



The Supreme Court of Canada confirms that methods of medical treatment cannot be patented under Canadian law.

This case is about whether methods of medical treatment can be patented. Methods of medical treatment generally involve decisions that doctors and other health professionals make about how to treat their patients. A patent is a legal right that gives the patent-holder exclusive authority to use or sell a particular invention, which can include a product or process.

Beginning in the early 1990s, the pharmaceutical company Janssen developed an injectable drug used to treat schizophrenia. Through extensive research and trials, Janssen developed regimens designed to achieve an optimal concentration of the drug in patients. In 2016, Janssen was successful in obtaining a patent that sets out, among other things, specific dosing regimens of the drug in patients.

In 2020, Pharmascience, a generic drug manufacturer, attempted to obtain approval to market a generic version of Janssen's drug. Janssen opposed the approval and brought lawsuits in the Federal Court alleging that Pharmascience's proposed generic product would infringe its patent. Pharmascience argued that Janssen's patent is invalid because it protects methods of medical treatment, which have historically not been patentable in Canada. The Federal Court found that the patent does not cover methods of medical treatment, and it upheld its validity. The Federal Court of Appeal agreed and dismissed Pharmascience's appeal. Pharmascience then appealed to the Supreme Court of Canada.

The Supreme Court dismissed the appeal.

The patent for dosing regimens is valid because it does not focus on professional medical skill and judgment.

Writing for the majority, Justice Jamal said that methods of medical treatment cannot be patented under Canadian law because professional skills are not patentable. A proposed patent that focuses on a method of medical treatment will be invalid because it is essentially trying to monopolize professional medical skill and judgment.

Justice Jamal made three general observations that can help guide the analysis of whether a proposed patent focuses on methods of medical treatment. First, courts should focus on whether the invention itself depends on professional medical skill and judgment, not whether medical skill and judgment would be applied in deciding whether or not to use the invention. Second, the more a treatment must be tailored to individual patients, the more likely it will be considered to be a method of medical treatment. Third, the more medical professionals would be expected to develop or improve the subject matter of a particular invention, the more likely it is to be considered a method of medical treatment. Justice Jamal emphasized that these observations are not exhaustive and do not replace a case-by-case analysis.

Justice Jamal concluded that the specific dosing regimens protected in Janssen's patent do not require a physician's exercise of professional skill and judgment. Although physicians must still decide whether the treatment is appropriate for an individual patient, the patent itself tells them how the regimen is to be administered. Janssen's patent does not focus on a method of medical treatment, and is therefore valid.

Breakdown of the decision: *Majority*: Justice [Jamal](#) dismissed the appeal (Chief Justice [Wagner](#) and Justices [Karakatsanis](#), [Côté](#), [Rowe](#), [Martin](#) and [Kasirer](#) agreed) | *Concurring*: Justices [O'Bonsawin](#) and [Moreau](#) would have also dismissed the appeal

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