme Court of Canada (SCC) released its decision in *Pharmascience v Janssen* on July 17, 2026, and it is now the latest SCC authority on patentable subject matter and the leading authority on whether methods of medical treatment are patentable in Canada. This marks the Supreme Court's first substantive patent decision in nine years.

Background & Decision on Appeal

Janssen owns Canadian Patent No. 2,655,335 (the '335 Patent), which focuses on a specific dosing regimen for INVEGA SUSTENNA, a treatment for schizophrenia. The '335 Patent teaches a regimen to achieve an optimum plasma concentration-time profile.

The '335 Patent contained four types of claims including claims to "vendible products," (meaning prefilled syringes for use according to the claimed dosing regimens) and claims to the use of a dosage form according to the claimed dosing regimens.

Pharmascience (PMS) challenged the '335 Patent, arguing the claims constitute an unpatentable method of medical treatment. PMS argued that the maintenance dose claimed is not the only maintenance dose used in practice, thus indicating that no particular dose will work for every patient, and that selection of the appropriate dose for a specific patient will require skill and judgment from the prescriber. The Federal Court rejected the argument and held that the '335 Patent discloses patentable subject matter. PMS appealed, and the Federal Court of Appeal (FCA) dismissed the appeal.

As noted by the FCA, "The jurisprudence at the Federal Court level has developed an approach whereby a claim [to the administration of a drug] may be found to be either patentable subject matter or an unpatentable method of medical treatment based on whether it defines a fixed dosage (or interval of administration) or a range of dosages (or intervals)."

The FCA rejected this bright-line rule and held that it would go too far to say that any drug regimen that requires a physician to monitor a patient is unpatentable. It also stated that while a fixed

dosage and schedule may suggest that no skill and judgment would be required, evidence may indicate otherwise. The FCA also held that a claim that includes a dosing regimen as an essential element can be a patentable claim to a vendible product.

Supreme Court of Canada Decision

PMS sought and was granted leave to appeal to the SCC. In that appeal, PMS asked the SCC to reverse the long line of Federal Court authority allowing the patentability of dosing regimens. It urged the Court to find that dosing regimens are not inventions under the *Patent Act*, no matter the type of regimen or skill and judgment needed to follow the method.

Majority Decision: Status Quo

Writing for seven judges, Justice Jamal held that methods of medical treatment remain unpatentable in Canada, and Janssen's dosing-regimen patent does not claim a method of medical treatment. The majority grounded the exclusion not in a repealed statutory provision (former s. 41(1) of the *Patent Act*, which had restricted patenting of food and medicine and underpinned the Court's 1974 *Tennessee Eastman* decision), but in a broader principle: professional skills, being unrelated to trade, industry, or commerce, are not proper subject matter for a patent.

The Court reasoned that a physician's professional skill and judgment cannot be monopolized because physicians already operate under a state-sanctioned license and ethical duties to use and share their skills for public benefit and do not need patent incentives to do so. The majority found nothing in Parliament's repeal of s. 41(1), the legislative history, international law, or subsequent case law suggesting Parliament meant to overturn this settled rule.

The majority framed the key question as whether a patent "seeks to monopolize professional medical skill and judgment" or "fence in" an area of medical practice. This inquiry requires purposively construing the claims and privileging substance over form. The majority also clarified that this analysis "depends neither on a literal reading of the claims nor on the 'spirit of the invention' or the 'inventive concept.'" The majority offered three (non-exhaustive, non-bright-line) guideposts:

1. The analysis focuses on whether the claimed subject matter is professional skill and judgment (not merely whether such judgment is used to select it for a patient).

2. The more a claim requires tailored treatment for individual patients, the more likely it is an unpatentable

method of medical treatment.

3. The more a physician would already be incentivized to develop the subject matter in ordinary practice, the more likely it is to be unpatentable.

Importantly, the Court held that drug-dosing regimens can be patentable, and that the older distinction between “fixed” and “variable” dosages is at best a useful indicator courts look to as evidence but is “never dispositive.”

Applying this, the majority upheld the trial judge’s finding that physicians did not need skill or judgment to implement Janssen’s regimen once they selected it. The separate kidney-function dosage tiers, dosing windows, and injection-site choices do not constrain clinical judgment, and the latter two elements do not carry clinical implications. On this basis, the patent claims were valid subject matter.

Concurring Decision: No Blanket Prohibition

Justices O’Bonsawin and Moreau agreed the patent is valid but rejected the majority’s premise that methods of medical treatment are inherently unpatentable. In their view, the legal foundations of *Tennessee Eastman* have significantly eroded because that decision was tied to the now-repealed s. 41(1). Further, the rationale in *Tennessee Eastman* that healing the body has no commercial value, and that patents would interfere with professional skills, has become obsolete and unworkable.

They also criticized the “skill and judgment” test as arbitrary and nebulous, noting that courts have struggled to define how much skill and judgment is “too much,” and that any dosing regimen inherently involves some judgment. Instead, they reasoned that a method of medical treatment should be assessed like any other claimed invention, by applying s. 2 of the *Patent Act*, which defines an invention as including any “new and useful art, process, machine, manufacture, or composition of matter,” or an improvement thereof.

Since a practical, therapeutic application of medical knowledge can qualify as a patentable “art,” it is patentable. On their reading, Parliament’s large-scale liberalizing reforms to the *Patent Act* in the late 1980s and early 1990s signaled an intent to remove the blanket prohibition and let Parliament, not the courts, decide categorical exclusions.

Having rejected a blanket subject matter exclusion, Justices O’Bonsawin and Moreau argued that the *Patent Act*’s existing utility requirement is the doctrinally proper home for the concerns that the “method of medical treatment” doctrine has tried to address and is a sufficient safeguard against a flood of

medical method patents.

They observed the current doctrine, with its reliance on “skill and judgment,” is really grounded in considerations more closely tied to utility than to subject matter. Utility requires that an invention be capable of a “practical purpose” so that inventions which are inoperable, irreproducible, or uncontrollable fail for want of usefulness. Inventions depending on human skill, judgment, or subjective interpretation will typically flounder on exactly this ground because their outcomes cannot be reliably demonstrated: a method of advocacy or cross-examination, for instance, is unpatentable not because it falls outside the categories of “invention,” but because its success turns on the practitioner’s experience and judgment and cannot be reliably reproduced.

On this view, many genuine methods of medical treatment, such as those that truly depend on a physician’s individualized clinical judgment, would simply fail the utility criterion. Courts could filter them out through an established statutory test rather than the amorphous, policy-laden subject matter exclusion the majority retained.

Key Takeaways

Both sets of reasons converged on the same outcome: Janssen’s patent is valid and PMS’s appeal is dismissed. But the reasons reveal a significant doctrinal divide on medical method patents in Canada.

For businesses and litigants, the decision provides several practical takeaways:

- Methods of medical treatment remain unpatentable in Canada under the majority’s framework.
- Dosing regimens are not automatically excluded from patentability.
- Courts will focus on whether the claim monopolizes professional medical skill and judgment.
- Fixed and variable dosage language may matter, but it will not decide the issue on its own.
- Future cases will likely test how far the majority’s “skill and judgment” framework extends.

There is a lot in this decision to unpack, and pharmaceutical companies and IP litigators alike will be watching closely to see how the lower courts apply it.