SUPREME COURT OF CANADA

CITATION: Pharmascience Inc. *v.* Janssen Inc., 2026 SCC 26

APPEAL HEARD: October 9, 2025
JUDGMENT RENDERED: July 17, 2026
DOCKET: 41209

BETWEEN:

Pharmascience Inc.
Appellant

and

Janssen Inc. and
Janssen Pharmaceutica N.V.
Respondents

- and -

Canadian Generic Pharmaceutical Association,
International Federation of Intellectual Property Attorneys,
Innovative Medicines Canada,
BIOTECanada,
Canadian Organization for Rare Disorders,
David Homuth,
Marco Solmi and
Pierre Bleau
Interveners

CORAM: Wagner C.J. and Karakatsanis, Côté, Rowe, Martin, Kasirer, Jamal, O'Bonsawin and Moreau JJ.

REASONS FOR JUDGMENT: (paras. 1 to 124)	Jamal J. (Wagner C.J. and Karakatsanis, Côté, Rowe, Martin and Kasirer JJ. concurring)
JOINT CONCURRING REASONS: (paras. 125 to 285)	O'Bonsawin and Moreau JJ.

Pharmascience Inc. *Appellant*

v.

Janssen Inc. and
Janssen Pharmaceutica N.V. *Respondents*

and

Canadian Generic Pharmaceutical Association,
International Federation of Intellectual Property Attorneys,
Innovative Medicines Canada, BIOTECanada,
Canadian Organization for Rare Disorders,
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Present: Wagner C.J. and Karakatsanis, Côté, Rowe, Martin, Kasirer, Jamal, O'Bonsawin and Moreau JJ.

ON APPEAL FROM THE FEDERAL COURT OF APPEAL

Intellectual property — Patents — Subject matter — Patentability — Methods of medical treatment — Dosing regimens — Pharmaceutical company owning patent for dosing regimens for drug used to treat schizophrenia — Generic drug manufacturer seeking to have patent invalidated on basis that patent impermissibly claims method of medical treatment — Whether methods of medical treatment constitute unpatentable subject matter — If so, whether impugned patent claims method of medical treatment — Patent Act, R.S.C. 1985, c. P-4, s. 2 "invention".

Janssen owns a patent for dosing regimens for a long-acting injectable formulation of paliperidone palmitate used to treat schizophrenia and related disorders. The patent teaches a first dose administered in the deltoid muscle on Day 1 of treatment; a second dose administered in the deltoid muscle on Day 8 of treatment ± 2 days; and then doses administered in either the deltoid or gluteal muscle monthly ± 7 days. For patients without impaired kidney function, the first and second doses are 150 and 100 mg-eq., respectively, and the subsequent monthly doses are 75 mg-eq. For patients with impaired kidney function, the first and second doses are 100 and 75 mg-eq., respectively, and the subsequent monthly doses are 50 mg-eq. The product monograph for Janssen's formulation of paliperidone palmitate sets out the dosing regimens disclosed in the patent.

Pharmascience attempted to obtain approval to market its generic version of Janssen's formulation of paliperidone palmitate. This gave rise to proceedings before the Federal Court. The Federal Court rejected Pharmascience's argument that Janssen's

patent is invalid on the basis that its claims involve unpatentable subject matter, namely methods of medical treatment. The Court of Appeal dismissed Pharmascience's appeal and affirmed that the patent claims patentable subject matter.

Held: The appeal should be dismissed.

Per Wagner C.J. and Karakatsanis, Côté, Rowe, Martin, Kasirer and **Jamal** JJ.: Methods of medical treatment are not patentable subject matter under Canadian law because professional skills are unpatentable. Canadian courts have consistently excluded methods of medical treatment from the definition of "invention" in s. 2 of the *Patent Act*, and rightly so. However, Janssen's patent does not impermissibly claim a method of medical treatment; therefore, it cannot be invalidated on that basis.

The rule that methods of medical treatment constitute unpatentable subject matter was affirmed by the Court in *Tennessee Eastman Co. v. Commissioner of Patents*, [1974] S.C.R. 111, a decision grounded in part in the former s. 41(1) (later s. 39(1)) of the *Patent Act*, which was repealed in 1993. Section 41(1) prohibited the patenting of a substance intended for food or medicine except when prepared or produced by particular methods or processes of manufacture. However, the rule against patenting methods of medical treatment does not rest on that repealed provision alone. Rather, the Court and other courts have recognized the broader principle that professional skills are not proper subject matter for a patent. The principle that methods of medical treatment are not patentable is a specific application of the broader principle that professional skills — which are unrelated to trade, industry, or commerce — are

not patentable subject matter.

A purposive interpretation of s. 2 of the *Patent Act*, which defines a patentable "invention" as "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", confirms that methods of medical treatment are not patentable subject matter. Distinguishing unpatentable professional skills from patentable innovations in trade, industry, or commerce is fully consistent with the *Patent Act*'s purpose of encouraging desirable inventiveness. A physician's professional skill and judgment cannot be patented because this would be inconsistent with the purpose of the *Patent Act*. The Act seeks to incentivize desirable inventiveness by granting a temporary monopoly to those who share their new knowledge with the public. Physicians already benefit from a state-granted monopoly to practise and share their skills for the public benefit and do not require the prospect of extracting monopoly profits under a patent to do so. Further, professionals such as physicians are already under ethical obligations to exercise their skills in their clients' best interests and to share those skills widely. They neither need nor should they receive patent protection to do so. Nor is it the role of the patent system to regulate professionals in the exercise of their professional skills and judgment.

In keeping with the principle that professional skills are not patentable, Canadian courts have continued to affirm that methods of medical treatment are not patentable after the repeal of s. 41(1). In *Apotex Inc. v. Wellcome Foundation Ltd.*, 2002

SCC 77, [2002] 4 S.C.R. 153, the Court applied this rule and upheld the validity of the patent at issue, rejecting the argument that a patent for a new use of a known drug in treating a particular disease sought to monopolize a method of medical treatment. Likewise, a substantial and unbroken line of decisions from the Federal Court and Federal Court of Appeal has held that methods of medical treatment remain unpatentable notwithstanding the repeal of s. 41(1). No court at any level has ruled otherwise, and the scholarly literature reflects the same broad consensus.

Nothing indicates that Parliament intended to displace the settled jurisprudence holding that methods of medical treatment fall outside the definition of "invention" in s. 2 of the *Patent Act*. Section 41(1) was repealed as part of broader reforms to the former compulsory licensing scheme under Canadian patent law, a scheme concerned exclusively with food and pharmaceutical substances. The repeal of s. 41(1) did not change the patentability of methods of medical treatment; it merely removed restrictions on patenting pharmaceutical substances. Nothing in the legislative debates, the text of the amendments, or the contemporaneous commentary suggests that these reforms were intended to permit the patenting of methods of medical treatment or to overrule *Tennessee Eastman*. When Parliament has wished to overrule a decision of the Court as to the interpretation of the *Patent Act*, it has done so expressly.

International law does not support the view that methods of medical treatment are patentable in Canada. Article 27(3)(a) of the *Agreement on Trade-Related Aspects of Intellectual Property Rights*, 1869 U.N.T.S. 299 ("*TRIPS Agreement*"), to

which Canada is a signatory, expressly permits — but does not require — signatories to exclude "diagnostic, therapeutic and surgical methods for the treatment of humans" from patentability. Canada's decision not to enact legislation expressly excluding methods of medical treatment as a patentable invention in response to the *TRIPS Agreement* is of no significance because it has been settled law since *Tennessee Eastman* that methods of medical treatment are unpatentable in Canada. That conclusion flows from the consistent judicial interpretation of s. 2 of the *Patent Act*. No legislative amendment was required to preserve the status quo.

A patent impermissibly claims a method of medical treatment only if it seeks to monopolize professional medical skill and judgment. The question is whether the subject matter amounts to professional medical skill and judgment or, put differently, whether the claimed invention seeks to "fence in" an area of medical treatment. This ensures that the patent regime does not fence in areas within the field of medical practice, while also not stifling commercial innovation involving medical applications. The question must be approached by construing the patent claims purposively, privileging substance over form. The answer to the question will depend on the nature of the specific claims and the facts of each case. Three general observations from the jurisprudence may help guide the analysis. First, the analysis should focus on whether the subject matter of the claimed invention amounts to professional medical skill and judgment, not whether professional medical skill and judgment would be applied in selecting the claimed invention for a particular patient or use. The need for professional skill and judgment in determining whether the subject

matter is or continues to be an appropriate treatment option for a particular patient will generally not affect its patentability. Second, the more the subject matter involves tailoring treatment to individual patients, the more likely it is that it amounts to a method of medical treatment. Treating a patient based on their individual characteristics engages professional skill and judgment in making treatment decisions. By contrast, where the subject matter of the claimed invention can be applied generally to a broad class of patients without individual adjustment, it is less likely to be a method of medical treatment. Third, the more a medical professional would already be incentivized to develop or improve a given subject matter in the course of their professional practice, the more likely it is that the subject matter amounts to a method of medical treatment. These three points of guidance are not exhaustive and do not establish bright-line rules.

Drug-dosing regimens can be patentable subject matter. Determining the patentability of a dosing regimen is a factually suffused exercise that depends on the evidence and how the dosing regimen is intended to be, or has been, applied. The analysis may consider whether the dosing regimen is fixed or variable, but it must remain tied to the ultimate question of whether the claimed dosing regimen amounts to professional medical skill and judgment. A categorial distinction between fixed and variable dosages skirts the ultimate issue of whether the claimed dosing regimen amounts to professional medical skill and judgment. Such a distinction is, at best, an evidentiary proxy that is sometimes useful but never dispositive of whether the claims are for unpatentable methods of medical treatment. That question relates to the degree

of individualization of the claim, which is a helpful but not determinative consideration.

In the instant case, the trial judge correctly focused on professional skill and judgment when applying the test for methods of medical treatment. He found that skill and judgment are not required to implement Janssen's claimed dosing regimens after a physician has chosen a specific dosing regimen. The separate dosing regimens for patients with and without impaired kidney function do not constrain a physician's exercise of professional judgment, and the choices around dosing windows and the injection site for the monthly maintenance doses do not have clinical implications. Although some drug-dosing patents may seek to claim a method of medical treatment, the trial judge's findings support the conclusion that the impugned patent does not and, therefore, claims patentable subject matter. His findings amply support his conclusion that the dosing regimens in the impugned patent do not amount to professional medical skill and judgment.

Per **O'Bonsawin** and **Moreau** JJ.: There is agreement with the majority that the patent for Janssen's dosing regimen is valid. However, there is disagreement that methods of medical treatment constitute inherently unpatentable subject matter. A claimed method of medical treatment should be assessed in the same manner as any other claimed invention, that is, by determining whether the subject matter of the claim fits the definition of "invention" in the *Patent Act* rather than whether it fits the unclear and impractical definition of a method of medical treatment according to the majority's suggested skill and judgment test.

Methods of medical treatment, and dosing regimens specifically, can qualify as patentable subject matter under the *Patent Act*. This does not mean that all methods of medical treatment are automatically patentable. Rather, a blanket prohibition on the patenting of methods of medical treatment should no longer exist because the legal foundations of *Tennessee Eastman* — which stands for the proposition that methods of medical treatment are not patentable — have significantly eroded, and its *ratio* has proven unworkable.

The analysis in *Tennessee Eastman* is no longer applicable to the modern statutory patent scheme nor aligned with the Court's subsequent jurisprudence. The *ratio* of *Tennessee Eastman* is inextricably linked to the statutory language of the former s. 41(1) of the *Patent Act*. Section 41(1) prohibited the patenting of a pharmaceutical substance *per se*; under s. 41, patents were issued not for the chemical compound or the medicine itself, but for the method used to produce the compound. The Court in *Tennessee Eastman* reasoned that the text of s. 41(1) necessarily implied that the therapeutic use of a substance could not be claimed by a process claim apart from the substance itself. Otherwise, inventors could easily circumvent the restriction in s. 41(1) and functionally patent a medicine by claiming protection for its therapeutic use regardless of the method used to prepare it. Accordingly, the Court held that s. 41(1) prevented the patenting of methods of medical treatment, including surgical methods.

Since *Tennessee Eastman*, the Court has commented on the prohibition on

patenting methods of medical treatment on three occasions: in *Shell Oil Co. v. Commissioner of Patents*, [1982] 2 S.C.R. 536, in *Wellcome*, and in *Harvard College v. Canada (Commissioner of Patents)*, 2002 SCC 76, [2002] 4 S.C.R. 45. However, the patentability of methods of medical treatment was not squarely before the Court in those three instances. Those decisions do not directly engage with the patentability of methods of medical treatment and are therefore of limited guidance. In each of those decisions, there was an apparent inclination toward adopting the reasoning of the Exchequer Court in *Tennessee Eastman Co. v. Commissioner of Patents* (1970), 62 C.P.R. 117, that methods of medical treatment are not patentable because (1) their results are not related to trade, industry or commerce and (2) they lie in the professional field of medical treatment. In light of more recent case law, it can no longer be said that a method (that is, an "art" or "process") aimed at healing the human body is not patentable because its effect has no commercial application or economic value. Indeed, this approach has become obsolete given the recognition in *Wellcome* of the patentability, as an "art", of the use of a known substance for treating the human body. Further, the "interference with professional skills" justification for excluding methods of medical treatment from patentability presents insurmountable issues: it hinges on the potential undesirable effects of patenting methods of medical treatment, rather than their patentability *per se*, and it is difficult to reconcile with the fact that the new uses of known drugs, along with certain diagnostic and other quasi-medical methods, are patentable.

Policy concerns, such as the ethical responsibility of professionals to

exercise professional skills in the best interests of their clients and to disseminate those skills, cannot be the sole basis for excluding categories of invention from patentability. Using policy as the guiding light for determining patentability breeds uncertainty and inconsistent analyses. This is evident in the context of the doctrine prohibiting the patenting of methods of medical treatment: its application is inconsistent and creates results that are difficult to reconcile. The only unifying principle that holds together the case law to justify the doctrine's existence is the idea that patenting methods of medical treatment will interfere with a physician's ability to treat patients.

There are significant practical difficulties in applying the prohibition on patenting methods of medical treatment, as there has been no definitive pronouncement on the test to determine whether a challenged subject matter is a method of medical treatment. Courts have attempted to apply an unclear, nebulous doctrine by relying on tests such as whether the use of a given invention requires the exercise of a physician's "skill and judgment" or whether a given invention constitutes a "vendible product". It is unclear how the skill and judgment inquiry and vendible product inquiry relate to one another in the context of the analysis relating to methods of medical treatment.

Reliance on skill and judgment breeds arbitrary distinctions between inconsequential skill and judgment and clinical skill and judgment without expressly recognizing such distinctions. There is a dissonance in the case law in determining how much skill and judgment is too much, thereby taking an invention outside the realm of a valid patent and inside the prohibition on methods of medical treatment. In the case

of a dosing regimen, skill and judgment are required regardless of whether the dosing regimen is variable, fixed, a range, or formulated in any other manner. Trying to quantify the degree of skill and judgment involved is arbitrary and formalistic. Moreover, reliance on skill and judgment ignores the nature of the patented invention: but for the invention, medical professionals would never use the patented invention in the exercise of their ordinary skill and judgment because the invention is new, non-obvious, and useful. It is unconvincing to claim that a dosing regimen is within the ordinary skill and judgment of a medical professional if it had not been conceptualized before the disclosure of the patent. Similarly, reliance on the vendible product inquiry is tenuous. Almost any pharmaceutical invention, and many medical inventions, can be categorized as vendible products. There would be no need to seek patent protection for an invention that was not commercially valuable.

The *Patent Act* no longer contains any express or implied restrictions on the patentability of methods of medical treatment. A principled reading of the *Patent Act* compels the conclusion that methods of medical treatment are not inherently unpatentable. A method of medical treatment is *prima facie* either a "process" or an "art" within the meaning of "invention" in s. 2 of the *Patent Act*. An art can be a concrete application of skill or knowledge that produces results that are commercially useful to the public, and an art aimed at treating a disease is commercially useful. Thus, a concrete and practical application of medical knowledge whose effect is therapeutic can *prima facie* qualify as an "art" or "process". Furthermore, where Parliament intends to exclude potential subject matter from patentability, it does so expressly. Although

the common law may develop to restrict some subject matter from patentability when courts engage in their proper role in interpreting the *Patent Act*, Parliament is best suited to determine what should and should not constitute patentable subject matter.

The *Patent Act*'s internal and external contexts demonstrate that Parliament intended to remove the prohibition on methods of medical treatment. Parliament's approach to patenting pharmaceuticals in the latter portion of the 20th century prioritized public policy considerations, notably by protecting access to the healthcare system through an extensive compulsory licensing regime and through the limitations of the former s. 41 of the *Patent Act*. However, in instituting large-scale reforms to the *Patent Act* throughout the late 1980s and early 1990s, Parliament liberalized the Canadian pharmaceutical industry and rebalanced the patent scheme to be more technical rather than guided by public policy. This marked a shift where Parliament signalled its intent to cultivate Canada's pharmaceutical economy. In repealing s. 41(1), Parliament did not intend to preserve a blanket prohibition on substances intended for medicine. On the contrary, the repeal of s. 41(1) signalled Parliament's intention to rid the *Patent Act* of such a prohibition.

The broader regulatory context is also relevant, as the practical function of the *Patented Medicines (Notice of Compliance) Regulations* and the Health Canada approval regime logically point to the potential patentability of methods of medical treatment in Canada. The regulatory environment compels a practical conclusion: a commercial offering in the context of drugs and pharmaceuticals is usually a package

of both the medicine itself and the instructions for its use.

Article 27(3)(a) of the *TRIPS Agreement*, to which Canada is a signatory, expressly allows, but does not require, signatories to exclude "diagnostic, therapeutic and surgical methods for the treatment of humans" from patentability. Several signatories explicitly exclude methods of medical treatment from patentability under their patent legislation. While Canada has made other amendments to the *Patent Act* in light of the *TRIPS Agreement*, the exclusion of methods of medical treatment has not been incorporated. Had Parliament wished to firmly prohibit patenting methods of medical treatment, then it could have integrated a prohibition, as many other signatories have done. Moreover, in other *TRIPS* jurisdictions where, as in Canada, no statutory exclusion of methods of medical treatment from patentable subject matter exists, methods of medical treatment are not regarded as inherently unpatentable, and practical tests for determining their patentability have been developed. In the absence of an express statutory prohibition against methods of medical treatment, a similar path commends itself in Canada.

Recognizing that methods of medical treatment can qualify as patentable subject matter is compatible with the patent bargain. The central purpose of the *Patent Act* is to incentivize innovation and invention through the patent bargain, that is, the promise of a temporally limited monopoly in return for disclosing the invention to the public. The *Patent Act* must be interpreted in a manner consistent with the patent bargain. A blanket prohibition on patent protection for methods of medical treatment

undermines the patent bargain by creating a chilling effect on invention and innovation. Since Parliament repealed s. 41(1) of the *Patent Act*, pharmaceuticals and medicine are no longer treated differently through legislation. It follows that Parliament intended these fields to obtain the full benefit of the patent bargain. Inventing new medical methods warrants the same patent protection as other discoveries that meet the requirements of the *Patent Act*.

Given that there is no principled basis to institute a blanket prohibition against patenting methods of medical treatment, such methods should be assessed in the same manner as any other claimed invention: if the subject matter comes within the definition of "invention" in s. 2 of the *Patent Act* and is novel, useful, and non-obvious, then a patent shall be issued. Many methods of medical treatment will fail to meet the utility criterion for patentability. In placing reliance on the utility framework, the focus rightly remains on the demonstration or sound prediction of utility and on the related principles of operability, reproducibility, and control, which roots the analysis in a principled and consistent approach. Inoperable inventions which cannot fulfill the purpose for which they were designed are not useful within the meaning of the *Patent Act*. Inventions that depend upon a person's skill, judgment, or reasoning will likely be deemed inoperable: inventions of this nature lack utility because the actual result for which they were designed is uncontrollable or irreproducible. A process that relies on human skill, judgment, interpretation, and reasoning is therefore unpatentable not because it falls outside of patentable subject matter, but because it lacks utility. As such, it is more than likely that a new and complex surgical method, or any other complex

medical method, is unpatentable by virtue of its irreproducibility flowing from its heavy reliance on the skill and judgment of a professional. In such cases, demonstrating that a claimed invention will achieve its practical purpose — in other words, its utility — will be impossible because of the necessity of subjective human involvement in operating the claimed invention.

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By Jamal J.

Approved: *Tennessee Eastman Co. v. Commissioner of Patents*, [1974] S.C.R. 111; **considered:** *Shell Oil Co. v. Commissioner of Patents*, [1982] 2 S.C.R. 536; *Apotex Inc. v. Wellcome Foundation Ltd.*, 2002 SCC 77, [2002] 4 S.C.R. 153; *Harvard College v. Canada (Commissioner of Patents)*, 2002 SCC 76, [2002] 4 S.C.R. 45; *Monsanto Canada Inc. v. Schmeiser*, 2004 SCC 34, [2004] 1 S.C.R. 902; *Tennessee Eastman Co. v. Commissioner of Patents* (1970), 62 C.P.R. 117; *Pioneer Hi-Bred Ltd. v. Canada (Commissioner of Patents)*, [1989] 1 S.C.R. 1623; **referred to:** *Teva Canada Ltd. v. Janssen Inc.*, 2023 FCA 68, [2023] 3 F.C.R. 355; *Apotex Inc. v. Janssen Inc.*, 2024 FCA 9; *Janssen Inc. v. Apotex Inc.*, 2023 FCA 253, 205 C.P.R. (4th) 141; *Hospira Healthcare Corp. v. Kennedy Trust for Rheumatology Research*, 2020 FCA 30; *Commissioner of Patents v. Farbwerke Hoechst Aktiengesellschaft Vormals Meister Lucius & Bruning*, [1964] S.C.R. 49; *Teva Canada Ltd. v. Pfizer Canada Inc.*, 2012 SCC 60, [2012] 3 S.C.R. 625; *AstraZeneca Canada Inc. v. Canada (Minister of Health)*, 2006 SCC 49, [2006] 2 S.C.R. 560; *Celgene Corp. v. Canada (Attorney*

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By O'Bonsawin and Moreau JJ.

Overruled: *Tennessee Eastman Co. v. Commissioner of Patents*, [1974] S.C.R. 111; **considered:** *Harvard College v. Canada (Commissioner of Patents)*, 2002 SCC 76, [2002] 4 S.C.R. 45, rev'g [2000] 4 F.C. 528; *Shell Oil Co. v. Commissioner of Patents*, [1982] 2 S.C.R. 536; *Apotex Inc. v. Wellcome Foundation Ltd.*, 2002 SCC 77, [2002] 4 S.C.R. 153; *Apotex Pty. Ltd. v. Sanofi-Aventis Australia Pty. Ltd.*, [2013] HCA 50, 253 C.L.R. 284; *Tennessee Eastman Co. v. Commissioner of Patents* (1970), 62 C.P.R. 117; *Lawson v. Commissioner of Patents* (1970), 62 C.P.R. 101; *C. & W.'s Application, Re* (1914), 31 R.P.C. 235; *National Research Development Corp. v. Commissioner of Patents* (1959), 102 C.L.R. 252; *Re Application No. 016,962* (1973), 17 C.P.R. (2d) 177; **referred to:** *Housen v. Nikolaisen*, 2002 SCC 33, [2002] 2 S.C.R. 235; *Commissioner of Patents v. Farbwerke Hoechst Aktiengesellschaft Vormals Meister Lucius & Bruning*, [1964] S.C.R. 49; *Apotex Inc. v. Sanofi-Synthelabo Canada*

Inc., 2008 SCC 61, [2008] 3 S.C.R. 265; *Formea Chemicals Ltd. v. Polymer Corp. Ltd.*, [1968] S.C.R. 754; *Apotex Inc. v. Sanofi-Aventis*, 2013 FCA 186, [2015] 2 F.C.R. 644; *Synthon BV v. SmithKline Beecham plc*, [2005] UKHL 59, [2006] 1 All E.R. 685; *Pioneer Hi-Bred Ltd. v. Canada (Commissioner of Patents)*, [1989] 1 S.C.R. 1623; *Consolboard Inc. v. MacMillan Bloedel (Sask.) Ltd.*, [1981] 1 S.C.R. 504; *Cadbury Schweppes Inc. v. FBI Foods Ltd.*, [1999] 1 S.C.R. 142; *Free World Trust v. Électro Santé Inc.*, 2000 SCC 66, [2000] 2 S.C.R. 1024; *SmithKline Beecham Pharma Inc. v. Apotex Inc.*, 2002 FCA 216, [2003] 1 F.C. 118; *Kirkbi AG v. Ritvik Holdings Inc.*, 2005 SCC 65, [2005] 3 S.C.R. 302; *Eli Lilly Canada Inc. v. Apotex Inc.*, 2008 FC 142, 63 C.P.R. (4th) 406, aff'd 2009 FCA 97, 78 C.P.R. (4th) 388; *AstraZeneca Canada Inc. v. Apotex Inc.*, 2017 SCC 36, [2017] 1 S.C.R. 943; *Nova Chemicals Corp. v. Dow Chemical Co.*, 2022 SCC 43, [2022] 3 S.C.R. 352; *Bristol-Myers Squibb Co. v. Canada (Attorney General)*, 2005 SCC 26, [2005] 1 S.C.R. 533; *Monsanto Canada Inc. v. Schmeiser*, 2004 SCC 34, [2004] 1 S.C.R. 902; *Canada (Attorney General) v. Bedford*, 2013 SCC 72, [2013] 3 S.C.R. 1101; *Canada v. Craig*, 2012 SCC 43, [2012] 2 S.C.R. 489; *John Howard Society of Saskatchewan v. Saskatchewan (Attorney General)*, 2025 SCC 6; *Canada (Minister of Citizenship and Immigration) v. Vavilov*, 2019 SCC 65, [2019] 4 S.C.R. 653; *R. v. Kirkpatrick*, 2022 SCC 33, [2022] 2 S.C.R. 480; *R. v. McGregor*, 2023 SCC 4, [2023] 1 S.C.R. 198; *Hospira Healthcare Corp. v. Kennedy Trust for Rheumatology Research*, 2020 FCA 30; *Cobalt Pharmaceuticals Co. v. Bayer Inc.*, 2015 FCA 116, 131 C.P.R. (4th) 99; *Hoffmann-La Roche Ltd. v. Sandoz Canada Inc.*, 2021 FC 384, 185 C.P.R. (4th) 167; *Janssen Inc. v. Teva Canada Ltd.*, 2020 FC 593; *Hospira Healthcare Corp. v. Kennedy Trust for Rheumatology Research*, 2018

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APPEAL from a judgment of the Federal Court of Appeal (de Montigny C.J. and Locke and Goyette JJ.A.), 2024 FCA 23, [2024] F.C.J. No. 261 (Lexis), 2024 CarswellNat 381 (WL), affirming a decision of Manson J., 2022 FC 1218, 198 C.P.R. (4th) 329, [2022] F.C.J. No. 1233 (Lexis), 2022 CarswellNat 3309 (WL). Appeal dismissed.

Andrew Brodkin, *Sandon Shogilev* and *Daniel Cappe*, for the appellant.

Catherine Beagan Flood, *Fiona Legere*, *Spencer Livingstone*, *Julie Desrosiers*, *Marian Wolanski* and *Megan Pocalyuko*, for the respondents.

J. Bradley White, *Nathaniel Lipkus* and *Daniel Hnatchuk*, for the intervener Canadian Generic Pharmaceutical Association.

Andrew Skodyn, *Sean Jackson* and *Eleanor Wilson*, for the intervener International Federation of Intellectual Property Attorneys.

Orestes Pasparakis and *Kristin Wall*, for the interveners Innovative Medicines Canada and BIOTECanada.

Melanie Baird, *Amy Grenon*, *Cole Meagher* and *Nick Morrow*, for the intervener Canadian Organization for Rare Disorders.

Christopher C. Van Barr, *Erin Creber*, *Will Boyer* and *Mackenzie Jamieson*, for the interveners David Homuth, Marco Solmi and Pierre Bleau.

The judgment of Wagner C.J. and Karakatsanis, Côté, Rowe, Martin, Kasirer and Jamal JJ. was delivered by

JAMAL J. —

I. Overview

[1] This appeal examines whether methods of medical treatment are patentable subject matter under the *Patent Act*, R.S.C. 1985, c. P-4 and how such methods should

be defined. Section 2 of the *Patent Act* defines a patentable "invention" as "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". At issue is whether s. 2 allows a physician's professional skill and judgment to be patented.

[2] For the past half-century, Canadian law has consistently treated methods of medical treatment as unpatentable subject matter. This Court affirmed that rule in *Tennessee Eastman Co. v. Commissioner of Patents*, [1974] S.C.R. 111, a decision grounded in part in the former s. 41(1) of the *Patent Act*, which was repealed in 1993.[1] But the rule against patenting methods of medical treatment does not rest on former s. 41(1) alone. This Court and other courts have also recognized the broader principle that professional skills are not proper subject matter for a patent (*Shell Oil Co. v. Commissioner of Patents*, [1982] 2 S.C.R. 536, at pp. 554-55; *Apotex Inc. v. Wellcome Foundation Ltd.*, 2002 SCC 77, [2002] 4 S.C.R. 153, at paras. 49-50). In keeping with that principle, a substantial and unbroken line of decisions from the Federal Court and Federal Court of Appeal has held that methods of medical treatment remain unpatentable notwithstanding the repeal of s. 41(1). No court at any level has ruled otherwise.

[1] *Tennessee Eastman* dealt with ss. 2(*d*) and 41(1) of the *Patent Act*, R.S.C. 1952, c. 203. Section 2(*d*) subsequently became s. 2 of the *Patent Act*, R.S.C. 1970, c. P-4, and was continued in the current *Patent Act*, R.S.C. 1985, c. P-4. Section 41(1) was continued in the *Patent Act*, R.S.C. 1970, c. P-4; it subsequently became s. 39(1) of the *Patent Act*, R.S.C. 1985, c. P-4, and was repealed in 1993.

[3] This Court is now invited to disrupt this settled law in the context of actions brought by the respondents, Janssen Inc. and Janssen Pharmaceutica N.V. (together, "Janssen"), against the appellant, Pharmascience Inc., for infringing Janssen's patent for dosing regimens for a drug used to treat schizophrenia (Patent 2,655,335 ("335 Patent")). Both the Federal Court and Federal Court of Appeal affirmed that methods of medical treatment are unpatentable and upheld Janssen's patent because it does not claim such a method.

[4] Pharmascience invites this Court to invalidate Janssen's patent by broadening the test for an unpatentable method of medical treatment. Accepting Pharmascience's position would dramatically reduce the number and scope of medical patents in Canada. For its part, Janssen invites the Court to uphold its patent by ruling that all methods of medical treatment are patentable and asserts that the contrary ruling in *Tennessee Eastman* rested entirely on the now-repealed s. 41(1). Janssen effectively submits that the vast body of jurisprudence holding that methods of medical treatment are unpatentable notwithstanding the repeal of s. 41(1) has been based on a mistake. Accepting Janssen's position would dramatically increase the number and scope of medical patents in Canada.

[5] For the reasons that follow, I would not give effect to either party's position. I would reject Janssen's invitation to depart from the settled interpretation of s. 2 that methods of medical treatment are unpatentable. Under Canadian law, a physician's professional skill and judgment cannot be patented because this would be

inconsistent with the purpose of the *Patent Act*. The Act seeks to incentivize desirable inventiveness by granting a temporary monopoly to those who share their new knowledge with the public. Physicians already benefit from a state-granted monopoly to practise and share their skills for the public benefit and do not require the prospect of extracting monopoly profits under a patent to do so. I would also reject Pharmascience's invitation to broaden the test for an unpatentable method of medical treatment. A patent impermissibly claims a method of medical treatment only if it seeks to monopolize professional medical skill and judgment. Although some drug-dosing patents may seek to do so, the trial judge's findings support the conclusion that the 335 Patent does not and, therefore, claims patentable subject matter. I would accordingly dismiss the appeal.

II. Facts

A. *Schizophrenia and Its Treatment*

[6] Schizophrenia is a debilitating mental illness affecting over 300,000 Canadians. The symptoms of schizophrenia include hallucinations, delusions, disorganized behaviour, apathy, lack of motivation, and social withdrawal. Symptoms typically appear for the first time in a person's early to mid-twenties, often with a psychotic breakdown. Schizophrenia has no known cure and requires lifelong management with antipsychotic medications.

[7] Individuals with schizophrenia can generally manage their illness by adhering to treatment regimens. A major cause of relapse is non-adherence, which involves individuals not taking their medication as prescribed or at all. Non-adherence rates among individuals with schizophrenia are high. Individuals take their medication and then believe that they are well enough to stop doing so, leading to the return of symptoms and a vicious cycle of illness.

[8] Treatment adherence can be improved through the use of long-acting formulations of antipsychotic medications, including intramuscular injections known as “depot formulations” or “long-acting injectables”. Long-acting injectables release medication gradually from the injection site and, when they achieve stable concentrations of the medication in a patient’s blood plasma, can eliminate the need to take oral medications on a daily basis.

B. *Janssen Develops the 335 Patent to Treat Schizophrenia*

[9] In the early 1990s, Janssen began to develop a long-acting injectable formulation and dosing regimen for the drug paliperidone to treat schizophrenia. Paliperidone is the active antipsychotic molecule and can be taken as an oral medication. Paliperidone palmitate has a palmitate ester attached to the paliperidone molecule. The human body gradually breaks down the connection between the ester and the molecule, thereby making paliperidone available in the bloodstream. Paliperidone palmitate can be formulated as a long-acting suspension that is injected into a person’s muscle and then dissolves slowly in the body.

[10] Janssen conducted a series of phased studies to calibrate the optimal dosing regimen for paliperidone palmitate. The process was marked by several setbacks, and the ideal dosing regimen emerged only after years of sustained research. In 1999, a Phase I study found that fixed doses of paliperidone palmitate injected into a patient's gluteal muscle on Days 1 and 8 of treatment, followed by monthly doses, led to stable blood plasma concentrations of paliperidone in the first month. In 2003, Janssen formed a global research team and conducted a successful Phase II study. Between 2004 and 2006, Janssen designed and conducted two large-scale Phase III clinical trials involving over 850 patients to test fixed doses of 25, 50, 100, and 150 milligrams equivalent ("mg-eq.") of paliperidone palmitate administered on Days 1 and 8, followed by monthly doses. These trials had unexpectedly disappointing results, leading Janssen to create a special task force to study and improve the dosing regimen. In 2007, an advisory board consisting of Janssen representatives and external advisors met to review the clinical trial data, and the advisors rejected Janssen's then-proposed dosing regimen. Janssen continued research for another six months, before arriving at a dosing regimen that became the basis of the 335 Patent.

C. *The 335 Patent*

[11] On December 17, 2008, Janssen filed a patent application in Canada for dosing regimens of an injectable formulation of paliperidone palmitate used to treat schizophrenia and related disorders. The 335 Patent, titled "Prolonged-Release Injectable Suspensions of Paliperidone Palmitate, and Dosage Forms and Delivery

Systems Incorporating Same", was issued on September 6, 2016. At the time, Janssen held two existing patents that disclosed the use of long-acting injectables of paliperidone palmitate to treat schizophrenia. Both patents had expired before this proceeding began.

[12] Janssen markets its formulation of paliperidone palmitate under the brand name INVEGA SUSTENNA. The product monograph for INVEGA SUSTENNA sets out the dosing regimens disclosed in the 335 Patent.

[13] The 335 Patent teaches or discloses dosing regimens for a paliperidone palmitate suspension that achieve an optimum blood plasma concentration of paliperidone over time. It teaches a first dose administered in the deltoid muscle on Day 1 of treatment; a second dose administered in the deltoid muscle on Day 8 of treatment ± 2 days; and then doses administered in either the deltoid or gluteal muscle monthly ± 7 days. For patients without impaired kidney function, the first and second doses are 150 and 100 mg-eq., respectively, and the subsequent monthly doses are 75 mg-eq. For patients with impaired kidney function, the first and second doses are 100 and 75 mg-eq., respectively, and the subsequent monthly doses are 50 mg-eq.

[14] The 335 Patent contains 63 claims, all of which incorporate the dosing regimens. Some of the claims relate to the use of a delivery system for drug administration according to the dosing regimens (claims 17-32). The *Manual of Patent Office Practice* — which reflects the practices and procedures of the Canadian Intellectual Property Office based on its interpretation of the *Patent Act*, the *Patent*

Rules, SOR/2019-251, and the relevant jurisprudence — classifies these kinds of claims as "use claims", which follow formats such as "[u]se of compound X as a herbicide" or "[u]se of machine Z for cutting" (s. 16.10.02). The rest of the claims relate to prefilled syringes, preparations of paliperidone palmitate, and the delivery system for administering the drug, all adapted in accordance with the dosing regimens (claims 1-16 and 33-63). The *Manual* classifies these kinds of claims as "product claims", which describe an embodiment of the claimed invention in concrete form, such as by its structure, physical or chemical properties, or process of manufacture (s. 16.08).

D. *Patent Infringement Proceedings Against Other Generic Drug Companies*

[15] Generic drug companies Teva Canada Limited and Apotex Inc. have also tried, without success, to obtain approval to market generic versions of INVEGA SUSTENNA before the expiry of the 335 Patent. In each case, the validity of the 335 Patent has been upheld (*Teva Canada Ltd. v. Janssen Inc.*, 2023 FCA 68, [2023] 3 F.C.R. 355, at paras. 4-6 and 116-17; *Apotex Inc. v. Janssen Inc.*, 2024 FCA 9, at paras. 4-6; *Janssen Inc. v. Apotex Inc.*, 2023 FCA 253, 205 C.P.R. (4th) 141, at para. 71).

III. Judicial History

[16] Pharmascience's attempt to obtain approval to market its generic version of INVEGA SUSTENNA, known as pms-PALIPERIDONE PALMITATE, gave rise to patent proceedings before the Federal Court and the Federal Court of Appeal. The issues of infringement and invalidity were heard and decided separately.

[17] Both courts held that Pharmascience's generic drug product would infringe the 335 Patent (2022 FC 62, 190 C.P.R. (4th) 1, aff'd 2024 FCA 10, 206 C.P.R. (4th) 207). Infringement is not at issue before this Court.

[18] The Federal Court also rejected Pharmascience's arguments that the 335 Patent is invalid on the basis that its claims (1) are obvious or lack inventiveness; and (2) involve unpatentable subject matter, namely methods of medical treatment (2022 FC 1218, 198 C.P.R. (4th) 329). On appeal, Pharmascience challenged the validity of the 335 Patent solely on the latter ground. The Federal Court of Appeal dismissed that appeal (2024 FCA 23). This is the sole issue remaining before this Court. The reasons of the courts below on that point are summarized below.

A. *Federal Court, 2022 FC 1218, 198 C.P.R. (4th) 329 (Manson J.)*

[19] The trial judge ruled that the 335 Patent claims patentable subject matter, not unpatentable methods of medical treatment.

[20] The trial judge noted that the jurisprudence recognizes "vendible product" claims as patentable, not as unpatentable claims to methods of medical treatment (para. 163). He therefore concluded that the 335 Patent's product claims (claims 1-16 and 33-63) are not claims to methods of medical treatment.

[21] As for the use claims (claims 17-32), the trial judge focused on their essential elements to determine "whether professional skill and judgment is required to

practice the invention *as claimed*" (para. 164 (emphasis in original)). He noted that the case law distinguishes between, on the one hand, "claims restricted to particular dosages and specific administration schedules . . . where the amounts and timing are fixed", which are patentable; and, on the other hand, "claims to dosages or schedules with ranges within which the physician must exercise skill and judgment", which are not vendible products and are therefore unpatentable (para. 164). Although he described that distinction as having a "questionable underpinning", he accepted that it reflects the current state of the law (para. 165). He further noted that, in either case, "a medical professional will be constrained in their exercise of skill" and that "a drug is arguably no less a vendible product simply because its dosage or interval of administration is not fixed" (para. 166, quoting *Hospira Healthcare Corp. v. Kennedy Trust for Rheumatology Research*, 2020 FCA 30, at para. 52).

[22] Applying these principles, the trial judge concluded that the use claims are not methods of medical treatment. He noted that Pharmascience's expert agreed that the claims "do not prevent physicians from practicing in a manner they had previously" (para. 167). Nor do the claims require the exercise of professional skill and judgment, because "there are no choices in respect of possible ranges for the dosage amounts" (para. 168). For patients with and without impaired kidney function, the claims specify fixed dose amounts, fixed intervals, and fixed injection sites. The trial judge also found that the choices concerning dosing windows and injection sites for the monthly doses "do not have clinical implications" (para. 170). The dosing windows are intended "to allow flexibility in order to avoid a missed dose without significant clinical difference",

and the injection site for the monthly dose is "clinically interchangeable" (para. 170). In his view, "no skill and judgment is required that would interfere with or restrict a physician's skill or judgment in deciding to prescribe the dosing regime[n] within the claimed invention" (para. 170). The 335 Patent therefore claims patentable subject matter.

B. *Federal Court of Appeal, 2024 FCA 23 (Locke J.A., de Montigny C.J. and Goyette J.A. Concurring)*

[23] The Court of Appeal dismissed Pharmascience's appeal and affirmed that the 335 Patent claims patentable subject matter. The court noted that, although the *Patent Act* does not expressly exclude methods of medical treatment from patentability, "a method of medical treatment is not patentable because it does not fall within the definition of 'invention' as contemplated in the *Patent Act*" (para. 24). Such a method is "unrelated to trade, industry or commerce, and concerns professional skills that are non-economic" (para. 24). As the court explained, "[a] patent should not seek to fence in the exercise of such skills (including how and when a drug is administered), but it may cover a commercial offering" (para. 24).

[24] The court added that this Court's references to "trade, industry or commerce" and "commercial offering[s]" have led lower courts to focus on whether the invention concerns a "vendible product"; that is, something with economic value, as distinguished from the skilled work of a physician and, therefore, "outside the realm of methods of medical treatment" (para. 26).

[25] After reviewing the relevant jurisprudence, the court held that "whether or not a patent claim to a dosing regimen relates to a method of medical treatment cannot be based exclusively on whether its dosing and schedule is fixed or not" (para. 37). Rather, "[t]he proper inquiry remains whether use of the invention (i.e., how to use it, not whether to use it) requires the exercise of skill and judgment, and the burden remains on the party challenging the patent" (para. 37 (emphasis in original)). The court acknowledged that "[i]t is difficult to provide more detailed guidance than this", because invalidity claims based on methods of medical treatment are "factually suffused": they "generally turn on the particulars of the case and the evidence on the record" about "how the patented invention is intended to be used" (paras. 35 and 37).

[26] Applying these principles, the court rejected Pharmascience's submission that the 335 Patent claims methods of medical treatment.

[27] First, the court held that the Federal Court did not err in concluding that the product claims (claims 1-16 and 33-63) are claims to a vendible product and therefore patentable subject matter. As the Court of Appeal put it, "a claim may concern a vendible product even if it includes a dosing regimen as an essential element" (para. 41).

[28] Second, the court held that the Federal Court did not err in finding that the use claims (claims 17-32) are patentable notwithstanding some variability in dosing and scheduling. It saw no reviewable error in the trial judge's conclusion that a physician's choices concerning dosing windows and injection sites merely "allow

flexibility in administering the drug", do not interfere with a physician's exercise of skill and judgment, and thus "have no clinical implications" (paras. 52-53). Nor did the trial judge err in concluding that the different dosage amounts for patients with and without impaired kidney function reflect "an objective distinction that does not involve the exercise of a physician's skill and judgment" (para. 56).

IV. Positions of the Parties

[29] Pharmascience submits that Canadian law is settled: methods of medical treatment are unpatentable subject matter under the *Patent Act*. It argues that this Court should clarify the governing test as follows: courts must (a) construe the claims of the patent in accordance with the established principles of claim construction; (b) determine whether the essential elements of the claims, as construed, are "therapeutic" or "medical"; and (c) determine whether those essential elements relate to "how" and "when" a medical practitioner administers a drug or treatment. If steps (b) and (c) are satisfied, the subject matter is presumptively directed at a method of medical treatment and therefore unpatentable. Pharmascience says that the 335 Patent is invalid because it claims a dosing regimen governing "how" and "when" paliperidone palmitate is to be administered to treat schizophrenia.

[30] Janssen responds that the *Patent Act* no longer excludes methods of medical treatment from patentable subject matter since the repeal of s. 41(1). In its submission, *Tennessee Eastman* rested on s. 41(1), and, with that provision now repealed, the statutory foundation for that rule has disappeared. In the alternative,

Janssen argues that Pharmascience's proposed "how" and "when" test is overbroad: it would effectively invalidate all dosing regimen patents, conflict with this Court's jurisprudence, and place Canada out of step with peer jurisdictions that recognize patents over drug-dosing regimens. Janssen submits that any exclusion from patentability for methods of medical treatment should be confined to non-economic activities unrelated to commercial products and should not extend to dosing regimen patents such as the 335 Patent.

V. Discussion

[31] I proceed in five parts. First, I review the purpose and general scheme of the *Patent Act*. Second, I consider whether methods of medical treatment constitute patentable subject matter under Canadian law and how such methods should be defined. Third, I address whether, and in what circumstances, drug-dosing regimens amount to methods of medical treatment. Fourth, I respond to the proposal of my colleagues to recognize methods of medical treatment as patentable subject matter for the first time in Canadian law. Finally, I apply the applicable legal principles to this case.

A. *The Purpose and Scheme of the Patent Act*

[32] Patents are purely creations of statute. There is no right to a patent at common law (*Commissioner of Patents v. Farbwerke Hoechst Aktiengesellschaft Vormals Meister Lucius & Bruning*, [1964] S.C.R. 49, at p. 57; *Teva Canada Ltd. v. Pfizer Canada Inc.*, 2012 SCC 60, [2012] 3 S.C.R. 625 ("*Teva Canada*"), at para. 45).

Courts must therefore begin with the terms of the *Patent Act*, as interpreted in the jurisprudence.

[33] Like all legislation, the *Patent Act* must be interpreted in accordance with the modern principle of statutory interpretation, having regard to its text, context, and purpose (*Harvard College v. Canada (Commissioner of Patents)*, 2002 SCC 76, [2002] 4 S.C.R. 45, at para. 154; *Monsanto Canada Inc. v. Schmeiser*, 2004 SCC 34, [2004] 1 S.C.R. 902, at para. 32; *AstraZeneca Canada Inc. v. Canada (Minister of Health)*, 2006 SCC 49, [2006] 2 S.C.R. 560, at para. 26; *Celgene Corp. v. Canada (Attorney General)*, 2011 SCC 1, [2011] 1 S.C.R. 3, at para. 21).

(1) The Purpose of the *Patent Act* Is to Promote Scientific and Technological Innovation Through the "Patent Bargain"

[34] The purpose of the *Patent Act* is to promote scientific and technological innovation for the benefit of society. It does so by creating economic incentives for research and development through the "patent bargain" between an inventor and the public, as represented by the Crown. Under that bargain, an inventor publicly discloses the knowledge underlying the invention in exchange for a patent conferring, for a limited time, "the exclusive right, privilege and liberty of making, constructing and using the invention and selling it to others to be used" (s. 42). The bargain benefits both society and the inventor. Through public disclosure, society gains new scientific and technological knowledge that may stimulate further innovation and technological progress. The inventor, in turn, gains a temporary monopoly that may provide a return

on the time, effort, and risk involved in making the invention (see *Nova Chemicals Corp. v. Dow Chemical Co.*, 2022 SCC 43, [2022] 3 S.C.R. 352, at para. 43; *Teva Canada*, at para. 32; S. J. Perry and T. A. Currier, *Canadian Patent Law* (5th ed. 2024), at §§3.02 and 3.04; M. Bourassa Forcier, W. Audet and G. Melançon, *Précis de propriété intellectuelle* (2020), at n^{o} 4.2).

[35] A patent is therefore "a method by which inventive solutions to practical problems are coaxed into the public domain by the promise of a limited monopoly for a limited time" (*Wellcome*, at para. 37; *AstraZeneca Canada Inc. v. Apotex Inc.*, 2017 SCC 36, [2017] 1 S.C.R. 943, at para. 52). It is often described as a metaphorical "fence" surrounding the "fields" of the inventor's monopoly, warning the public against trespassing on the inventor's property during the term of the patent (*Free World Trust v. Électro Santé Inc.*, 2000 SCC 66, [2000] 2 S.C.R. 1024, at para. 14, citing *Minerals Separation North American Corp. v. Noranda Mines, Ltd.*, [1947] Ex. C.R. 306, at p. 352; *Wellcome*, at paras. 45 and 50; Perry and Currier, at §3.03).

(2) Patentable Subject Matter

[36] Section 2 of the *Patent Act* defines an "invention" as "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". This definition identifies five categories of patentable subject matter: an "art", "process", "machine", "manufacture", or "composition of matter" (see *AstraZeneca* (2017), at para. 40; *Harvard College*, at para. 156; *Intellectual Property Disputes: Resolutions*

and Remedies (loose-leaf), by R. E. Dimock, ed., at § 1:3; D. Vaver, *Intellectual Property Law: Copyright, Patents, Trade-marks* (2nd ed. 2011), at pp. 290-97). By contrast, a "mere scientific principle or abstract theorem", such as Newton's theory of gravity or Einstein's theory of relativity, is excluded from the scope of patentable subject matter (*Patent Act*, s. 27(8); Vaver, at pp. 308-9). This is the Act's only express exclusion.

[37] The definition of "invention" in s. 2 has remained constant since 1923 and largely unchanged since 1869 (D. H. MacOdrum, A. McIntosh and M. Szweras, *Fox on the Canadian Law of Patents* (5th ed. (loose-leaf)), at § 3:8; *The Patent Act*, S.C. 1923, c. 23, s. 2(c); *An Act respecting Patents of Invention*, S.C. 1869, c. 11, s. 6). As Professor Vaver observes, the "taxonomy" of invention under s. 2 "traces back to the English *Statute of Monopolies* of 1624", which authorized patents for "'any manner of new manufactures,' leaving the definition for judges to work out" (pp. 285-86 (footnote omitted); see generally MacOdrum, McIntosh and Szweras, at §§ 3:8 and 3:10-3:14; Perry and Currier, at §§6.02-6.03; D. P. Clarizio et al., *Hughes & Woodley on Patents* (2nd ed. (loose-leaf)), at § 5; *Manual of Patent Office Practice*, at ch. 17).

[38] Judicial interpretation of "invention" under s. 2 is therefore central to defining the scope of patentable subject matter. Apart from scientific principles and abstract theorems, what is and is not patentable subject matter depends on how the courts have interpreted the concept of "invention" under s. 2 (see *Monsanto*, at para. 133, per Arbour J., dissenting in part, but not on this point; Perry and Currier, at §6.01).

Patent law has accordingly been described as "statutory but subject to multiple common law glosses" (R. H. Barrigar and A. M. Shaughnessy, *Canadian Patent Act Annotated* (2nd ed. (loose-leaf)), at § 1:2). Professor Vaver similarly observes that "the notion of invention is a legal term of art. It is defined by legislatures, and the legislative definitions are interpreted according to legal criteria by courts, tribunals and officials such as patent examiners and patent office appeal boards" ("Invention in Patent Law: A Review and a Modest Proposal" (2003), 11 *Int. J.L. Inf. Tech.* 286, at p. 288).

[39] In interpreting patentable subject matter, courts must remain attentive to the purpose of *Patent Act*. As the High Court of Australia explained, determining the scope of patentable subject matter "is an inquiry not into the meaning of a word so much as into the breadth of the concept which the law has developed by its consideration of the text and purpose" of the relevant patent legislation. For that reason, "any attempt to state the ambit" of the definition of an "invention" under patent legislation by "precisely defining" the words of the Act "is bound to fail" (*National Research Development Corp. v. Commissioner of Patents* (1959), 102 C.L.R. 252, at pp. 269-71, cited in *Tennessee Eastman Co. v. Commissioner of Patents* (1970), 62 C.P.R. 117 (Ex. Ct.), at pp. 136-38; see also Vaver (2003), at p. 288).

[40] Patentable subject matter must also be interpreted in a manner that is "attentive to the wisdom of the case law" (*Monsanto*, at para. 32, per McLachlin C.J. and Fish J. (emphasis in original); see also para. 39, per McLachlin C.J. and Fish J., and para. 132, per Arbour J., dissenting in part, but not on this point). This Court has

stated that the term "invention" is "broad" but not "unlimited"; it does not include as patentable "anything under the sun that is made by man" (*Harvard College*, at para. 158). By defining "invention" as it has, "Parliament signalled a clear intention to include certain subject matter as patentable and to exclude other subject matter as being outside the confines of the Act" (para. 158).

[41] This Court has applied these interpretive principles in determining what subject matter falls within, and what falls outside, the definition of "invention". In *Harvard College*, this Court held that a higher life form — a genetically modified mouse predisposed to cancer — was neither a "manufacture" nor a "composition of matter" within the meaning of the *Patent Act* and was therefore not patentable subject matter (para. 155). In *Monsanto*, by contrast, the Court held that genetically modified plant cells and genes conferring herbicide resistance on canola constituted patentable subject matter (paras. 21-24). Similarly, in *Wellcome*, the Court held that a new use for an existing pharmaceutical compound — the treatment of HIV and AIDS with the known cancer drug AZT — constituted patentable subject matter and was not unpatentable as a method of medical treatment (paras. 48-50; see also *Shell Oil*, at pp. 548-56; Vaver (2011), at p. 295; MacOdrum, McIntosh and Szweras, at § 3:8).

(3) Other Requirements for Patentability Are Not at Issue in This Appeal

[42] Patentable subject matter is a necessary but not sufficient condition for a valid patent. A claimed innovation must also satisfy the *Patent Act*'s other requirements. It must be "new" (ss. 2 and 28.2); inventive or not "obvious" (s. 28.3;

see also *Apotex Inc. v. Sanofi-Synthelabo Canada Inc.*, 2008 SCC 61, [2008] 3 S.C.R. 265, at paras. 51-71); and "useful" (s. 2; see also *AstraZeneca* (2017), at paras. 26 and 52-58; *Teva Canada*, at paras. 37-40; *Wellcome*, at paras. 52-56; *Consolboard Inc. v. MacMillan Bloedel (Sask.) Ltd.*, [1981] 1 S.C.R. 504, at pp. 525-27) (see generally Vaver (2011), at pp. 338-41; Dimock, at § 1:3; E. F. Judge and D. J. Gervais, *Intellectual Property: The Law in Canada* (2nd ed. 2011), at pp. 724-27). None of those statutory requirements is in issue on this appeal. The sole issue is whether the claims in the 335 Patent disclose patentable subject matter.

B. *Methods of Medical Treatment Are Not Patentable Subject Matter Under Canadian Law*

[43] The parties agree that this Court's decision in *Tennessee Eastman* held that methods of medical treatment are unpatentable subject matter. Janssen and several interveners nevertheless submit that the decision rested entirely on former s. 41(1) of the *Patent Act*, and that once this provision was repealed, no legal basis remained for excluding methods of medical treatment from patentability.

[44] I respectfully disagree with Janssen's submission. Even after the repeal of s. 41(1), this Court has continued to apply the rule that methods of medical treatment are unpatentable subject matter (*Wellcome*). More broadly, this Court has affirmed that professional skills are not patentable (*Shell Oil*; *Wellcome*). The Federal Court and the Federal Court of Appeal have repeatedly held that methods of medical treatment are unpatentable; no court at any level has held otherwise. Most of the academic and expert

commentary is to the same effect. The rule also rests on a sound public policy rationale rooted in the purpose of the *Patent Act*. Medical professionals do not require the incentives of the patent bargain to exercise their skill and judgment in their patients' best interests or to disseminate their knowledge widely.

[45] I begin with this Court's decision in *Tennessee Eastman*, which has generated some uncertainty and debate. As I explain below, the precise basis on which methods of medical treatment were held to be unpatentable shifted as the case moved through the courts. In the end, however, nothing turns on parsing *Tennessee Eastman*. Canadian law has consistently affirmed that methods of medical treatment are unpatentable subject matter because professional skills are unpatentable.

(1) *Tennessee Eastman*

[46] In *Tennessee Eastman*, the applicant sought to patent a method of closing surgical incisions or wounds using a known adhesive substance to bond human tissue. The application was rejected by the patent examiner, the Commissioner of Patents, the Exchequer Court, and this Court, though for different reasons at each stage.

[47] The patent examiner rejected the patent application on two grounds. First, the examiner concluded that it claimed unpatentable subject matter, namely a method of medical treatment. The examiner noted that the applicant claimed the use of an adhesive "in a known surgical process" whose success depended on a physician's skill, and was therefore "strictly in the medical arts" and "not within the bounds of the subject

matter covered by [the definition of "invention" under] Section 2(d) of the Patent Act" (*Tennessee Eastman* (Ex. Ct.), at p. 123; see also *Tennessee Eastman* (S.C.C.), at pp. 113-14).

[48] Second, the examiner added that granting the patent would offend s. 41(1) of the *Patent Act*. The examiner observed that "it [was] even less in the public interest to grant a patent for the use of such a material than to grant a patent for the material itself which would be contrary to Section 41 of the Patent Act" (*Tennessee Eastman* (Ex. Ct.), at p. 123). At the time, s. 41(1) prohibited the patenting of a substance intended for food or medicine except when prepared or produced by particular methods or processes of manufacture:

> **41.** (1) In the case of inventions relating to substances prepared or produced by chemical processes and intended for food or medicine, the specification shall not include claims for the substance itself, except when prepared or produced by the methods or processes of manufacture particularly described and claimed or by their obvious chemical equivalents.

[49] Section 41(1) confined patents for new medicines to so-called "process" claims (the process or processes by which the article or substance is made) and "product-by-process" claims (the process and the product made by that process) (*Report of the Commission of Inquiry on the Pharmaceutical Industry* (1985), at pp. xxiii and 2-3; R. A. Wilkes, "The New Canadian Patent Act" (1989), 71 *J.P.T.O.S.* 202, at pp. 225 and 227; M. Goudreau, "Le droit canadien des brevets en capsule" (2007), 86 *Can. Bar Rev.* 39, at p. 49). As one commentator explains, "[a] new substance that was useful in the medical or surgical treatment of humans or animals was an invention,

as was the process for making such a substance", but "the substance could only be claimed as an invention deserving patent protection when prepared or produced by such a process" (S. Melnychuk, "Drug Dosage Regimes and Patent-Eligible Subject Matter in Canada" (2013), 29 *C.I.P.R.* 297, at p. 300).

[50] A request for review of the examiner's decision was dismissed. The Acting Commissioner of Patents held that the claims were unpatentable because they related to a method of medical treatment. The application concerned "a process of medical or surgical treatment of living tissues", and "[a] method of medical or surgical treatment does not constitute patentable subject matter under Section 2(d) of the Canadian Patent Act" (*Tennessee Eastman* (Ex. Ct.), at p. 126). The Acting Commissioner did not rely on s. 41(1).

[51] The Exchequer Court (per Kerr J.) dismissed the appeal from the Acting Commissioner's decision solely on the ground that the patent application claimed a method of medical treatment "in the professional field of surgery", which was neither a patentable "art" nor "process", and therefore not an "invention" under s. 2(*d*) (pp. 154-55). In reviewing the authorities, the court quoted Cattanach J.'s reasons in *Lawson* in support of the view that methods of surgery and medical treatment are not patentable subject matter because they "belon[g] to the professional field", and therefore "lie outside the concept of invention because the whole subject is conceived as essentially non-economic" (*Tennessee Eastman* (Ex. Ct.), at p. 129, citing *Lawson v.*

Commissioner of Patents (1970), 62 C.P.R. 101 (Ex. Ct.), at pp. 110-11). Like the Acting Commissioner, Kerr J. did not rely on s. 41(1) of the *Patent Act*.

[52] A further appeal to this Court was dismissed. Writing for the Court, Pigeon J. concluded that methods of medical treatment are "not contemplated in the definition of 'invention' as a kind of 'process'" (*Tennessee Eastman* (S.C.C.), at pp. 116-19). He cited s. 41(1) and stated that allowing a claim for a method of medical treatment "embodying the use of [a] new drug" to be patentable as "a process claim" would provide "an easy way out of the restriction in s. 41(1)" (pp. 118-19).

[53] In my respectful view, it is unclear from this Court's reasons in *Tennessee Eastman* whether the conclusion that methods of medical treatment are unpatentable subject matter rested solely on s. 41(1), on ss. 2(d) and 41(1) in combination, or on each of ss. 2(d) and 41(1) independently. The Federal Court of Appeal has taken the latter view. It has held that Pigeon J.'s statement that "methods of medical treatment are not contemplated in the definition of 'invention' as a kind of 'process'" is a "clear and unequivocal statement", in "unmistakable and unambiguous language", such that "the force of [the] pronouncement" that methods of medical treatment are not patentable subject matter "cannot be restricted merely to factual situations where subsection 41(1) of the Act applies" (*Imperial Chemical Industries Ltd. v. Commissioner of Patents*, [1986] 3 F.C. 40 (C.A.), at p. 50; see also *Hospira*, at para. 50; *Merck & Co. v. Apotex Inc.*, [1995] 2 F.C. 723 (C.A.), at p. 758; *Axcan Pharma Inc. v. Pharmascience Inc.*, 2006 FC 527, 50 C.P.R. (4th) 321, at paras. 49-50; *Novartis Pharmaceuticals Canada*

Inc. v. Cobalt Pharmaceuticals Co., 2013 FC 985, 115 C.P.R. (4th) 399, at paras. 73-78, aff'd 2014 FCA 17, 459 N.R. 17).

[54] On the other hand, as Janssen notes, Bastarache J. for the majority in *Harvard College* stated that this Court's decision in *Tennessee Eastman* was based "primarily" on s. 41(1) (para. 145). In *Wellcome*, released the same day, Binnie J. wrote that this Court's decision in *Tennessee Eastman* was "based on the former s. 41 of the *Patent Act*, now repealed" (para. 49). Relying on those statements, and on the ambiguity in this Court's decision in *Tennessee Eastman*, some commentators have argued that the repeal of s. 41(1) removed any obstacle to patenting methods of medical treatment, because this Court's decision in *Tennessee Eastman* has been effectively overtaken by legislation (see A. S. Ross, "Methods of Medical Treatment: A Second Opinion" (2005), 22 *C.I.P.R.* 187; see also N. Siebrasse, *A Rule Without a Principle: Patentability of Methods of Medical Treatment*, January 19, 2015 (online)). For the reasons that follow, I respectfully disagree with this position.

(2) Methods of Medical Treatment Are Not Patentable Independent of *Tennessee Eastman*

[55] In my view, nothing turns on an exegesis of this Court's decision in *Tennessee Eastman*. For more than half a century, it has been settled law in Canada that methods of medical treatment are not patentable subject matter. I reach that conclusion for four reasons: (1) professional skills are not patentable under Canadian law; (2) Canadian courts have continued to affirm that methods of medical treatment

are unpatentable even after the repeal of s. 41(1); (3) the repeal of s. 41(1) did not address the patentability of methods of medical treatment; and (4) international law leaves that question to be decided by each state in accordance with its own public policy. The first two reasons justify the unpatentability of methods of medical treatment under Canadian law. The second two reasons answer specific arguments advanced by Janssen.

(a) *Professional Skills Are Not Patentable*

[56] First, the principle that methods of medical treatment are not patentable is a specific application of the broader principle, affirmed by this Court, that professional skills — which are unrelated to trade, industry, or commerce — are not patentable subject matter.

[57] After *Tennessee Eastman* (S.C.C.), this Court in *Shell Oil* endorsed the Exchequer Court's conclusion in *Tennessee Eastman* on that broader basis. It did so without relying on s. 41(1), which remained in force when *Shell Oil* was decided. Wilson J. held that a patent could issue for a new use for an old substance; in that case, the discovery was that known chemical compounds could be used to regulate plant growth. She explained that the method of closing surgical incisions with an adhesive in *Tennessee Eastman* was unpatentable because it was not an "art" or "process", but instead "related to professional skills rather than to trade, industry or commerce" (p. 555; see also p. 554). In support of this view, Wilson J. cited with approval the Exchequer Court's decision in *Lawson*. In that case, Cattanach J. held that it "is obvious

. . . that professional skills are not the subject-matter of a patent" (p. 111). As he explained:

> If a surgeon were to devise a method of performing a certain type of operation he cannot obtain an exclusive property or privilege therein. Neither can a barrister who has devised a particular method of cross-examination or advocacy obtain a monopoly thereof so as to require imitators or followers of his methods to obtain a licence from him. [p. 111]

[58] In *Wellcome* (at para. 49), this Court affirmed Wilson J.'s articulation of the broader "policy rationale" of *Tennessee Eastman* (S.C.C.), a rationale that continues to apply despite the repeal of s. 41(1). Binnie J. noted that s. 41(1) had been repealed, but he also emphasized that methods of medical treatment were "essentially non-economic and unrelated to trade, industry, or commerce" (para. 49, citing *Shell Oil*, at p. 554). He held that the AZT patent, which claimed a new use for an existing pharmaceutical compound, related to a "commercial offering" and therefore did not improperly monopolize a method of medical treatment (para. 50).

[59] A purposive interpretation of s. 2 confirms that methods of medical treatment are not patentable subject matter. Allowing professional skills to be patentable would not advance the purpose of the *Patent Act*, which is to stimulate innovation. Professionals are already under ethical obligations to exercise their skills in their clients' best interests and to share those skills widely. They neither need nor should they receive patent protection to do so. Because professional skills do not respond to the incentives of the patent bargain, patenting them is unjustified. The

exercise of professional skills is simply not the kind of inventiveness that the *Patent Act* is intended to encourage. As Professor Vaver explains:

> [Professional skills are unpatentable] partly [for] a mixture of ethical and public policy reasons. These include the fact that professionals, often already benefiting from a state-granted monopoly to practise their skills for the public benefit, should not seek to enclose their skills through monopoly or other means, but should rather share them as widely as possible for the public benefit. Professionals, moreover, do not need the spur of a patent to do their best for their clients; professional codes of conduct require that of them in any event. . . .
>
> . . .
>
> . . . Patents should be awarded to encourage desirable inventiveness. Therefore, where the activity is adequately encouraged and would occur even without the prospect of a patent, patenting is unjustified.
>
> (Vaver (2003), at pp. 291 and 304)

[60] Nor is it the role of the patent system to regulate professionals in the exercise of their professional skills and judgment. Professionals should not be permitted to fence in their professional skills and judgment in order to extract monopoly profits. As has been observed:

> In the prevailing view, the patent system should not intrude into the realm of a leading liberal profession where expectations of renown and reward have traditionally taken quite different forms from those which flow from exclusive rights over commercialisation. The spectre of a single doctor reserving the performance of the most satisfactory, possibly life-saving, operation to his or her own team and extracting therefrom monopoly profits on the scale of a successful pop star seemed to put the matter beyond argument.
>
> (W. Cornish, D. Llewelyn and T. Aplin, *Intellectual Property: Patents, Copyright, Trade Marks and Allied Rights* (8th ed. 2013), at para. 5-65)

[61] The scholarly literature identifies many similar public policy reasons for treating professional skills and judgment — and methods of medical treatment in particular — as unpatentable subject matter, even though some authors question the soundness of these reasons (see, e.g., Vaver (2011), at pp. 315-16; T. Scassa, "Patents for Second Medical Indications and Their Potential Impact on Pharmacare in Canada" (2001), 9 *Health L.J.* 23, at pp. 24-25; Melnychuk, at pp. 301-2; E. A. Crowne-Mohammed, "The patentability of professional skills and business methods in Canada" (2010), 5 *J.I.P.L.P.* 119, at p. 120; N. Lipkus and M.-C. Albanese, "Patentability of New and Useful Arts in Canada: In Need of New and Useful Doctrine?" (2011), 27 *C.I.P.R.* 61, at p. 96; Judge and Gervais, at pp. 658-59; Barrigar and Shaughnessy, at § 2:19; T. Martin, "Patentability of Methods of Medical Treatment: A Comparative Study" (2000), 82 *J.P.T.O.S.* 381, at pp. 383-89 and 422-23; M. Goudreau, "Brevetabilité, traitement médical et ordre public social" (2008), 67 *R. du B.* 77, at paras. 48-65; O. Mitnovetski and D. Nicol, "Are patents for methods of medical treatment contrary to the *ordre public* and morality or 'generally inconvenient'?" (2004), 30 *J. Med. Ethics* 470, at pp. 473-74; Bourassa Forcier, Audet and Melançon, at n^{o} 4.9.1.5; T. Yasui, "Protecting a Drug Dosage Regime Using Medical Method or Medical Use Patents" (2014), 96 *J.P.T.O.S.* 316, at p. 342).

(b) *Canadian Courts Continue to Affirm That Methods of Medical Treatment Are Not Patentable After the Repeal of Section 41(1)*

[62] Second, after the repeal of s. 41(1), this Court in *Wellcome* applied the rule that methods of medical treatment are unpatentable and upheld the validity of the patent

at issue. The Court rejected the argument that a patent for the use of AZT in treating HIV/AIDS sought to monopolize a method of medical treatment, noting that there was "no serious challenge . . . to subject matter patentability" (para. 48). As Binnie J. explained:

> The AZT patent does not seek to "fence in" an area of medical treatment. It seeks the exclusive right to provide AZT as a commercial offering. How and when, if at all, AZT is employed is left to the professional skill and judgment of the medical profession. [para. 50]

[63] *Wellcome* therefore refutes Janssen's argument that the majority in *Harvard College* — released the same day — cast doubt on whether methods of medical treatment remained unpatentable after the repeal of s. 41(1) (see also *Hospira*, at para. 50). Two years later, four judges of this Court in *Monsanto* reiterated that methods of medical treatment are unpatentable subject matter (para. 133, per Arbour J., dissenting in part, but not on this point, citing *Tennessee Eastman* (S.C.C.)).

[64] It is also noteworthy that when the High Court of Australia surveyed the law of several jurisdictions, including Canada, it concluded that methods of medical treatment are unpatentable subject matter under Canadian law (*Apotex Pty. Ltd. v. Sanofi-Aventis Australia Pty. Ltd.*, [2013] HCA 50, 253 C.L.R. 284, at para. 273, citing *Tennessee Eastman* (S.C.C.), *Shell Oil*, and *Wellcome*). To a dispassionate observer, the Canadian law on this point has been clear for the past half-century.

[65] Moreover, although the Federal Court of Appeal has suggested in *obiter* that the basis of the rule merits "full consideration" (*Cobalt Pharmaceuticals Co. v. Bayer Inc.*, 2015 FCA 116, 131 C.P.R. (4th) 99, at para. 101) and "deep analysis" (*Hospira*, at para. 53), the federal courts have consistently affirmed that methods of medical treatment are unpatentable under Canadian law (see, e.g., *Bayer*, at para. 101; *Hospira*, at paras. 47-56; *AbbVie Corp. v. JAMP Pharma Corp.*, 2023 FC 1520, at paras. 186-87; *Hoffmann-La Roche Ltd. v. Sandoz Canada Inc.*, 2021 FC 384, 185 C.P.R. (4th) 167, at para. 195; *Biogen Canada Inc. v. Taro Pharmaceuticals Inc.*, 2020 FC 621, at para. 202; *Novartis*, at paras. 72-78; *Janssen Inc. v. Mylan Pharmaceuticals ULC*, 2010 FC 1123, 88 C.P.R. (4th) 359, at paras. 20-26 and 53; *Axcan*, at paras. 42-50).

[66] This is also the administrative position taken in the *Manual of Patent Office Practice*, which states that methods of medical treatment or surgery are not patentable in Canada because they do not fall within the scope of an "invention" under s. 2 (see *Manual*, at ss. 17.03.02 and 23.03.01; see also Canadian Intellectual Property Office, *March 2026 Practice Notice on Patentable Subject-Matter under the Patent Act*, last updated March 24, 2026 (online)).

[67] The scholarly literature reflects the same broad consensus (see, e.g., Vaver (2011), at pp. 315-16; MacOdrum, McIntosh and Szweras, at § 3:31; Perry and Currier, at §6.03[10]; Clarizio et al., at § 5; Judge and Gervais, at pp. 658-59; Barrigar and Shaughnessy, at § 2:19; B. Stratton, *Annotated Patent Act* (loose-leaf), at §§ 2:26 and

2:32; A. M. Blanchard, *Life Sciences Law in Canada* (2nd ed. (loose-leaf)), at § 6:6(2); T. Piper, "A Common Law Prescription for a Medical Malaise", in C. W. Ng, L. Bently and G. D'Agostino, eds., *The Common Law of Intellectual Property* (2010), 143, at pp. 157-58; Scassa, at pp. 24-25; Goudreau (2007), at pp. 49-50; Goudreau (2008), at paras. 1, 6-10 and 77; J. Gauvreau, "Évolution des critères de brevetabilité et de validité de 2015 à 2017: fin d'une décennie marquée par la multiplication des interprétations, et autres sujets", in Service de la formation continue du Barreau du Québec, vol. 437, *Développements récents en droit de la propriété intellectuelle* (2017), 129, at para. 3.2.1.1; Melnychuk, at pp. 300-304; Crowne-Mohammed, at p. 124; Martin, at pp. 416-17).

[68] Therefore, it remains settled law in Canada that methods of medical treatment are unpatentable subject matter.

(c) *The Repeal of Section 41(1) Did Not Address Methods of Medical Treatment*

[69] Third, Janssen's submission that the repeal of s. 41(1) transformed methods of medical treatment into patentable subject matter is, with respect, without merit. The repeal of s. 41(1) did not change the patentability of *methods* of medical treatment. It merely removed restrictions on patenting pharmaceutical *substances*.

[70] Section 41(1) was repealed as part of broader reforms to the former compulsory licensing scheme under Canadian patent law, a scheme concerned

exclusively with food and pharmaceutical *substances*. The scheme generally required the Commissioner of Patents to grant import licences for pharmaceutical substances, thereby facilitating the early introduction of new drugs in Canada and increasing domestic competition (*Report of the Commission of Inquiry on the Pharmaceutical Industry*, at pp. xix-xx). It permitted generic firms to purchase drugs in bulk from countries with weak patent protection and to repackage them for sale in Canada. As one commentator observed, because of this scheme and s. 41(1)'s restrictions on the patenting of pharmaceutical substances, Canada's domestic innovative pharmaceutical industry "very nearly died" (Wilkes, at p. 226). In 1987, Parliament reformed the compulsory licensing regime and narrowed the restriction in former s. 41(1), granting innovative domestic drug companies greater market exclusivity by suspending the licence holders' import rights for specified periods (*An Act to amend the Patent Act and to provide for certain matters in relation thereto*, S.C. 1987, c. 41 ("1987 Amendments"), ss. 14 and 15). At the same time, Parliament removed the restriction on the patentability of most pharmaceutical substances (1987 Amendments, s. 14). A few years later, Parliament abolished the compulsory licensing scheme and repealed s. 41(1) altogether (*Patent Act Amendment Act, 1992*, S.C. 1993, c. 2 ("1993 Amendments"), s. 3).

[71] Nothing in the legislative debates, the text of the amendments, or the contemporaneous commentary suggests that these reforms were intended to permit the patenting of methods of medical treatment or to overrule this Court's decision in *Tennessee Eastman*. That was neither their purpose nor their effect.

[72] This conclusion is reinforced by the principle of stability in the law. As this Court has held, "[a]bsent clear legislative intention to the contrary, a statute should not be interpreted as substantially changing the law" (*R. v. D.L.W.*, 2016 SCC 22, [2016] 1 S.C.R. 402, at para. 21; see also *R. v. Wolfe*, 2024 SCC 34, at para. 54; P.-A. Côté and M. Devinat, *Interprétation des lois* (5th ed. 2021), at para. 1642). This principle "reflects the common sense idea that Parliament is deemed to know the existing law and is unlikely to have intended any significant changes to it unless that intention is made clear" (*D.L.W.*, at para. 21).

[73] Here, nothing indicates that Parliament intended to displace the settled jurisprudence holding that methods of medical treatment fall outside the definition of "invention". As noted in *Fox on the Canadian Law of Patents*, when s. 41(1) of the *Patent Act* was repealed, "Parliament did not also amend the definition of 'invention', for example to include expressly methods of medical treatment and effectively overrule the *Tennessee Eastman* decision" (MacOdrum, McIntosh and Szweras, at § 3:31). By contrast, when Parliament has wished to overrule a decision of this Court as to the interpretation of the *Patent Act*, it has done so expressly. For example, after this Court in *Pioneer Hi-Bred Ltd. v. Canada (Commissioner of Patents)*, [1989] 1 S.C.R. 1623, held that the deposit of seed samples with public authorities did not constitute sufficient disclosure under the *Patent Act* to obtain a patent for a new soybean variety, Parliament enacted s. 38.1 to expressly permit such deposits to form part of the specification, effectively overruling that aspect of the decision (MacOdrum, McIntosh and Szweras, at § 3:31, fn. 7).

[74] Nor, in my respectful view, should the doctrine excluding methods of medical treatment from patentability be abolished by reference to the broader legislative objective underlying the 1987 and 1993 amendments, namely the promotion of pharmaceutical innovation. The legislative record shows that Parliament pursued that objective in a measured way. Parliament recognized that incentives for pharmaceutical innovation must be balanced against consumer protection, and therefore created the Patented Medicine Prices Review Board to monitor drug prices (*House of Commons Debates*, vol. I, 2nd Sess., 33rd Parl., November 20, 1986, at p. 1369; 1987 Amendments, s. 15; *House of Commons Debates*, vol. X, 3rd Sess., 34th Parl., September 17, 1992, at pp. 13258-59; 1993 Amendments, s. 7). Absent a clear indication that Parliament intended to alter the patentability of methods of medical treatment, this Court should not dramatically expand the scope of medical patents or disturb the balance that Parliament sought to strike under the *Patent Act*.

(d) *The TRIPS Agreement Leaves the Patentability of Methods of Medical Treatment to Signatory States*

[75] Finally, contrary to Janssen's claim, international law does not support the view that methods of medical treatment are patentable in Canada. Janssen notes that Article 27(3)(a) of the *Agreement on Trade-Related Aspects of Intellectual Property Rights*, 1869 U.N.T.S. 299 ("*TRIPS Agreement*"), to which Canada is a signatory, expressly permits — but does not require — signatories to exclude "diagnostic, therapeutic and surgical methods for the treatment of humans" from patentability (R.F., at para. 51). As Janssen points out, some signatories, such as the United Kingdom, have

enacted legislation expressly providing for such an exclusion (see *Patents Act 1977* (U.K.), 1977, c. 37, s. 4A(1)). Janssen further observes that although Canada amended the *Patent Act* and other statutes in response to the *TRIPS Agreement*, it did not enact legislation providing expressly that methods of medical treatment are unpatentable. Janssen says that this omission is "highly significant" (R.F., at para. 51).

[76] I respectfully disagree. Canada's decision not to enact legislation expressly *excluding* methods of medical treatment as a patentable invention is of no significance because it has been settled law since 1972 — when this Court rendered its judgment in *Tennessee Eastman* — that methods of medical treatment are unpatentable in Canada. That conclusion flows from the consistent judicial interpretation of s. 2 of the *Patent Act*. No legislative amendment was required to preserve the status quo.

[77] The *TRIPS Agreement* leaves signatory states free to decide, as a matter of their domestic public policies, whether to exclude methods of medical treatment from patentable subject matter. It is therefore neither necessary nor helpful to canvass the different choices made by different countries. In any event, even had the *TRIPS Agreement* required signatories to exclude methods of medical treatment from patentability, this would not determine the interpretation of the *Patent Act*. Although the *Patent Act* is presumed to comply with the *TRIPS Agreement*, courts must still give effect to Parliament's legislative intent where Parliament has chosen to depart from the *TRIPS Agreement* (*Society of Composers, Authors and Music Publishers of Canada v. Entertainment Software Association*, 2022 SCC 30, [2022] 2 S.C.R. 303, at paras. 46-

48; *Fraser v. Janes Family Foods Ltd.*, 2012 FCA 99, 101 C.P.R. (4th) 441, at paras. 14-16, citing *Baker Petrolite Corp. v. Canwell Enviro-Industries Ltd.*, 2002 FCA 158, [2003] 1 F.C. 49, at para. 25).

[78] In short, Parliament has not sought to disturb the consistent interpretation of the *Patent Act* reflected in *Tennessee Eastman* (S.C.C.), *Wellcome*, and the federal courts' jurisprudence. Any change to the law would unsettle more than a half-century of commercial expectations built on that case law. If such a change is to occur, it must come from Parliament, not this Court.

(3) Conclusion

[79] Canadian courts have consistently excluded methods of medical treatment from the definition of "invention" under s. 2 of the *Patent Act*, and rightly so. Distinguishing unpatentable professional skills from patentable innovations in trade, industry, or commerce is fully consistent with the *Patent Act*'s purpose of encouraging desirable inventiveness. Professionals who already benefit from a state-granted monopoly to practise their skills for the public benefit are not entitled to fence in those skills in order to extract monopoly profits. Methods of medical treatment are therefore not patentable subject matter under Canadian law.

C. *Drug-Dosing Regimens Can Be Patentable Subject Matter*

[80] Having concluded that methods of medical treatment are unpatentable, the next question is when a drug-dosing regimen patent, such as the 335 Patent at issue here, amounts to a method of medical treatment. This requires the Court to articulate a test for a method of medical treatment, a point on which the parties disagree.

(1) The Test for Methods of Medical Treatment

(a) *Pharmascience's "How and When" Test Should Be Rejected*

[81] Pharmascience asserts that the Court of Appeal applied a "skill and judgment" test for a method of medical treatment, under which "[t]he proper inquiry remains whether use of the invention (i.e., how to use it, not whether to use it) requires the exercise of skill and judgment" (C.A. reasons, at para. 37 (emphasis in original)). Pharmascience contends that a test focusing on whether the claim monopolizes an area involving a physician's skill and judgment is impractical and impossible to apply with any degree of certainty. Rather than focusing on professional skill and judgment, Pharmascience urges this Court to adopt the approach in *Wellcome*, which it submits identifies a method of medical treatment by determining whether a patent claims "how and when" a drug should be administered. It contends that this test reflects good public policy because it will help avoid the "double patenting" or "evergreening" of pharmaceutical patents, which involves artificially extending the life of drug patents by "adding bells and whistles to a pioneering product even after the original patent for that pioneering product has expired" (*AstraZeneca* (2006), at para. 39).

[82] I respectfully disagree with Pharmascience's submission. As Janssen correctly notes, this Court in *Wellcome* did not establish a "how and when" test for a method of medical treatment. The Court simply observed that the AZT patent in that case did not seek to monopolize an area of medical treatment, and then added: "How and when, if at all, AZT is employed is left to the professional skill and judgment of the medical profession" (para. 50). In keeping with *Tennessee Eastman* (Ex. Ct.), *Shell Oil*, and *Lawson*, this Court in *Wellcome* properly focused on whether the patent claimed "the professional skill and judgment of the medical profession".

[83] In addition, as Janssen also notes, applying a "how and when" test would have led to the opposite result in *Wellcome*: the AZT patent would have been found to be a method of medical treatment. The claims in *Wellcome* (a unit dose of 10 to 1500 mg of AZT for the treatment of HIV/AIDS) could easily have been recharacterized as relating to *how* to take AZT (by specified methods of formulation such as capsule or injectable solution in an amount from 10 to 1500 mg) and *when* to do so (for the treatment or prophylaxis of HIV/AIDS). Such an approach would also prevent an inventor from patenting any subsequent use for a known compound, contrary to the result in *Shell Oil* and *Wellcome* (see *Hospira Healthcare Corp. v. Kennedy Trust for Rheumatology Research*, 2018 FC 259, at para. 147).

[84] Nor should this Court distort the approach to methods of medical treatment to address conceptually distinct concerns about "double patenting" or "evergreening". It is settled that "[t]here may only be one patent covering an invention" (*Sanofi-*

Synthelabo, at para. 95, citing *Whirlpool Corp. v. Camco Inc.*, 2000 SCC 67, [2000] 2 S.C.R. 1067, at para. 63). If an inventor tries to improperly extend the life of their patent by "evergreening" an invention, the subsequent patent is subject to challenge under the distinct rules against double patenting (see *Whirlpool*, at paras. 63-67; *Sanofi-Synthelabo*, at paras. 95-97). No such challenge was made here.

(b) *Janssen's Focus on Economic Versus Non-Economic Activities Is Unhelpful*

[85] For its part, Janssen asserts that any exclusion of the patentability of methods of medical treatment "should be narrowly focused on non-economic medical activities unrelated to commercial products" (R.F., at para. 58). Janssen says that this principle is rooted in language from *Shell Oil* that a claimed invention "having economic value in the field of trade, industry and commerce" is patentable (pp. 554-55).

[86] I respectfully disagree with Janssen's view that the test should focus on whether the medical patent is for "non-economic" or "economic" activities. The treatment of patients by a medical professional will always have an economic value, broadly construed. My colleagues express the same concern and reject the "vendible product" inquiry applied by lower courts on this basis (para. 230). However, the key idea from *Shell Oil* is that subject matter is patentable where it relates to "the field of trade, industry and commerce", as opposed to professional fields, like the practice of medicine, where economic value does not drive the exercise of skill and judgment. In

the jurisprudence on methods of medical treatment, this same idea is captured by the term "vendible product", which describes patentable subject matter that does not amount to the exercise of professional skill and judgment and therefore responds to the economic incentives of the patent bargain (see C.A. reasons, at paras. 26-27). Whether framed in terms of "vendible product" or "economic value in the field of trade, industry and commerce", the focus has always been to distinguish the skill and judgment of medical professionals, for which patent protection is neither desirable nor required, from adjacent commercial activity spurred on by such protection.

[87] Janssen's focus on economic versus non-economic activities would also effectively make all dosing regimens patentable. Janssen argues that dosing regimens are never methods of medical treatment because they are "commercial offerings" (R.F., at paras. 58-59). This is contrary to the existing jurisprudence, under which some dosing regimens have been found to be unpatentable (see *Novartis*, at para. 101; *Mylan*, at para. 56; *Axcan*, at para. 52; *Hoffmann-La Roche*, at para. 231). Janssen's position therefore would have the effect of dramatically expanding the scope of the patent protection for medicines in Canada. This, too, would substantially disrupt commercial expectations in the marketplace.

(c) *The Federal Court of Appeal's Approach Should Be Adopted*

[88] Instead of the extreme positions proposed by the parties, I would, like the Federal Court of Appeal, adopt a balanced approach to the test for methods of medical treatment grounded in the doctrine's purpose. The test should distinguish between the

exercise of professional skill and judgment, which need not be incentivized by the patent bargain, and other medical innovations (see *Wellcome*, at para. 49, citing *Shell Oil*, at p. 554). This ensures that the patent regime does not fence in areas within the field of medical practice, while also not stifling commercial innovation involving medical applications.

[89] To determine whether a given subject matter is unpatentable as a method of medical treatment, the "ultimate question" is whether that subject matter amounts to professional medical skill and judgment (see C.A. reasons, at para. 28, citing *Mylan*, at para. 26). Put differently, the question is whether the claimed invention seeks to "'fence in' an area of medical treatment" (*Wellcome*, at para. 50; see also *Abbott Laboratories (Bermuda) Ltd., Re*, 2014 FC 1251, 126 C.P.R. (4th) 51, at para. 120).

[90] In answering this question, it is helpful to begin by construing the claims to determine the subject matter. A court reads the claims in an informed and purposive way, based on the common knowledge of the worker skilled in the art to which the patent relates (*Whirlpool*, at paras. 42-50; *Free World Trust*, at paras. 31-67). Purposive construction ensures that identifying methods of medical treatment depends neither on a literal reading of the claims nor on the "spirit of the invention" or the "inventive concept" (*Free World Trust*, at paras. 46 and 50; *Amazon.com, Inc. v. Canada (Attorney General)*, 2011 FCA 328, [2012] 2 F.C.R. 459, at paras. 43 and 47).

[91] The analysis for methods of medical treatment is then applied to "the real subject matter of the claim", regardless of how the claim is drafted (*Novartis*, at para.

101; see also *Bayer Inc. v. Cobalt Pharmaceuticals Co.*, 2013 FC 1061, 121 C.P.R. (4th) 14, at para. 162). For example, the drafting of a claim as a product claim does not mean that its subject matter is necessarily a "vendible product". I agree with the Court of Appeal that "it would be an error to focus on form over substance" (para. 42).

[92] As the Court of Appeal correctly noted, applying the test for methods of medical treatment to the subject matter of the claim, once it has been properly construed, is a "factually suffused" issue that "depends on the evidence" (para. 35). At the same time, the jurisprudence provides much useful guidance. I would highlight three points in particular.

[93] First, the analysis should focus on whether the subject matter of the claimed invention amounts to professional medical skill and judgment, not whether professional medical skill and judgment would be applied in *selecting* the claimed invention for a particular patient or use. Medical judgment is often required in deciding *whether* a claimed invention is appropriate for a given patient, but this does not make it unpatentable (see C.A. reasons, at para. 31; *Abbott*, at paras. 110 and 121). For example, a medical professional prescribing a particular drug to a given patient exercises clinical judgment in determining the appropriate course of treatment. But this simply means that the prescribing decision is unpatentable subject matter. It does not make the drug itself unpatentable.

[94] Similarly, once a medical professional has selected a medical treatment — such as by prescribing a given drug — they may still need to monitor the patient to

decide whether to continue that treatment or to stop it and explore other treatment options. The Court of Appeal correctly noted that if such monitoring made the treatment itself unpatentable subject matter, this prohibition "would cast too wide a net, potentially encompassing almost any drug" (para. 30). Once again, the key is to avoid confusing the professional medical skill and judgment exercised in monitoring a patient to decide whether a claimed invention remains appropriate with the claimed invention itself.

[95] Second, the more the practice of a claimed invention involves tailoring it to the circumstances of a particular patient, the more likely it is that its subject matter amounts to professional medical skill and judgment. By contrast, where the subject matter of the claimed invention can be applied generally to a broad class of patients without individual adjustment, it is less likely to be a method of medical treatment. Treating a patient based on their individual characteristics engages professional skill and judgment in making treatment decisions. Commercial actors aim to offer vendible products at scale, while an essential aspect of medical professional practice is treating each patient according to their own unique needs.

[96] The degree of tailoring to specific patients is a recurring feature in the jurisprudence on methods of medical treatment (see, e.g., *Axcan*, at paras. 42-51; *Mylan*, at paras. 50-52; *Novartis*, at paras. 94-99). For example, evidence that the claimed invention, in practice, has often required individualized adjustment has been cited as a potential indicator of unpatentability (see *Hoffmann-La Roche*, at paras. 204-

12; see also *Abbott*, at paras. 121-22; *JAMP*, at para. 339). This is not to suggest that this factor is determinative, or that there is a bright line between subject matter that is individualized and subject matter that is not. The point is merely that individualization as a core feature of medical practice can serve as one indicator of professional medical skill and judgment.

[97] Third, the application of the test must remain focused on the purpose of the rule that methods of medical treatment are unpatentable subject matter. Methods of medical treatment need not be incentivized through the patent bargain because medical professionals are expected to innovate within their areas of professional practice regardless of such an incentive (see generally Vaver (2003), at pp. 291 and 304; Cornish, Llewelyn and Aplin, at para. 5-65). The more a medical professional would already be incentivized to develop or improve a given subject matter in the course of their professional practice, the more likely it is that the subject matter amounts to a method of medical treatment.

[98] This Court's jurisprudence illustrates how the above points of guidance apply in concrete circumstances. In *Tennessee Eastman*, the unpatentable claims described "a surgical method for joining or bonding the surfaces of incisions or wounds in living animal tissue" by applying an already well-known adhesive compound (p. 112). That method would have to be adapted to each patient and each potential use of the compound, depending on, for example, the nature of the incision, wound, and tissue. Professional medical skill and judgment would be engaged not just in choosing to

follow this method but also in applying it to treat a patient. By contrast, in *Wellcome*, the patentable claims were for the use of AZT to treat HIV/AIDS. Professional medical skill and judgment would be engaged in deciding whether to prescribe AZT to a patient for this purpose based on their individual medical circumstances, but much less so in the actual use of AZT to treat HIV/AIDS. The claimed invention was not the kind of innovation that a medical professional would be expected to develop and refine in treating individual patients within their practice, but instead was "a commercial offering" (para. 50).

[99] These three points of guidance are not exhaustive and do not establish bright-line rules. At the end of the day, although there is an understandable desire for certainty and predictability, a judicial test can provide only as much certainty and predictability as the nature of the subject permits. Cases involving methods of medical treatment are factually suffused and must be decided accordingly, drawing on the considerable expertise of the federal courts in patent matters.

(d) *Summary of the Test for Methods of Medical Treatment*

[100] To summarize, a given subject matter is unpatentable as a method of medical treatment if it amounts to professional medical skill and judgment. The question must be approached by construing the patent claims purposively, privileging substance over form. The answer to the question will depend on the nature of the specific claims and the facts of each case. At the same time, three general observations from the jurisprudence may help guide the analysis. First, the need for professional skill

and judgment in determining *whether* the subject matter is or continues to be an appropriate treatment option for a particular patient will generally not affect its patentability. Second, the more the subject matter involves tailoring treatment to individual patients, the more likely it is that it amounts to a method of medical treatment. Third, the more a medical professional would be able to develop or improve the subject matter in the ordinary course of treating patients, the more likely it is that the subject matter constitutes a method of medical treatment. In the final analysis, the determination must be guided by the facts of each case and the expert jurisprudence of the federal courts.

(2) Application to Drug-Dosing Regimens

[101] I now consider how the test for a method of medical treatment applies to drug-dosing regimens.

[102] Janssen asserts categorically that dosing regimens are inherently patentable and thus can never be unpatentable as methods of medical treatment. It highlights the Regulatory Impact Analysis Statement ("RIAS") accompanying regulations that amended the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 (Regulatory Impact Analysis Statement, SOR/2006-242, *Canada Gazette*, Part II, vol. 140, No. 21, October 18, 2006). Janssen notes that the RIAS specifically identifies dosing regimen claims as eligible to be included on the patent register created under the *Patented Medicines (Notice of Compliance) Regulations*, which it says confirms that dosing regimens are necessarily patentable. Janssen argues that any test for a

method of medical treatment under the *Patent Act* must preserve patent protection for dosing regimens.

[103] I respectfully disagree with Janssen's submission. Registering a dosing regimen on the patent register does not confirm patentability; it merely prevents generic manufacturers from receiving regulatory approval to market the product until patent issues are resolved (see *Patented Medicines (Notice of Compliance) Regulations*, ss. 6 and 7(1)). A patent may be included on the register even before the validity of the patent is determined, and such a patent remains subject to challenge. In any event, while the views expressed in the RIAS may be relevant in interpreting the accompanying amendment to the regulations (see *Bristol-Myers Squibb Co. v. Canada (Attorney General)*, 2005 SCC 26, [2005] 1 S.C.R. 533, at para. 46), they do not assist in interpreting the definition of the term "invention" that Parliament enacted in the *Patent Act* decades earlier (*Professional Institute of the Public Service of Canada v. Canada (Attorney General)*, 2012 SCC 71, [2012] 3 S.C.R. 660, at para. 98, citing *United States of America v. Dynar*, [1997] 2 S.C.R. 462, at para. 45). As a result, contrary to Janssen's position, a dosing regimen is not invariably patentable subject matter.

[104] The Court of Appeal similarly rejected the bright-line rule seen in some decisions of the Federal Court whereby a claim is "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)" (para. 27). As the courts below observed, this distinction has a "questionable underpinning" (trial

reasons, at para. 165; C.A. reasons, at para. 28, citing *Hospira* (F.C.A.), at para. 52). The Court of Appeal preferred a nuanced approach that asks whether the claims seek to circumscribe "the skilled work of a physician" (para. 26). It stated that the analysis under the method of medical treatment doctrine may consider "whether the dosing regimen is fixed or variable", but must remain "tied to the ultimate question of whether professional skill is applied in using the invention" (para. 28).

[105] I agree with the Federal Court of Appeal's nuanced approach. The categorial distinction between fixed and variable dosages skirts the ultimate issue of whether the claimed dosing regimen amounts to professional medical skill and judgment. As noted by the courts below, whether the dosing regimen patent claims fixed versus variable dosing is, at best, an evidentiary proxy that is sometimes useful but never dispositive of whether the claims are for unpatentable methods of medical treatment (trial reasons, at paras. 164-66; C.A. reasons, at para. 28 and 45). That question relates to the degree of individualization of the claim, which is a helpful but not determinative consideration.

[106] Determining the patentability of a dosing regimen is a factually suffused exercise that depends on the evidence and how the dosing regimen is intended to be, or has been, applied. The appropriate evidence could include, for example, expert or other "evidence to contradict th[e] claimed dosage", which could suggest that the dosing regimen requires individualized adjustment and potentially constitutes a method of

medical treatment (*Abbott*, at paras. 114 and 121; see also *Hoffmann-La Roche*, at paras. 195 and 197; *Mylan*, at paras. 26-52).

[107] Even so, the fact that "a minority of physicians wish to deviate from the claimed [dosing] regimens at some point" does not necessarily render them unpatentable (*JAMP*, at para. 339). The Court of Appeal was correct to reject the argument that "a claimed dosage regimen that will not be appropriate for all patients constitutes an unpatentable method of medical treatment" (para. 33). As the court explained, such a test sets an impossible standard, since "few drug [dosing] regimens could be anticipated to be effective for all patients at a particular dosage" (para. 34).

D. *There Is No Basis to Overrule the Consistent Jurisprudence That Methods of Medical Treatment Are Unpatentable Subject Matter*

[108] Before applying the above legal principles to this case, I explain my respectful disagreement with the view of my colleagues O'Bonsawin and Moreau JJ. that this Court should recognize — for the first time in Canadian law — that methods of medical treatment are patentable subject matter.

[109] My colleagues and I agree that the unpatentability of methods of medical treatment is "the present state of Canadian law" (para. 143). As they acknowledge, in *Wellcome* — decided after the repeal of s. 41(1) — this Court accepted that "subject matter that 'fences in' an area of medical treatment where professional skill and judgment are required cannot be patented" (O'Bonsawin and Moreau JJ.'s reasons, at

para. 172). We also agree that there is broad consensus among the federal courts and patent law commentators that the unpatentability of methods of medical treatment survived the repeal of s. 41(1) (paras. 175-76).

[110] Where I respectfully part company with my colleagues is as to whether this Court should overrule this consistent line of jurisprudence. In their view, the current law is unworkable, lacks theoretical grounding, and rests on policy rationales they find unpersuasive (paras. 128, 144, 146-80, 207 and 218-32). They also regard this Court's confirmation in *Shell Oil* and *Wellcome* that methods of medical treatment are unpatentable as *obiter* (paras. 172 and 177) and view the federal courts' continuous refinement of this rule as lacking meaningful engagement with it (para. 149).

[111] In response to their concerns, I note that no party to this appeal asked this Court to overrule any of its precedents. The parties asked this Court to clarify existing law by deciding whether the unpatentability of methods of medical treatment rested on a repealed statute (A.F., at paras. 2-3 and 53-105; R.F., at paras. 10, 38 and 41-57). They did not argue that *Tennessee Eastman*, *Shell Oil*, or *Wellcome* should be overruled on grounds of eroded legal foundation or unworkability.

[112] Further, as this Court explained in *John Howard Society of Saskatchewan v. Saskatchewan (Attorney General)*, 2025 SCC 6, a decision to depart from this Court's precedent "should not be taken lightly", given the importance of certainty and predictability in the law (para. 33). A "compelling reason" outweighing the benefits of adherence to this Court's past decisions is required (para. 33). I see no such reason here.

[113] First, it has not been shown that the existing law is unworkable. The test to identify a method of medical treatment has been refined over decades through purposive judicial interpretation of the definition of "invention" under the *Patent Act*. This has long been recognized as the appropriate method for setting the bounds of patentable subject matter. Such an approach does not involve result-oriented policy reasoning; it is rooted in the statute itself and reflects the modern approach to interpretation, which recognizes the indispensable role of legislative purpose or policy. For example, this Court in *Harvard College* applied the modern approach to conclude that higher life forms are not patentable subject matter, even without explicit language in the *Patent Act* to that effect.

[114] Second, I am unable to agree with my colleagues' proposed new framework for the patentability of methods of medical treatment. They would preserve the principle that professional skill and judgment is unpatentable — in keeping with the patent bargain — but relocate that analysis from the question of whether the subject matter is patentable to the question of whether the usefulness requirement for patentability is met (paras. 271-82). The proposed new rule would examine similar policy concerns, but would do so under the utility doctrine.

[115] This approach was not advanced by any party or intervener before this Court, nor was the utility requirement in issue before this Court or the courts below. Adopting such an approach would unsettle commercial expectations and risk significant disruption in Canada's innovative and generic drug industries.

[116] More specifically, my colleagues propose adding new "principles of operability, reproducibility, and control" to the utility requirement (paras. 276 and 281). These principles appear to be drawn from a line of Patent Appeal Board cases that this Court has never endorsed. They do not appear in *AstraZeneca* (2017) — this Court's governing authority on utility — which defined utility simply as the subject matter being "capable of a practical purpose (i.e. an actual result)" (para. 54; see also MacOdrum, McIntosh and Szweras, at § 6:5; Perry and Currier, at §7.03). My colleagues would require that the "actual result" be controllable and reproducible without relying on "a person's skill, judgment, or reasoning" or "intuition, creativity, conjecture, and approximation" (paras. 273 and 281). No guidance is offered on how this rule would operate in practice or would resolve the claimed difficulties in quantifying professional skill and judgment (paras. 226-28). This approach risks making the utility requirement more stringent and potentially confusing for all patents, medical or otherwise.

[117] Alternatively, if the proposed new rule were understood as merely an expression of the existing utility requirement (O'Bonsawin and Moreau JJ.'s reasons, at paras. 269-70), substituting it for the rule against patenting methods of medical treatment would greatly expand the patentability of medical inventions. Under existing law, utility is a low threshold, requiring only "a scintilla of utility" (*AstraZeneca* (2017), at para. 55; see also Perry and Currier, at §7.01). Dosing regimens that are unpatentable as methods of medical treatment under existing law could easily satisfy this threshold (see, e.g., *Hoffmann-La Roche*, at paras. 231-32). The practical effect

would be to render patentable what has long been considered as being outside the scope of patentable subject matter, significantly changing the law and disrupting settled commercial expectations in the marketplace. Respectfully stated, such a departure from established law would not resolve the claimed doctrinal and practical difficulties; it would simply exchange them for new ones.

E. *The 335 Patent Concerns Patentable Subject Matter*

[118] Finally, I will apply the legal principles discussed above to the 335 Patent. The trial judge has construed the claims (at paras. 94-111), all of which incorporate the dosing regimens that Pharmascience alleges to amount to methods of medical treatment.

[119] In my view, the trial judge correctly based the analysis for methods of medical treatment on the exercise of professional medical skill and judgment. He asked "whether professional skill and judgment is required to practice the invention as claimed" and whether patenting the dosing regimens "would interfere with or restrict a physician's skill or judgment" (paras. 164 and 170 (emphasis deleted)). He acknowledged the "dichotomy" between fixed and variable dosages in the Federal Court's jurisprudence (paras. 164-65). The Federal Court of Appeal concluded that the trial judge's reasons "properly focused on whether use of the claims required the exercise of skill and judgment" (para. 49). I agree with the Court of Appeal.

[120] As properly emphasized by the Court of Appeal, the application of the test for a method of medical treatment must be guided by the facts of the case (paras. 35 and 37). The trial judge's findings amply support his conclusion that the dosing regimens in the 335 Patent do not amount to professional medical skill and judgment. As he found, "skill and judgment are not required to implement the claimed dosing regimens" after a physician has chosen a specific dosing regimen (para. 171). This is consistent with the idea, discussed above, that the need for professional judgment in determining *whether* the subject matter is appropriate for a given patient generally does not affect its patentability.

[121] The trial judge also ruled that aspects of the dosing regimens that Pharmascience claimed required individualized adjustment did not render the 335 Patent invalid. First, he held that the separate dosing regimens for patients with and without impaired kidney function do not constrain a physician's exercise of professional judgment. As he found, "[o]nce a physician chooses to use the products for the purpose claimed, each of the claims teaches fixed dose amounts, fixed intervals, and fixed injection sites" (para. 169). The Court of Appeal noted that the different dosing for patients with and without impaired kidney function "is an objective distinction that does not involve the exercise of a physician's skill and judgment" (para. 56). While some individualized adjustment is required, the choice between the two dosing regimens is binary and depends on only one aspect of the patient's medical history. It does not amount to exercising professional skill and judgment, and therefore does not render the dosing regimens unpatentable.

[122] Second, the trial judge found that the choices around dosing windows (Day 8 ± 2 days; monthly ± 7 days) and the injection site for the monthly maintenance doses (gluteal or deltoid muscle) "do not have clinical implications" (para. 170). He grounded this finding in the expert evidence, noting that "[t]he experts explained the dosing windows are incorporated into the regimen to allow flexibility in order to avoid a missed dose without significant clinical difference, and the maintenance dose injection site is clinically interchangeable" (para. 170). The trial judge concluded that "no skill and judgment is required that would interfere with or restrict a physician's skill or judgment in deciding to prescribe the dosing regime[n] within the claimed invention" (para. 170). The Court of Appeal saw no basis to interfere with these findings, noting that Pharmascience did "not assert any palpable and overriding error of fact or of mixed fact and law" (para. 52; see also para. 53). No such error has been established.

[123] In my view, the trial judge correctly focused on professional skill and judgment when applying the test for methods of medical treatment. His findings disclose no reviewable error. They amply support his conclusion that the dosing regimens in the 335 Patent do not amount to professional skill and judgment.

VI. Disposition

[124] I would dismiss the appeal. Because I would reject the principal positions of both parties, I would not award costs to either party.

The following are the reasons delivered by

O'BONSAWIN AND MOREAU JJ. —

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I. Overview

[125] Schizophrenia is a notoriously difficult mental illness to treat that affects hundreds of thousands of Canadians. Individuals suffering from schizophrenia often struggle to adhere to their treatment, which leads to relapses. The respondents, Janssen Inc. and Janssen Pharmaceutica N.V. (together, "Janssen"), developed a new dosing regimen for its long-acting injectable formulation of the drug paliperidone, which proved effective to help solve this problem. The patent application, which was eventually granted, made several claims, including claims for a specified dosing regimen dictating the quantity of the drug to be injected, the timing of the injections, and the frequency of the injections. Janssen commercializes the slow-release injection under the name INVEGA SUSTENNA.

[126] The appellant, Pharmascience Inc., challenges the patent on the basis that the dosing regimen does not constitute patentable subject matter, asserting that it amounts to a method of medical treatment ("MMT"), long recognized in Canada as falling outside the scope of patentable subject matter. This bar on patentability is what we refer to as the "MMT doctrine".

[127] The MMT doctrine has been the subject of scrutiny since its genesis. One author summarized its main criticisms as follows: "Not only is the legal basis for the

prohibition tenuously reasoned and the policy rationale for it controversial, the application of the prohibition by Patent Examiners, the Commissioner of Patents and the courts is often unpredictable or illogical" (M. S. Wilke, "Prohibiting Medical Method Patents: A Criticism of the Status Quo" (2011), 9 *C.J.L.T.* 209, at p. 232). This appeal requires the Court to determine whether dosing regimens are considered unpatentable MMTs. As a corollary, this Court must consider whether its decision in *Tennessee Eastman Co. v. Commissioner of Patents*, [1974] S.C.R. 111, holding that MMTs are unpatentable, should continue to apply in light of subsequent jurisprudence and amendments to the *Patent Act*, R.S.C. 1985, c. P-4. The parties agree that the appeal raises only one issue: Is Patent 2,655,335 ("335 Patent") invalid insofar as it claims an unpatentable MMT?

[128] For the following reasons, we conclude that the holding in *Tennessee Eastman* must be reconsidered. The reasoning in *Tennessee Eastman* hinged on a repealed section of the *Patent Act*. The *Patent Act* no longer contains any express or implied restrictions on the patentability of MMTs. Additionally, the *ratio* of *Tennessee Eastman* has been obscured by subsequent case law, as courts have attempted to apply an unclear, nebulous doctrine by relying on tests such as whether the use of a given invention requires the exercise of a physician's "skill and judgment" or whether a given invention constitutes a "vendible product". The principles used to determine whether the MMT doctrine applies are unworkable, lack internal coherency, and produce inconsistent results. This warrants reconsideration of the following question: Can MMTs be considered patentable subject matter? Interpreting the *Patent Act* using the

modern approach to statutory interpretation leads to the conclusion that MMTs, and dosing regimens specifically, can qualify as valid subject matter for patent protection.

[129] To be clear, these reasons do not endorse the patenting of all MMTs. Rather, these reasons recognize that MMTs are not inherently unpatentable. By removing the prohibition on patenting MMTs, we propose that the criteria for patentability set out in the *Patent Act* can filter out all subject matter that does not meet the relevant requirements. In particular, the utility criterion already operates to preclude the patentability of certain MMTs in a manner that aligns with the broader patent regime.

[130] We would dismiss the appeal.

II. Facts and Decisions Below

[131] We adopt the majority's recitation of the facts and decisions below.

III. Issues

[132] The issue on appeal is whether the 335 Patent is invalid insofar as it claims an unpatentable MMT. This raises two further questions: (1) Are MMTs unpatentable under the *Patent Act*? (2) If so, what constitutes an unpatentable MMT?

[133] Since we conclude that MMTs are patentable, it is not necessary to determine what constitutes an unpatentable MMT.

IV. Standard of Review

[134] The issues raised on appeal are pure questions of law. Therefore, correctness is the appropriate standard of review (see *Harvard College v. Canada (Commissioner of Patents)*, 2002 SCC 76, [2002] 4 S.C.R. 45, at paras. 148-50; *Housen v. Nikolaisen*, 2002 SCC 33, [2002] 2 S.C.R. 235, at para. 8).

V. Analysis

[135] We address the issues in four parts. First, we discuss the basic architecture of the patent regime as it exists in Canadian law. Second, we explain why, depending on the circumstances, MMTs can be considered patentable subject matter based on the statutory scheme and jurisprudential developments. Third, we clarify the future direction of patenting MMTs. Finally, we apply the relevant legal principles to this case.

A. *General Operation of the Canadian Patent Regime*

(1) Patents Are Wholly Statutory

[136] To contextualize this appeal, it is important to lay out the basic architecture of the Canadian patent system. Patent rights arise from statute, not common law. Guidance from this Court in *Commissioner of Patents v. Farbwerke Hoechst Aktiengesellschaft Vormals Meister Lucius & Bruning*, [1964] S.C.R. 49, at p. 57, is instructive on this point: "There is no inherent common law right to a patent. An inventor gets his patent according to the terms of the *Patent Act*, no more and no less" (see also *Apotex Inc. v. Sanofi-Synthelabo Canada Inc.*, 2008 SCC 61, [2008] 3 S.C.R. 265, at para. 12).

[137] Patent law in Canada was directly inherited from the common law of England (D. H. MacOdrum, A. McIntosh and M. Szweras, *Fox on the Canadian Law of Patents* (5th ed. (loose-leaf)), at § 1:5). Before any formal statutory framework existed, "[i]n England, the granting of a patent for an invention was an exercise of the Royal Prerogative", in which the Crown granted a monopoly to provide a patentee with exclusive rights to make, sell, or do a certain thing (*Formea Chemicals Ltd. v. Polymer Corp. Ltd.*, [1968] S.C.R. 754, at p. 759; MacOdrum, McIntosh and Szweras, at § 1:6). In Canada, our statutory scheme effectively replaced the royal prerogative, such that "the right to obtain a patent and the rights granted by a patent are wholly statutory" (MacOdrum, McIntosh and Szweras, at § 1:5). Therefore, though "the Courts have added to the fabric of patent law in Canada, the starting point for any analysis is the *Patent Act* . . ., as it read at the material time" (*Apotex Inc. v. Sanofi-Aventis*, 2013 FCA 186, [2015] 2 F.C.R. 644, at para. 34; see also *Harvard College*, at para. 145; *Synthon*

BV v. SmithKline Beecham plc, [2005] UKHL 59, [2006] 1 All E.R. 685, at paras. 57-58).

(2) The Patent Bargain

[138] The *Patent Act* works to incentivize innovation and invention through the promise of a temporally limited monopoly. The "patent bargain" is therefore a central tenet to the overarching scheme. It contemplates an inventor receiving the "reward of a time-limited monopoly of the industrial use of its invention in return for disclosing to the public the invention and its operation and use" (MacOdrum, McIntosh and Szweras, at § 1:2, citing *Pioneer Hi-Bred Ltd. v. Canada (Commissioner of Patents)*, [1989] 1 S.C.R. 1623, at p. 1636; *Consolboard Inc. v. MacMillan Bloedel (Sask.) Ltd.*, [1981] 1 S.C.R. 504, at p. 517; *Cadbury Schweppes Inc. v. FBI Foods Ltd.*, [1999] 1 S.C.R. 142, at para. 46; *Free World Trust v. Électro Santé Inc.*, 2000 SCC 66, [2000] 2 S.C.R. 1024, at para. 13; *SmithKline Beecham Pharma Inc. v. Apotex Inc.*, 2002 FCA 216, [2003] 1 F.C. 118, at para. 11; *Kirkbi AG v. Ritvik Holdings Inc.*, 2005 SCC 65, [2005] 3 S.C.R. 302; *Eli Lilly Canada Inc. v. Apotex Inc.*, 2008 FC 142, 63 C.P.R. (4th) 406, at paras. 68-72, aff'd 2009 FCA 97, 78 C.P.R. (4th) 388; *AstraZeneca Canada Inc. v. Apotex Inc.*, 2017 SCC 36, [2017] 1 S.C.R. 943 ("*AstraZeneca*"), at para. 39; *Nova Chemicals Corp. v. Dow Chemical Co.*, 2022 SCC 43, [2022] 3 S.C.R. 352, at para. 43).

[139] Patents protect inventions to ensure that those who engage in the risk of research and development receive a return on investment commensurate with the value purchasers place on the invention (see MacOdrum, McIntosh and Szweras, at § 1:2).

This stimulates the economy and advancements in research and development (see *Free World Trust*, at para. 42; *Harvard College*, at para. 185; MacOdrum, McIntosh and Szweras, at § 1:2). These considerations must also be balanced against encouraging public disclosure of inventions and, importantly for this appeal, "the desire to reduce health care costs while being fair to those whose ingenuity brought the drugs into existence in the first place" (*Bristol-Myers Squibb Co. v. Canada (Attorney General)*, 2005 SCC 26, [2005] 1 S.C.R. 533, at para. 2; see also *Harvard College*, at para. 185).

(3) Patentability Requirements

[140] To be eligible for a patent under the *Patent Act*, claims must qualify as an invention and fall within the proper subject matter. "Invention" is defined as "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" (s. 2). Embedded in the definition of "invention" is the qualification that the subject matter must be "new" and "useful" (see also *Farbwerke*, at p. 56). The requirement that the subject matter be non-obvious to a person skilled in the art is expressly stated in s. 28.3 of the *Patent Act*. Each of the individual requirements to obtain a valid patent has been the subject of significant judicial consideration, which is outside the scope of this analysis. The appellant does not challenge the trial judge's findings as to the 335 Patent's novelty, non-obviousness, and utility. Rather, it challenges the patent for lack of patentable subject matter.

[141] Accordingly, even if a claim satisfies the novelty, non-obviousness, and utility conditions, it still may not meet the s. 2 subject matter requirement. In other words, it may still fail to qualify as an art, process, machine, manufacture, or composition of matter, or as an improvement thereof, as interpreted by the relevant jurisprudence. Beyond s. 2, the *Patent Act* imposes further limits on patentable subject matter. For example, s. 27(8) states that a "mere scientific principle or abstract theorem" constitutes excluded subject matter. The common law, in interpreting the *Patent Act*, may also develop to restrict patentable subject matter. For example, MMTs, professional skills, arts or processes that lack commercial value, and higher life forms all fail for lack of patentable subject matter (see, e.g., *Tennessee Eastman*, at pp. 118-19; *Shell Oil Co. v. Commissioner of Patents*, [1982] 2 S.C.R. 536, at pp. 554-55; *Apotex Inc. v. Wellcome Foundation Ltd.*, 2002 SCC 77, [2002] 4 S.C.R. 153, at paras. 49-50; *Harvard College*, at para. 155; *Monsanto Canada Inc. v. Schmeiser*, 2004 SCC 34, [2004] 1 S.C.R. 902, at para. 133; Wilke, at p. 211; MacOdrum, McIntosh and Szweras, at § 3:8; S. J. Perry and T. A. Currier, *Canadian Patent Law* (5th ed. 2024), at ¶6-8).

[142] The Commissioner of Patents is required to grant a patent for an invention upon an application meeting the appropriate requirements (see *Patent Act*, s. 27(1)). Every patent issued under the seal of the Patent Office will be presumed valid in the absence of any evidence to the contrary (see s. 43(2)). The burden therefore rests on the challenger of a claim to show otherwise (see D. Cayne, "The Presumption of Validity in Canadian Patent Law" (1968), 14 *McGill L.J.* 726). The Commissioner of

Patents does not retain any discretion to refuse a patent for public policy reasons independent of an express provision in the *Patent Act* (see *Harvard College*, at para. 144).

B. *MMTs Can Qualify as Patentable Subject Matter Under the Patent Act*

[143] As we will explain, the present state of Canadian law is that MMTs are inherently unpatentable (see generally *Tennessee Eastman*). Any reconsideration of their patentability engages tension between two competing factors. On the one hand, the development of new legal rules implicating major public policy considerations and the reconciliation of competing societal interests lies chiefly with the legislature. On the other hand, at issue is a legal principle that has become so anomalous that its elimination would strengthen the logical and normative coherence of the law (see *Apotex Pty. Ltd. v. Sanofi-Aventis Australia Pty. Ltd.*, [2013] HCA 50, 253 C.L.R. 284, at para. 44).

[144] In deciding whether to overrule one of the Court's precedents, we must balance the competing values of certainty and correctness (see *Canada (Attorney General) v. Bedford*, 2013 SCC 72, [2013] 3 S.C.R. 1101, at para. 47; *Canada v. Craig*, 2012 SCC 43, [2012] 2 S.C.R. 489, at para. 27). In our view, balancing these values compels the conclusion that MMTs should no longer be considered inherently unpatentable subject matter. We are not recognizing that *all* MMTs are *automatically* patentable. Rather, we are expressly recognizing that a blanket prohibition on MMTs should no longer exist. This is because the legal foundations of *Tennessee Eastman*

have significantly eroded and its *ratio* has proven unworkable, undermining core tenets of *stare decisis*: legal certainty and predictability (see *John Howard Society of Saskatchewan v. Saskatchewan (Attorney General)*, 2025 SCC 6, at para. 33; *Canada (Minister of Citizenship and Immigration) v. Vavilov*, 2019 SCC 65, [2019] 4 S.C.R. 653, at paras. 18-22; *R. v. Kirkpatrick*, 2022 SCC 33, [2022] 2 S.C.R. 480, at paras. 207-12, 217-21 and 233-44, per Côté, Brown and Rowe JJ., concurring).

[145] *Tennessee Eastman* is over 50 years old. Developments arising out of the medical and pharmaceutical fields are rapid, complex, continually evolving, and have exposed the inconsistencies in MMT jurisprudence. In short, the MMT doctrine is no longer fit for its purpose. Support for this conclusion will be discussed in four parts. First, we will analyze this Court's seminal decision in *Tennessee Eastman* and chart subsequent jurisprudential developments that support its reconsideration. Second, we will examine the tenuous legal underpinnings of the MMT doctrine advanced in the Exchequer Court's decision in *Tennessee Eastman*. Third, we will discuss the inconsistent policy rationales justifying the MMT doctrine's continued existence. Finally, we will apply the modern approach to statutory interpretation to conclude that an MMT can be the proper subject matter of a patent.

(1) *Tennessee Eastman* Must Be Re-Examined

[146] *Tennessee Eastman* stands for the proposition that MMTs are not patentable. One basis for this conclusion was the now-repealed s. 41 of the *Patent Act*. Since the repeal of this provision in 1993, this Court has never directly considered

whether there is still a valid reason to exclude MMTs from patentability. This appeal allows us to consider this question anew, which requires a brief analysis of *Tennessee Eastman*.

[147] Before turning to the substance of this appeal, we wish to briefly respond to two general criticisms expressed by our colleague concerning our approach.

[148] First, our colleague opposes our re-examination of the MMT doctrine and *Tennessee Eastman* on the ground that "no party to this appeal asked this Court to overrule any of its precedents" (reasons of Jamal J., at para. 111). While we agree that, as a general rule, the Court should refrain from overruling a precedent without having been asked to do so by a party (see *R. v. McGregor*, 2023 SCC 4, [2023] 1 S.C.R. 198, at para. 23), the question of whether *Tennessee Eastman* should be overruled was the subject of full submissions by the parties in this case. Our colleague recognizes this at the outset of his reasons, as he notes that this Court was "invited to disrupt this settled law" based on Janssen's submissions (see reasons of Jamal J., at para. 3). In its factum, Pharmascience recognized that the patentability of MMTs was a live issue before the Court and put forth extensive arguments on the matter (A.F., at paras. 2-3 and 53-105). Further, Pharmascience stated that *Tennessee Eastman* remains good law (para. 58). For its part, Janssen clearly urged this Court to conclude that, in light of the repeal of s. 41 of the *Patent Act*, there is no longer any foundation for maintaining a general prohibition on the patentability of MMTs (R.F., at paras. 10, 38 and 41-57). As well, four interveners argued that continued reliance on *Tennessee Eastman* and its progeny

is incorrect (see I.F., International Federation of Intellectual Property Attorneys, at paras. 7 and 30; I.F., Canadian Organization for Rare Disorders, at paras. 14-20; I.F., Innovative Medicines Canada and BIOTECanada, at paras. 11-25; *contra* I.F., Canadian Generic Pharmaceutical Association, at paras. 12-19). In its reply factum, Pharmascience reasserted its submission that *Tennessee Eastman* should not be overruled (paras. 13-23). Accordingly, we are squarely within our role in re-examining this Court's previous decision in *Tennessee Eastman*.

[149] Second, our colleague challenges our conclusion on the basis that the federal courts have consistently refined the MMT doctrine over time (reasons of Jamal J., at para. 110). However, as we will explain in greater detail, the federal courts have never substantively re-examined the principle established in *Tennessee Eastman*, considering themselves bound by the rules of vertical *stare decisis*. The fact that "[n]o court at any level has ruled" that MMTs are no longer unpatentable, or that "the federal courts have consistently affirmed that methods of medical treatment are unpatentable under Canadian law", as our colleague points out, is therefore unsurprising (reasons of Jamal J., at paras. 2 and 65).

[150] The MMT doctrine has been described by the federal courts as deserving "deep analysis" and "full consideration" from this Court (*Hospira Healthcare Corp. v. Kennedy Trust for Rheumatology Research*, 2020 FCA 30, at para. 53; *Cobalt Pharmaceuticals Co. v. Bayer Inc.*, 2015 FCA 116, 131 C.P.R. (4th) 99, at para. 101; see also trial reasons, 2022 FC 1218, 198 C.P.R. (4th) 329, at para. 161; *Hoffmann-La*

Roche Ltd. v. Sandoz Canada Inc., 2021 FC 384, 185 C.P.R. (4th) 167, at para. 195; *Janssen Inc. v. Teva Canada Ltd.*, 2020 FC 593, at para. 143; *Hospira Healthcare Corp. v. Kennedy Trust for Rheumatology Research*, 2018 FC 259, at para. 141). As some authors state, "[t]he law [in this domain] appears ripe for further evolution" (Perry and Currier, at ¶6-119).

[151] In this context, it is difficult to see how judicial consensus can serve as a justification for declining to engage substantively with the MMT doctrine. It does not preclude this Court from questioning the prohibition, recognizing its logical inconsistencies, and charting a responsive path forward.

[152] Having made these general observations, we now examine *Tennessee Eastman* and subsequent jurisprudence.

(a) *The Reasoning in Tennessee Eastman Hinged on a Repealed Provision of the Patent Act*

[153] The Tennessee Eastman Company discovered a new and non-obvious use for certain known compounds. These compounds were particularly effective in bonding the surfaces of incisions or wounds in living tissue. The company applied for a patent claiming the *use* of the compound as an adhesive for bonding or joining living tissues. In other words, the Tennessee Eastman Company attempted to patent a surgical method (p. 112).

[154] The patent examiner rejected the application for lack of patentable subject matter, noting that "medical or surgical processes are not involved in commerce, trade and industry and are therefore outside the scope of a process which fall [*sic*] under Section 2(*d*) of the Patent Act" (p. 114). This decision was upheld by the acting Commissioner of Patents, and later by the Exchequer Court. After a thorough review of the jurisprudence, Kerr J. concluded:

> . . . the method here does not lay in the field of the manual or productive arts nor, when applied to the human body, does it produce a result in relation to trade, commerce or industry or a result that is essentially economic. The adhesive itself may enter into commerce, and the patent for the process, if granted, may also be sold and its use licensed for financial considerations, but it does not follow that the method and its result are related to commerce or are essentially economic in the sense that those expressions have been used in patent case judgments. The method lies essentially in the professional field of surgery and medical treatment of the human body, even although it may be applied at times by persons not in that field. Consequently, it is my conclusion that in the present state of the patent law of Canada and the scope of subject-matter for patent, as indicated by authoritative judgments that I have cited, the method is not an art or process or an improvement of an art or process within the meaning of s. 2(*d*) of the *Patent Act*. [Emphasis added.]
>
> (*Tennessee Eastman Co. v. Commissioner of Patents* (1970), 62 C.P.R. 117 (Ex. Ct.), at pp. 154-55)

[155] Since the claimed method did not relate to commerce, but rather to the professional field of surgery and medical treatment of the human body, the Exchequer Court deemed it unpatentable for lack of subject matter falling within the ambit of the definition of "invention" at s. 2(*d*) of the *Patent Act*, R.S.C. 1952, c. 203.

[156] This Court, in an opinion authored by Pigeon J., reached the same conclusion. Pigeon J. reasoned that the claims in question were limited to a method of treatment through the use of a substance and thus did not disclose patentable subject matter. The use of the adhesive for bonding tissues could not be considered a "process" within the meaning of the *Patent Act*. However, the rationale advanced in support of this conclusion was different than that of the Exchequer Court: Pigeon J. concluded that the now-repealed s. 41 of the *Patent Act* prohibited the patenting of MMTs and of surgical methods (pp. 118-19).

[157] Section 41 was enacted for the purpose of restricting the scope of patents "relating to substances prepared or produced by chemical processes and intended for food or medicine" (*Tennessee Eastman*, at pp. 118-19). Section 41(1) provided that in those cases, "the specification shall not include claims for the substance itself, except when prepared or produced by the methods or processes of manufacture particularly described and claimed or by their obvious chemical equivalents". Under s. 41, patents were issued not for the chemical compound or the medicine itself, but for the method used to produce the compound. Consequently, patent protection applied to the product only when it was manufactured using the patented process (Library of Parliament, *Patent protection for pharmaceutical products*, Background Paper BP-354E (November 1993), at p. 5). In other words, s. 41 made it impossible to patent a medicine *per se* (see *Parke, Davis & Co. v. Fine Chemicals of Can. Ltd.*, [1959] S.C.R. 219, at pp. 222-23).

[158] Pigeon J. considered, in brief reasons, whether a method of medical or surgical treatment could be claimed as an invention, stating:

> In the case of a drug, the desirable effects must be ascertained as well as the undesirable side effects. The proper doses have to be found as well as methods of administration and any counter-indications. May these therapeutic data be claimed in themselves as a separate invention consisting in a method of treatment embodying the use of the new drug? I do not think so, and it appears to me that s. 41 definitely indicates that it is not so. [Emphasis added; p. 118.]

[159] Pigeon J. reasoned that the text of s. 41(1) necessarily implied that the therapeutic use of a substance "cannot be claimed by a process claim apart from the substance itself" (p. 119). Otherwise, the inventor could easily circumvent the restriction in s. 41(1) and functionally patent a medicine by claiming protection for its therapeutic use regardless of the method used to prepare it (p. 119). Accordingly, s. 41(1) prevented the patenting of MMTs, including surgical methods. Pigeon J.'s reasoning can be distilled as follows:

1. Section 41(1) of the *Patent Act* prohibits the patenting of a substance *per se* if that substance is intended for medicine;

2. This prohibition necessarily implies that the therapeutic use of such a substance cannot be claimed as a process, as this would amount to circumventing the prohibition on patenting a substance;

3. If the therapeutic use of such a substance cannot be patented as a process, then MMTs are logically not patentable; and

4. If MMTs are not patentable, then surgical methods are not patentable either.

[160] We note that although Pigeon J. appeared to be of the opinion that an MMT was not an invention within the meaning of the *Patent Act*, notwithstanding s. 41 (*Tennessee Eastman*, at pp. 118-19), he did not offer any explanation for his opinion. Accordingly, the *ratio decidendi* of Pigeon J.'s reasons in *Tennessee Eastman* is inextricably linked to the statutory language of s. 41(1) (see *Wellcome*, at para. 49; *Harvard College*, at para. 145; A. S. Ross, "Methods of Medical Treatment: A Second Opinion" (2005), 22 *C.I.P.R.* 187, at pp. 187-92). Case in point, after reviewing foreign decisions cited by counsel, Pigeon J. wrote: ". . . I fail to see anything that would tend to overbear the implication of s. 41(1) with respect to the exclusion of a surgical or medical method *per se* from the area of patentable process" (p. 121 (emphasis added)).

[161] While Pigeon J. acknowledged that MMTs are unpatentable by virtue of s. 41, his brief comment regarding whether such methods are encompassed by the definition of "invention" was made in *obiter*. Moreover, Pigeon J.'s reasoning does not tie the MMT prohibition to the definition of "art" or "process" generally, but rather makes such a conclusion with reference to s. 41.

[162] In our view, the precedential value of *Tennessee Eastman* is doubtful. We do not share our colleague's view that it is unclear whether this Court's reasoning rests on s. 41 (see reasons of Jamal J., at para. 53). Indeed, considering the fact that patents are creatures of statute, it is incontrovertible that s. 41 was the central guidepost driving the Court's conclusion that MMTs are unpatentable. Pigeon J.'s analysis, on which rests his conclusion that MMTs are not patentable, is no longer applicable to the modern statutory patent scheme nor aligned with this Court's subsequent jurisprudence.

[163] We also do not share our colleague's view that "nothing turns on parsing *Tennessee Eastman*" (reasons of Jamal J., at para. 45). On the contrary, it is *necessary* to question the reasoning underpinning *Tennessee Eastman* in analyzing the substantive merits of the MMT doctrine because it has not been the subject of direct challenge to this Court since the repeal of s. 41. Finding justification for the MMT doctrine in the unpatentability of professional skills, as our colleague suggests, does not align with this Court's reasoning in *Tennessee Eastman*.

(b) *Judicial Consideration of Tennessee Eastman and the Development of the MMT Doctrine*

[164] Since its ruling in *Tennessee Eastman*, this Court has commented on the prohibition on patenting MMTs on three occasions. To a certain extent, these cases appear to revive the reasons of the Exchequer Court in *Tennessee Eastman*, but they do not directly engage with the patentability of MMTs and are therefore of limited guidance.

[165] To be clear, our analysis does not seek to overrule several of this Court's precedents since *Tennessee Eastman* (see, e.g., reasons of Jamal J., at paras. 110-11). The thrust of the following analysis is a discussion of the jurisprudential evolution of the MMT doctrine. As we will explain below, the MMT doctrine was not squarely before this Court in the three instances in which it has been commented on since *Tennessee Eastman*, but was only the subject of *obiter* comments.

(i) *Shell Oil*

[166] In *Shell Oil*, the Court put a gloss on the reasoning in *Tennessee Eastman*. The appellant claimed the use of a known substance for the regulation of plant growth as an "art". The jurisprudential development from this case stems from the Court's confirmation that the new use of a known substance can be patentable.

[167] Writing for the Court, Wilson J. described *Tennessee Eastman* as affirming "that 'art' was a word of very wide connotation and was not to be confined to new processes or products or manufacturing techniques but extended as well to new and innovative methods of applying skill or knowledge provided they produced effects or results commercially useful to the public" (p. 554). The analysis in *Shell Oil* tethers the idea of patenting professional skills or methods to commercial use. In doing so, Wilson J. cited *Lawson v. Commissioner of Patents* (1970), 62 C.P.R. 101 (Ex. Ct.), noting that in that case, the patent was rejected because it related to professional skills rather than to trade, industry, or commerce (p. 555). In applying these rationales, Wilson J. contrasted the newly discovered means of regulating the growth of plants with the claim

in *Tennessee Eastman*. The former had economic value in the field of trade, industry, and commerce, but the latter, according to the Exchequer Court in *Tennessee Eastman*, was non-economic and unrelated to trade. It was instead related to professional skills (pp. 554-56).

[168] Thus, in *Shell Oil*, the Court did not squarely engage with the question of whether there was a general prohibition on patenting MMTs. It merely referred to the Exchequer Court's reasoning in *Tennessee Eastman* to illustrate that a new use for a known substance can be patentable, provided it has economic value in trade, industry or commerce.

(ii) *Wellcome* and *Harvard College*

[169] *Tennessee Eastman* was considered for the last time by this Court 20 years after *Shell Oil* in *Wellcome* and *Harvard College*, two decisions released concurrently in 2002. *Harvard College* dealt with the patentability of higher life forms. Bastarache J., writing for the majority of the Court, referred to *Tennessee Eastman* when discussing whether the Commissioner of Patents had any discretion to refuse a patent solely on the basis of public policy concerns (paras. 143-45). In concluding that the Commissioner did not, Bastarache J. noted that while *Tennessee Eastman* presumably excluded MMTs from patentability with policy concerns in mind, their exclusion was based primarily on the former s. 41 of the *Patent Act* (para. 145). Noting that courts have excluded certain categories of invention from patentability with policy concerns in mind, he stressed that such exclusions from patentability "were justified by reference

to explicit provisions of the *Patent Act*" (para. 145). Neither the majority nor the dissenting reasons in *Harvard College* addressed the validity of *Tennessee Eastman*'s prohibition on patenting MMTs.

[170] *Wellcome* dealt with the patentability of a new therapeutic use of a known chemical compound, AZT, for the treatment of HIV and AIDS. The patentability of MMTs generally was not a live issue in that case. The issues in *Wellcome* mainly pertained to clarifying concepts such as inventorship and utility. There was no serious challenge to the patentability of the subject matter, and the Court noted that the argument "that the patent was invalid as seeking to monopolize a method of medical treatment contrary to *Tennessee Eastman* . . . was rightly rejected" in the courts below (para. 49).

[171] Binnie J., writing for the Court, remarked that even though *Tennessee Eastman* was decided in light of the former s. 41 of the *Patent Act*, the policy rationale for concluding that the MMTs were not patentable was that the claim was "essentially non-economic and unrelated to trade, industry, or commerce. It was related rather to the area of professional skills" (para. 49, citing *Shell Oil*, at p. 554). Binnie J. added that the patent in question did not seek to "fence in" an area of medical treatment: *how* and *when* the substance was to be employed was left to the professional skill and judgment of medical professionals (para. 50).

[172] The Court in *Wellcome* seemingly accepted that, per *Tennessee Eastman*, subject matter that "fences in" an area of medical treatment where professional skill

and judgment are required cannot be patented. However, this discussion was incidental, as the AZT patent was aimed at fencing in a new use for a known compound, which was clearly patentable subject matter in light of *Shell Oil*. Binnie J. did not discuss the validity of the *Tennessee Eastman* ruling and, interestingly, implicitly overruled Pigeon J.'s reasoning that the therapeutic use of a substance was a form of MMT (see para. 159 above).

[173] We are of the view that *Wellcome* introduced a shift: what *Shell Oil* described as the rationale behind the broad prohibition on patenting MMTs appears to have transformed into the test for determining what constitutes an MMT. In other words, the question in *Wellcome* was not whether the effect of the claimed "art" or "process" was the treatment of a medical condition (which would have led to the conclusion that the use of AZT to treat HIV/AIDS was unpatentable per *Tennessee Eastman*), but rather whether the "art" or "process" related in some measure to the professional skill and judgment of a medical practitioner. With time, the law evolved from a blanket prohibition against MMTs towards a prohibition focusing on whether the claimed subject matter requires the exercise of professional skill and judgment (see Perry and Currier, at ¶6-119; see also D. Vaver, *Intellectual Property Law: Copyright, Patents, Trade-marks* (2nd ed. 2011), at p. 317). As we explain below, this shift in framing coloured subsequent lower court jurisprudence and added complexity to the MMT analysis.

[174] We also note, parenthetically, that our colleague draws on *Monsanto* as a pronouncement from this Court that MMTs are unpatentable subject matter (reasons of Jamal J., at para. 63). While this is true on the face of the judgment, our colleague draws on a dissenting opinion. The majority does not engage with MMTs, as the doctrine was not in issue in that appeal. Moreover, the persuasive thrust of *Monsanto* is limited, as the quoted paragraph simply rearticulates prior precedent regarding subject matter that is excluded under the patent regime without engaging in any substantive analysis (see para. 133, per Arbour J., dissenting in part).

(iii) Federal Court Decisions

[175] The federal courts have taken the position that this Court has, through *Shell Oil*, *Harvard College* and *Wellcome*, maintained the exclusion on patenting MMTs on the grounds advanced by the Exchequer Court in *Tennessee Eastman* (see C.A. reasons, 2024 FCA 23, at para. 22; *Hospira* (F.C.A.), at paras. 48-50; *Novartis Pharmaceuticals Canada Inc. v. Cobalt Pharmaceuticals Co.*, 2014 FCA 17, 459 N.R. 17, at paras. 2-3; see also *Imperial Chemical Industries Ltd. v. Commissioner of Patents*, [1986] 3 F.C. 40 (C.A.), at pp. 47-50).

[176] Patent law commentators appear to widely accept, often in light of the federal courts' jurisprudence, that the prohibition on patenting MMTs has survived the repeal of s. 41 of the *Patent Act*, specifically seizing upon the notion of professional skill and judgment to justify the inherent unpatentability of MMTs (see Perry and Currier, at ¶¶6-110 to 6-122; D. P. Clarizio et al., *Hughes & Woodley on Patents* (2nd

ed. (loose-leaf)), at § 5; see also § 7; R. H. Barrigar and A. M. Shaughnessy, *Canadian Patent Act Annotated* (2nd ed. (loose-leaf)), at § 2:19; A. M. Blanchard, *Life Sciences Law in Canada* (2nd ed. (loose-leaf)), at § 6:6; MacOdrum, McIntosh and Szweras, at § 3:31; B. Stratton, *Annotated Patent Act* (loose-leaf), at § 2:32; E. F. Derényi, "Patents", in S. C. McCormack, ed., *Intellectual Property Law of Canada* (2nd ed. 2010), 307, at pp. 338-39). While our colleague similarly points to this being the predominant view (see reasons of Jamal J., at para. 44), our reasons below explain why the foundations of the MMT doctrine have eroded and no longer justify its continued application.

[177] Although *obiter* comments in *Shell Oil*, *Harvard College* and *Wellcome* warrant careful consideration, they do not resolve nor engage with the question before this Court on appeal: Since s. 41 of the *Patent Act* has been repealed, is the prohibition against patenting MMTs still fit for its purpose?

[178] There has been no definitive pronouncement on the test to determine whether a challenged subject matter is an MMT. However, a few central themes surface when analyzing the case law and academic commentary. Generally, an MMT analysis can hinge on whether the process: "fences in" an area of medical treatment (*Wellcome*, at para. 50); "impedes" physicians in the practice of their profession (*Harvard College*, at para. 145); "teaches" professional skills (*Visx Inc. v. Nidek Co.* (1999), 3 C.P.R. (4th) 417 (F.C.T.D.), at para. 173, aff'd 2001 FCA 215, 16 C.P.R. (4th) 251); "constrains" a medical professional in their exercise of skill (*Hospira* (F.C.A.), at para. 52);

"prevent[s] or restrict[s]" the application of a physician's skill and judgment (*Hoffmann-La Roche*, at para. 195); "requires" the exercise of skill and judgment (C.A. reasons, at para. 37); "substitutes" for clinical skill and judgment, as opposed to a process that enables medical practitioners in their practice (N. Lipkus and M.-C. Albanese, "Patentability of New and Useful Arts in Canada: In Need of New and Useful Doctrine?" (2011), 27 *C.I.P.R.* 61, at p. 98); is not a vendible product (*Hospira* (F.C.A.), at para. 51); or concerns the human body and falls within that unique relationship between the healthcare professional and the patient (M. Goudreau, "Brevetabilité, traitement médical et ordre public social" (2008), 67 *R. du B.* 77, at para. 79).

[179] Each of these tests has slightly different requirements, and the case law is largely unclear on how to apply them, thus leading to inconsistent results, as the Federal Court has observed several times (see trial reasons, at para. 161; *Hoffmann-La Roche*, at para. 195; *Teva Canada*, at para. 143; *Hospira* (F.C.), at para. 141). Absent clear guidance from this Court, the prohibition on patenting MMTs is "unstable" (Vaver, at p. 317).

[180] We conclude that *Tennessee Eastman* must be re-examined. In so doing, we will examine the Exchequer Court's reasons in *Tennessee Eastman* to highlight how the prohibition on patenting MMTs came to be in Canada and explain why a cogent rationale for the MMT doctrine no longer exists.

(2) The Exchequer Court's Decision in *Tennessee Eastman* No Longer Provides a Cogent Rationale for the Exclusion of MMTs From Patentability

[181] As mentioned earlier, this Court has tangentially commented on the prohibition on patenting MMTs on three occasions. Each time, there was an apparent inclination toward adopting the reasoning of the Exchequer Court that MMTs are not patentable because (1) their results are not related to trade, industry or commerce and (2) they lie in the *professional* field of medical treatment. In the following section, we will clarify how the Exchequer Court came to adopt these two rationales and explain why its reasoning requires re-examination.

(a) *Rationale 1: Treatment of the Human Body Is Not Commercial*

[182] As Kerr J. highlighted in *Tennessee Eastman*, early in the development of patent law in England, it was accepted that a process could be patented only if it was "a vendible product", i.e., if it could "be used in making something that is, or may be, of commercial value" (p. 130). Concurrent with the "vendible product" concept was the idea that a process aimed at treating the human body could not be considered patentable subject matter because it did not produce anything of commercial value (see *Tennessee Eastman* (Ex. Ct.), at p. 130; see also H. Cunynghame, *English Patent Practice* (1894), at pp. 42-43; T. Piper, "A Common Law Prescription for a Medical Malaise", in C. W. Ng, L. Bently and G. D'Agostino, eds., *The Common Law of Intellectual Property* (2010), 143, at p. 144).

[183] The MMT doctrine was first officially recognized as a common law rule in *C. & W.'s Application, Re* (1914), 31 R.P.C. 235 (cited by Kerr J., at pp. 130-32), an appeal that concerned the refusal to grant a patent for a process designed to extract lead from the human body and that was heard in the United Kingdom by the Solicitor General (see Piper, at p. 144; T. Martin, "Patentability of Methods of Medical Treatment: A Comparative Study" (2000), 82 *J.P.T.O.S.* 381, at pp. 411-12). It was found that "[s]o far as human beings are concerned, it cannot be suggested that the extraction of lead from their bodies is a process employed in any form of manufacture or of trade, though the human being may be a better working organism when the lead is extracted" (*C. & W.'s Application*, at p. 236).

[184] To better understand how the "vendible product" concept interacts with the prohibition on patenting MMTs, it is worth briefly examining *National Research Development Corp. v. Commissioner of Patents* (1959), 102 C.L.R. 252, at pp. 269-77, a ruling of the High Court of Australia on which Kerr J. heavily relied. The High Court conducted a thorough review of the case law pertaining to the notion of a "vendible product" and concluded that a process is patentable if (1) its new and useful effect can be observed (the "product" requirement) and (2) it is of utility in practical affairs (the "vendible" requirement). At common law, an MMT was considered unpatentable because, even though the effect of the process — the healing of the human body — could be observed, and even if it could have commercial value for the patentee, it was not considered to have utility in practical terms (*National Research Development*, at

pp. 275-76; see also *Maeder v. Busch* (1938), 59 C.L.R. 684 (H.C.A.), at p. 706, also cited by Kerr J.).

[185] In sum, the process for healing the human body is not "vendible", as the improved functioning of a human organism has nothing to do with trade (see *Apotex Pty. Ltd.*, at para. 93, per Hayne J., dissenting). The emphasis is not on the economic value of the process itself, but on the economic value of the *effects* or *consequences* of the process, which are deemed to be outside the realm of trade and commerce (see *Apotex Pty. Ltd.*, at paras. 87-88, per Hayne J., dissenting).

[186] This is precisely how Kerr J. reasoned in *Tennessee Eastman*, observing that the bonding method could have commercial value for the patentee, but that it was nevertheless unrelated to commerce, and therefore could not be the subject matter of a patent (pp. 154-55).

[187] However, in light of more recent case law, it can no longer be said that a method (or, in the *Patent Act*'s terminology, an "art" or "process" (see *Tennessee Eastman* (S.C.C.), at pp. 116-17)) aimed at healing the human body is not patentable because its effect has no commercial application or economic value. Indeed, this approach has become obsolete given the recognition of the patentability, as an "art", of the use of a known substance for treating the human body.

[188] Recall that in *Shell Oil*, a new use for a known compound was found to be an "art" within the meaning of the *Patent Act* because it was an application of "new

knowledge to effect a desired result which has an undisputed commercial value" (p. 549 (emphasis added)). This phrasing echoes the "vendible product" doctrine, tying the patentability of an "art" to the commercial value of its result. In *Wellcome*, a similar issue was raised, but this time, it was whether a new use for a known drug — the use of AZT to treat HIV/AIDS — could be patented as an art. The Court, relying on *Shell Oil*, stated that unrecognized therapeutic properties can constitute a patentable new use for a known substance (para. 48). It pointed out that the patent did not attempt to claim a monopoly on an MMT, but instead was related to trade, industry, or commerce, as it was aimed at providing the drug as a commercial offering (para. 50). Reading *Shell Oil* and *Wellcome* together necessarily leads to the conclusion that using a known drug for a new use, such as curing a disease, has commercial value and may thus constitute an "art".

[189] The outcome in *Wellcome* would have been different had the Court strictly applied the Exchequer Court's reasoning in *Tennessee Eastman*, as it was implicitly endorsed in *Shell Oil*. Indeed, the following conclusion would have been unavoidable: using AZT to treat HIV/AIDS is not patentable, since its practical effects are aimed at healing the human body, which has no commercial application. *Wellcome* marks an important departure from the Exchequer Court's reasoning in *Tennessee Eastman*: what was once considered unrelated to commerce, even though it could be embodied in a commercial product (i.e., an art that treats the human body), can now be considered related to commerce and thus patentable.

[190] The reasons in *Apotex Pty. Ltd.*, a decision of the High Court of Australia, shed light on the schism between the reasoning of the Exchequer Court in *Tennessee Eastman* and that of this Court in *Wellcome*. The majority in *Apotex Pty. Ltd.* aligns with the perspective of this Court in *Wellcome*, while the dissent illustrates what would have happened had this Court applied the Exchequer Court's reasoning.

[191] *Apotex Pty. Ltd.* concerned a challenge to the validity of a patent for the use of a known drug for the treatment of psoriasis on the basis that it was an MMT (para. 1). Hayne J., dissenting, cited *National Research Development* (a case on which Kerr J. heavily relied in *Tennessee Eastman*) to conclude that an individual "is not a subject of commerce" and that "[t]he product of the process in the individual (having better health than might otherwise have been the case) cannot be sold" (para. 163). In this regard, a benefit to an individual, usually in the context of improved health, "is not a benefit that . . . can [be] turn[ed] to commercial account" (para. 163).

[192] Crennan and Kiefel JJ. in *Apotex Pty. Ltd.* adopted a different position, reasoning that it would be illogical to differentiate the economic value as between a new therapeutic product and a new use for a known therapeutic product for the purposes of patentability. The majority wrote: "It could not be said that a product claim which includes a therapeutic use has an economic utility which a method or process claim for a therapeutic use does not have" (para. 282; see also *Anaesthetic Supplies Pty. Ltd. v. Rescare Ltd.* (1994), 50 F.C.R. 1 (Austl.), at p. 18, stating that "there is no distinction in principle between a product for treating the human body and a method of treating

the human body"). The *Apotex Pty. Ltd.* majority noted that patent monopolies are just as much an appropriate reward for research into new *uses* of known substances as they are for research into new substances: "It is not possible to erect a distinction between such research based on public policy considerations" (para. 282).

[193] The differences between the two approaches in *Apotex Pty. Ltd.* shine a light on the departure *Wellcome* introduced into Canadian jurisprudence. In affirming the patentability of a new use for a known substance in *Wellcome,* this Court departed from the Exchequer Court's reasoning in *Tennessee Eastman*. Had that reasoning prevailed, the claim for the new use of AZT would have been invalid, as illustrated by the dissenting analysis in *Apotex Pty. Ltd.* Therefore, it can no longer be the case that a method aimed at healing the human body is not patentable because its effects have no commercial application or economic value.

(b) *Rationale 2: Patent Law Should Not Interfere With Professional Skills*

[194] A second rationale can be extracted from Kerr J.'s reasons. In support of his conclusion that the adhesive's surgical use was unpatentable, he pointed out that the method lay "essentially in the professional field of surgery and medical treatment of the human body" (*Tennessee Eastman* (Ex. Ct.), at p. 155). While Kerr J. provided no explanation for why this would prevent patenting a method, his comment echoes the reasoning from *Lawson,* another decision from the Exchequer Court rendered a few months earlier, which held that "professional skills are not the subject-matter of a patent" (p. 111).

[195] In *Lawson*, a patent was sought for a new method of describing the boundaries for plots of land. The Exchequer Court, again citing *National Research Development* for its discussion on the definition of "process", drew the following conclusion:

> It is obvious . . . that professional skills are not the subject-matter of a patent. If a surgeon were to devise a method of performing a certain type of operation he cannot obtain an exclusive property or privilege therein. Neither can a barrister who has devised a particular method of cross-examination or advocacy obtain a monopoly thereof so as to require imitators or followers of his methods to obtain a licence from him.
>
> It seems to me that a method of describing and laying out parcels of land in a plan of subdivision of a greater tract of land [is] the skill of a solicitor and conveyancer and that of a planning consultant and surveyor. It is an art which belongs to the professional field and is not a manual art or skill. [Emphasis added.]
>
> (*Lawson*, at p. 111, citing *National Research Development*, at p. 275.)

[196] The Exchequer Court did not provide any additional justification for this conclusion and proceeded to uphold the patent's invalidity on an unrelated ground, namely that the "art" did not produce any physical change in an object (*Lawson*, at pp. 109 and 115-16). Nevertheless, *Lawson* has been cited for the proposition that a claim directed at patenting a professional skill does not constitute patentable subject matter (see *Shell Oil*, at p. 555; MacOdrum, McIntosh and Szweras, at § 3:30).

[197] The rationale behind this principle appears to stem from concerns that patent law could prevent professionals from using the claimed skill out of fear of

infringing a patent. This echoes a traditional concern in English law. As the authors of *Intellectual Property: Patents, Copyright, Trade Marks and Allied Rights* write:

> The spectre of a single doctor reserving the performance of the most satisfactory, possibly life-saving, operation to his or her own team and extracting therefrom monopoly profits on the scale of a successful pop star seemed to put the matter beyond argument.
>
> (W. Cornish, D. Llewelyn and T. Aplin, *Intellectual Property: Patents, Copyright, Trade Marks and Allied Rights* (8th ed. 2013), at p. 231; see also Piper, at p. 143.)

[198] There is undoubtedly jurisprudential unease with the idea that patent law could allow for the monopolization of certain professional medical practices (see *Janssen Inc. v. Mylan Pharmaceuticals ULC*, 2010 FC 1123, 88 C.P.R. (4th) 359, at paras. 51-53). In *Wellcome*, the idea that a patent could not claim or "'fence in' an area of medical treatment" was advanced by this Court (para. 50). In *Harvard College*, Bastarache J. wrote that "patents on medical or surgical methods of treatment of animals, including humans, were disallowed, presumably so as not to impede physicians in the practice of their profession" (para. 145). The principle recognized by the Federal Court of Appeal in the present case is that a method that relies on professional skills is not patentable.

[199] However, we are of the view that the "interference with professional skills" justification for excluding MMTs from patentability presents insurmountable issues.

[200] Firstly, the interference justification hinges on the potential undesirable effects of patenting MMTs, rather than their patentability *per se*. While we do not take a position on whether a physician could, in practice, incur liability for infringing a patent on an MMT, we recognize that this possibility raises serious concerns (see W. Aoun and C. Massad, "Methods of Medical Treatment and (Mis)Use of an Invention: Clarifying Grant versus Scope of Patent Protection" (2025), 37 *I.P.J.* 165; G. Dworkin, "Patents Relating to Methods of Medical Treatment", in H. C. Hansen, ed., *International Intellectual Property Law & Policy* (2001), 12-1, at p. 12-20). However, it is unclear how these concerns fit into the scheme of the *Patent Act* absent express legislative guidance. In determining whether to grant a patent, the question of whether or not an invention ought to be patentable is irrelevant. What is relevant is if it fits within the definition set out in s. 2 of the *Patent Act* (see *Harvard College*, at para. 153). In that sense, the MMT doctrine "contradicts the technology-neutral, morally agnostic stance of patent law which leaves the regulation of polycentric disputes to other fora" (Piper, at p. 143).

[201] A similar justification was advanced, and rightly rejected, by the Court of Appeal of New Zealand. Currently, the New Zealand statutory patent scheme expressly provides an exclusion from patentability for MMTs (see *Patents Act 2013*, s. 16(2) and (3)), but this was not the case under previous versions of the statute (see *Patents Act 1953*). Under the previous statutory scheme, the Court of Appeal of New Zealand concluded that the jurisprudential exclusion of MMTs from patentability, in relying on the interference justification, was supported only on "policy (moral) grounds"

(*Pharmaceutical Management Agency Ltd. v. Commissioner of Patents*, [2000] 2 N.Z.L.R. 529, at para. 29; see also paras. 26-28; for similar reasoning, see *Joos v. Commissioner of Patents* (1972), 126 C.L.R. 611 (H.C.A.), at p. 623). Having "considerable sympathy for the view that individual medical practitioners should not be constrained in the practice of their art in the treatment of illness and disease by concerns . . . for patent infringement" (para. 28), the Court of Appeal nevertheless found that it could not be said, as a general rule, that MMTs did not qualify as an invention solely on policy or moral grounds.

[202] It is particularly noteworthy that in *Tennessee Eastman* (Ex. Ct.), Kerr J. was also reluctant to recognize that MMTs could be excluded from patentability merely on the basis of preventing interference with the practice of the medical profession. In addressing the interference justification, he made the following comment: ". . . if that were the only objection to . . . patentability I doubt that I would consider it to be a sufficient reason for rejection of the application for a patent" (p. 155).

[203] Secondly, asserting that inventions that interfere with medical practice are unpatentable is difficult to reconcile with the fact that the new uses of known drugs are patentable. In *Wellcome*, this Court upheld the AZT patent, noting that "[h]ow and when, if at all, AZT is employed is left to the professional skill and judgment of the medical profession" (para. 50). These comments are particularly salient here. The AZT patent clearly had an impact on certain decisions a physician would make. Indeed, the holder of the patent had an exclusive right to *use* AZT to treat HIV/AIDS. If one follows

the interference justification for the exclusion of MMTs from patentability, then physicians could not use AZT to treat HIV/AIDS without having a licence from the patent holder. Nevertheless, this Court found that the patent did not interfere with the professional skill and judgment of medical professionals and was therefore patentable (para. 50).

[204] We also note that certain methods of diagnosis are patentable under Canadian law, despite the diagnosis of disease striking at the heart of medical practice (see Perry and Currier, at ¶6-116; see also MacOdrum, McIntosh and Szweras, at § 3:32; S. Melnychuk, "Drug Dosage Regimes and Patent-Eligible Subject Matter in Canada" (2013), 29 *C.I.P.R.* 297, at p. 309). It is difficult to reconcile the rationale for excluding MMTs from patentability based on the interference justification with the patentability of certain diagnostic and other quasi-medical methods (see Wilke, at p. 233).

[205] It is also important to note that the policy rationale advanced by our colleague was not originally part of the reason for excluding MMTs from patentability in the Exchequer Court's decision in *Tennessee Eastman*. Our colleague states: "Professionals are already under ethical obligations to exercise their skills in their clients' best interests and to share those skills widely" (para. 59). While this policy rationale is *prima facie* compelling, it primarily represents *ex post facto* reasoning from academic commentators seeking a sound justification for the MMT doctrine's application.

[206] For these reasons, we are of the view that the two rationales on which the Exchequer Court's reasons in *Tennessee Eastman* rest no longer justify maintaining a general prohibition on patenting MMTs.

(3) Additional Policy Considerations Underpinning the MMT Doctrine

[207] Without a clear legal rationale tethered to the text of the *Patent Act*, the scope of the prohibition on patenting MMTs "remains arbitrary and uncertain" (N. Siebrasse, *What Is a "Method of Medical Treatment"?*, January 29, 2014 (online)). It is worth noting at the outset that an overreliance on policy can be symptomatic of a larger problem: a lack of cogent principles underpinning the MMT doctrine, as discussed earlier. This section will demonstrate that, as this Court warned in *Harvard College*, policy concerns cannot be the sole basis for excluding categories of invention from patentability.

(a) *Arguments in Favour of the MMT Doctrine*

[208] There has been significant debate surrounding the consequences of protecting MMTs through the patent regime. The core arguments supporting a prohibition on patenting MMTs warn that offering patent protection may: impede the free flow of information about new MMTs; deter physicians from performing unlicensed methods to avoid infringing patents; invade patients' privacy rights as a result of infringement lawsuits; increase healthcare costs; reduce access to healthcare; induce conflicts of interest in relation to choosing MMTs; and interfere with physician

autonomy (Melnychuk, at pp. 301-2, citing O. Mitnovetski and D. Nicol, "Are patents for methods of medical treatment contrary to the *ordre public* and morality or 'generally inconvenient'?" (2004), 30 *J. Med. Ethics* 470, at p. 473; T. Scassa, "Patents for Second Medical Indications and Their Potential Impact on Pharmacare in Canada" (2001), 9 *Health L.J.* 23, at p. 27; see also Martin, at pp. 383-87; Dworkin, at p. 12-1).

[209] Relatedly, Pharmascience argues that prohibiting the patenting of MMTs serves the additional purpose of tempering the "evergreening" problem that affects the pharmaceutical industry. For clarity, "evergreening" occurs when a patentee obtains successive patents for a single invention "by the expedient of obvious or uninventive additions" to "prolon[g] its monopoly beyond what the public has agreed to pay" (*Whirlpool Corp. v. Camco Inc.*, 2000 SCC 67, [2000] 2 S.C.R. 1067, at para. 37; see also *Bristol-Myers Squibb*, at para. 66; *Sanofi-Synthelabo*, at paras. 96-97; *AstraZeneca Canada Inc. v. Canada (Minister of Health)*, 2006 SCC 49, [2006] 2 S.C.R. 560, at paras. 23 and 39).

[210] As previously mentioned, our colleague has introduced a policy rationale justifying the existence of the MMT doctrine. He notes that because professionals are ethically bound to exercise professional skills in the best interests of their clients, and to disseminate those skills, they are not entitled to patent protection. This relates to the patent bargain, as professional skills are not the type of invention the *Patent Act* seeks to coax into the market (see reasons of Jamal J., at para. 59).

(b) *Arguments Against the MMT Doctrine*

[211] Some commentators respond that none of the policy rationales identified above warrant disqualifying MMTs from patentability (see Mitnovetski and Nicol, at pp. 473-74). If anything, the purposes of the *Patent Act* are best served by incentivizing research and development with respect to new medical commercial offerings. For example, in response to the argument that patenting MMTs can lead to a reluctance to perform patented methods for fear of infringement, Mitnovetski and Nicol note that there are many other restraints on a physician's practice, such as insurance, medical malpractice actions, and obtaining consent, that also create a reluctance towards certain MMTs (p. 473). Moreover, one commentator refers to the following inconsistency in the current jurisprudence:

> Furthermore, it is inconsistent that methods requiring the professional art of a medical practitioner are not patentable while methods directed to non-medical fields require the same level of specialized skill and judgment. Even methods for medically related fields can be patented, such as methods of diagnosis, methods of preventing pregnancy, methods for ameliorating adverse effects of aging, and methods for medical research. Are these medically related fields more economic or commercially useful than surgery or physiotherapy?
>
> (Wilke, at p. 233)

[212] With respect to the patentability of dosing regimens specifically, a patent for a specific range does not restrict the physician any more or less than a patent for the use of the drug or for a specific dosage (N. Siebrasse, *A Rule Without a Principle: Patentability of Methods of Medical Treatment*, January 19, 2015 (online)).

(c) *The Role of Policy in Determining the Validity of Patents*

[213] Recall that in *Harvard College*, Bastarache J. asserted that the Commissioner of Patents does not have the discretion to refuse a patent on the basis of policy concerns. At paragraph 145, he addressed the remark that Canadian courts have "excluded certain subject matter from patentability on moral, ethical or policy grounds". He noted that while some categories of invention were excluded from patentability with policy concerns in mind, the exclusions were still explicitly rooted in the *Patent Act* itself. Drawing on *Tennessee Eastman* as an example to support his analysis, Bastarache J. stated that "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*" (*Harvard College*, at para. 145 (emphasis added)).

[214] We echo the concern that it is "not an appropriate judicial function for the courts to create" and perpetuate "an exception from patentability" absent explicit guidance from Parliament (*Harvard College*, at para. 181). Indeed, "this Court does not possess the institutional competence to deal with issues of this complexity, which presumably will require Parliament to engage in public debate, a balancing of competing societal interests and intricate legislative drafting" (para. 183).

[215] Aside from our differing interpretations of *Tennessee Eastman*, we cannot agree with our colleague that the policy rationale underpinning the prohibition of MMTs is sufficient to justify the doctrine's continued existence. Simply because

"professional skills do not respond to the incentives of the patent bargain" (reasons of Jamal J., at para. 59) does not mean that this policy rationale alone is sufficient to maintain a prohibition on patenting MMTs.

[216] That is not to say that policy has no role to play in the context of the patent regime. On the contrary, Parliament integrates the delicate balancing guaranteed by the patent bargain into the *Patent Act* itself. The balancing of policy concerns is also integral to the interpretation of the legislation. However, the role of policy has limits. It is not for the courts to use policy as a tool to prevent certain subject matters from obtaining patent protection absent guidance from the legislature, especially when such express guidance was removed from the statute.

[217] Using policy as the guiding light for determining patentability breeds uncertainty and inconsistent analyses. This is evident in the context of the MMT doctrine: its application is inconsistent and creates results that are difficult to reconcile. The only unifying principle that holds together the case law to justify the doctrine's existence is the idea that patenting MMTs will interfere with a physician's ability to treat patients. This rationale, along with the others identified earlier in this section, is a conclusory assertion lacking evidentiary support, and it does not withstand close scrutiny.

(i) Solely Relying on Policy Creates Unprincipled Results

[218] The case at bar illustrates the practical impact of an overreliance on policy. Currently, there are significant practical difficulties in applying the MMT doctrine. This section explains the inconsistencies and practical limitations of the MMT doctrine, specifically with respect to dosing regimens.

1. *Practical Issues in Applying the MMT Doctrine*

[219] As previously mentioned, there has been no definitive pronouncement on the test to determine whether a challenged subject matter is an MMT. The most common references in the case law concern whether the claim attempts to patent a vendible product, which is "distinguishable from the skilled work of a physician, and hence outside the realm of methods of medical treatment" as contemplated by this Court's previous jurisprudence (C.A. reasons, at para. 26). The "vendible product" inquiry and the "skill and judgment" inquiry are explored further in this section.

[220] One of the core questions that emerges from the case law with respect to the patentability of dosing regimens is whether a dosing regimen requires individualization or adjustments, or any combination thereof. If so, then it necessarily involves a degree of skill and judgment, thereby making the dosing regimen unpatentable as an MMT.

[221] Born out of the reliance on the skill and judgment inquiry, the notion of "how and when" a drug is to be administered, as briefly alluded to in *Wellcome*, created a rift between fixed and variable dosing regimens. In our view, determining whether a

claim is an MMT based on whether it is a fixed or variable dosing regimen is tenuous. This view is underscored in *Hospira* (F.C.A.), at para. 52:

> This state of the jurisprudence has a tempting simplicity. However, it is not clear to me that the decisions of the Supreme Court of Canada that form the basis of the principle that methods of medical treatment are not patentable justify a distinction between a fixed dosage (or interval of administration) and a range of dosages (or intervals). It would seem that a medical professional will be constrained in their exercise of skill in either case. Also, a drug is arguably no less a vendible product simply because its dosage or interval of administration is not fixed.

[222] There is an attraction to using the bright-line "fixed versus variable" test to determine whether a dosing regimen is claiming an MMT, but it elevates form over substance and ignores the content of the claim itself. The truth of the matter is that dosing regimens themselves do not fit neatly into the MMT framework as it has developed.

[223] The lack of a principled approach to tie together the rationales underpinning the MMT analysis is further aggravated by the guidance offered by the Canadian Intellectual Property Office ("CIPO"). On March 18, 2015, in response to *Abbott Laboratories (Bermuda) Ltd., Re*, 2014 FC 1251, 126 C.P.R. (4th) 51, the CIPO published *Patent Notice: Revised Examination Practice Respecting Medical Uses — PN 2015-01* (online), to communicate specific instructions about how patent examiners should evaluate dosing regimens. The relevant guidance is as follows:

> Where an essential element [of a claim] only serves to instruct a medical professional "how" to treat a patient, rather than "what" to use to treat the

> patient, it must be determined whether the essential element prevents, interferes with or requires the professional skill of a physician. If the answer is "yes", this will lead to the conclusion that the claimed use encompasses a method of medical treatment that does not comply with section 2 of the *Patent Act*. [Footnotes omitted.]

The above-cited passage perpetuates reliance on the fixed versus variable dosage dichotomy.

[224] In addition to the practical difficulties that exist in applying the skill and judgment inquiry, there are also significant doctrinal difficulties that create logical inconsistencies. The problem with the MMT doctrine is one of practicality. Courts are required to determine whether a patent claims an MMT by examining its putative effects, which usually involves making arbitrary judgments. Of note, our colleague's suggested test — whether the impugned subject matter amounts to professional medical skill and judgment — encounters the same problems canvassed in this section (see reasons of Jamal J., at paras. 89-99).

[225] There are two high-level doctrinal criticisms that affect the skill and judgment inquiry. First, the skill and judgment inquiry injects a measure of uncertainty into the MMT analysis, as it creates distinctions between inconsequential skill and judgment and clinical skill and judgment without expressly recognizing such distinctions. Second, but for the invention, medical professionals would never use the patented invention in the exercise of their ordinary skill and judgment because the invention is new, non-obvious, and useful. We explain each of these criticisms below.

2. *Reliance on Skill and Judgment Breeds Arbitrary Distinctions*

[226] First, there is a dissonance in the case law in determining how much skill and judgment is *too* much, thereby taking an invention outside the realm of a valid patent and inside the prohibition on MMTs. This issue underlies the fixed versus variable dosage dichotomy, as the original line of thinking was that *any* skill and judgment involved in the use of dosing regimens (i.e., variable dosages) presupposes the conclusion that the invention is an MMT. This approach was concomitantly adopted as guidance by the CIPO, as outlined above. Professor Siebrasse illustrates this quagmire through an example:

> . . . if a patient comes in with HIV, and the physician's view is that the best treatment is 2.0 mg of AZT, the physician's skill is just as limited whether there is a patent on the use of AZT to treat HIV, or on the use of AZT in the range of 1-5 mg to treat HIV, or on the use [of] 2 mg of AZT to treat HIV. Whichever way you slice it, a patent over a range doesn't restrict the physician any more or less than a patent over the use of the drug, or over a specific dosage. [Emphasis added.]
>
> (Siebrasse (2015))

[227] We agree and find the reliance on the skill and judgment inquiry to be problematic. It is tenuous to advance patent protection for claims structured as "the use of X to treat Y" but not for claims structured as "the use of X in [the] range from A to B to treat Y" (Siebrasse (2015)). Presumably, the claim for the former cannot involve less skill and judgment than the latter, as a medical professional will need to exercise skill and judgment to determine the appropriate dosage regardless.

[228] This argument is buttressed by the idea that, to a degree, medical professionals will exercise skill and judgment in determining how and when to prescribe *any* treatment. In other words, skill and judgment are required *regardless* of whether the dosing regimen is variable, fixed, a range, or formulated in any other manner. Trying to quantify the degree of skill and judgment involved is arbitrary and formalistic.

3. *Reliance on Skill and Judgment Ignores the Nature of the Patented Invention*

[229] In terms of the second criticism, the main takeaway is that it is unconvincing to claim that a dosing regimen is within the ordinary skill and judgment of a medical professional if it had not been conceptualized before the disclosure of the patent (see Siebrasse (2015)). The facts of this case illustrate this problem. It would be difficult to say that the 335 Patent's dosing regimens restrained the exercise of a medical professional's skill and judgment despite the medical professional never having possessed the skill before the disclosure of the patent.

4. *Reliance on the Vendible Product Inquiry Is Tenuous*

[230] Finally, with respect to the vendible product inquiry, some commentators note that it is unconvincing to assert that the medical profession can be considered non-commercial (see Wilke, at p. 229; Mitnovetski and Nicol, at p. 471). Indeed, "medicine is generally practiced within a highly sophisticated commercial (and arguably

industrial) framework" in the modern day (Wilke, at p. 229). Almost any pharmaceutical invention, and many medical inventions, can be categorized as vendible products. In a sense, the vendible product inquiry is circular, as there would be no need to seek patent protection for an invention that was not commercially valuable.

[231] Furthermore, it is unclear how the skill and judgment inquiry and vendible product inquiry relate to one another in the context of the MMT analysis.

[232] The above analysis demonstrates how sole reliance on policy to justify a common law prohibition on patents leads to doctrinal confusion and creates inconsistent results. It is problematic to place continued reliance on a standard based on policy concerns that does not produce principled, or even consistently discernable, applications.

(4) The Modern Approach to Statutory Interpretation

[233] This Court has emphasized the importance of grounding the inquiry of whether subject matter is patentable in the words of the *Patent Act* (see *Harvard College*, at paras. 145 and 153). A principled reading of the *Patent Act* compels the conclusion that MMTs are not inherently unpatentable. The analysis in this section buttresses our conclusion that a general prohibition against MMTs is no longer fit for its purpose.

[234] In accordance with the modern approach to statutory interpretation, the Court must read the words of the statute "in their entire context and in their grammatical and ordinary sense harmoniously with the scheme of the Act, the object of the Act, and the intention of Parliament" (E. A. Driedger, *Construction of Statutes* (2nd ed. 1983), at p. 87, quoted in *Rizzo & Rizzo Shoes Ltd. (Re)*, [1998] 1 S.C.R. 27, at para. 21; see also *Bell Canada v. Canada (Attorney General)*, 2019 SCC 66, [2019] 4 S.C.R. 845, at para. 41). In that sense, "the meaning of a statutory provision is determined by reference to its text, context and purpose" (*Telus Communications Inc. v. Federation of Canadian Municipalities*, 2025 SCC 15, at para. 30, citing *Rizzo & Rizzo*, at para. 21, *R. v. Basque*, 2023 SCC 18, at para. 63; *Auer v. Auer*, 2024 SCC 36, at para. 64, and *Piekut v. Canada (National Revenue)*, 2025 SCC 13, at para. 42).

[235] The question we must answer is whether the terms "art" or "process", as set out in s. 2 of the *Patent Act*, are broad enough to encompass MMTs.

(a) *Text*

[236] The *Patent Act* no longer contains a textual prohibition against claims for MMTs. As previously explained, central to this Court's reasoning in *Tennessee Eastman* was reliance on the now-repealed s. 41(1) of the *Patent Act*. Nevertheless, it is useful to examine how the jurisprudence has ascribed meaning to the terms enumerated in s. 2 of the *Patent Act*.

[237] As we have discussed, patentable subject matter includes any new and useful art, process, machine, manufacture, or composition of matter, or any improvement thereof (see *Patent Act*, s. 2). An MMT is *prima facie* either a "process" or an "art" within the meaning of the *Patent Act* (see *Tennessee Eastman* (S.C.C.), at pp. 116-17; *Refrigerating Equipment Ltd. v. Waltham System Inc.*, [1930] Ex. C.R. 154, at p. 166). In *Tennessee Eastman*, at pp. 116-17, this Court explained the term "process" to mean the use of a method to obtain a given result when applied to any manufacture (see also *Commissioner of Patents v. Ciba Ltd.*, [1959] S.C.R. 378, at p. 383). The authors of *Fox on the Canadian Law of Patents* echo this definition, noting that "[a] process must consist of two elements, namely, a method or a procedure and the material or materials to which it is applied" (MacOdrum, McIntosh and Szweras, at § 3:11).

[238] *Shell Oil* provides a more precise explanation of the term "art", noting that it can be a concrete application of skill or knowledge that produces results that are commercially useful to the public (see pp. 554-56). Further, *Wellcome* confirms that an art aimed at treating a disease is commercially useful. Thus, a concrete and practical application of medical knowledge whose effect is therapeutic can *prima facie* qualify as an "art" or "process" (see E. A. Crowne-Mohammed, "The patentability of professional skills and business methods in Canada" (2010), 5 *J.I.P.L.P.* 119, at p. 120).

(b) *Context*

[239] In addition to the repeal of s. 41(1) and the *prima facie* compatibility of MMTs with the definition of "art" or "process", the *Patent Act*'s internal and external

contexts demonstrate that Parliament intended to remove the prohibition on MMTs. We point to four contextual factors that support the position that the MMT prohibition should be abandoned.

(i) The Evolution of Patents, the Canadian Pharmaceutical Industry, and Section 41 of the *Patent Act*

[240] Tracing the evolution of legislation is an integral part of Driedger's analysis of the "entire context" of a statute (see *Merk v. International Association of Bridge, Structural, Ornamental and Reinforcing Iron Workers, Local 771*, 2005 SCC 70, [2005] 3 S.C.R. 425, at para. 28). It is a trite principle that "[p]rior enactments may throw some light on the intention of Parliament in repealing, amending, replacing or adding to a statute" (*R. v. Ulybel Enterprises Ltd.*, 2001 SCC 56, [2001] 2 S.C.R. 867, at para. 33, cited in *Marche v. Halifax Insurance Co.*, 2005 SCC 6, [2005] 1 S.C.R. 47, at para. 99, per Bastarache J., dissenting, but not on this point, and *Bristol-Myers Squibb*, at para. 154, per Bastarache J., dissenting, but not on this point). In the same vein, the repeal of a provision without a corresponding replacement sends an obvious signal about Parliament's intentions. Legislation that has been repealed ceases to operate and to form part of the law (R. Sullivan, *Statutory Interpretation* (3rd ed. 2016), at p. 21). Our colleague notes that, absent clear legislative intent, "a statute should not be interpreted as substantially changing the law" (reasons of Jamal J., at para. 72, citing *R. v. D.L.W.*, 2016 SCC 22, [2016] 1 S.C.R. 402, at para. 21). Importantly, however, *D.L.W.* also advises that "[t]his principle, if applied too strictly, may lead to refusal to give effect to intended legislative change" (para. 21).

[241] Parliament's approach to patenting pharmaceuticals in the latter portion of the 20th century prioritized public policy considerations, notably by protecting access to the healthcare system through an extensive compulsory licensing regime and through the limitations of the former s. 41 of the *Patent Act*. Under s. 41, patents were only granted for the process by which a compound was made, not for the chemical compound or medicine itself (Library of Parliament, at pp. 5-6). This offered only minimal protection for pharmaceuticals, as a savvy manufacturer could find a way to create the same product by different means (pp. 5-6).

[242] However, Parliament later introduced large-scale reforms that marked a turning point for the patent scheme as it related to the Canadian pharmaceutical industry. In 1987, Parliament passed Bill C-22, known as *An Act to amend the Patent Act and to provide for certain matters in relation thereto*, S.C. 1987, c. 41, that modified s. 41(1) of the *Patent Act* and provided that it would cease to have effect four years later (s. 14). The effect of s. 41(1), which then became s. 39(1), ceased in November 1991, and the provision was officially repealed in 1993 (*Patent Act Amendment Act, 1992*, S.C. 1993, c. 2, s. 3; see *Aventis Pharma Inc. v. Mayne Pharma (Canada) Inc.*, 2005 FC 1183, 42 C.P.R. (4th) 481, at paras. 50-54). The objective of these amendments was to gradually renovate the patent regime for pharmaceuticals, thus strengthening protection for patent holders.

[243] Through this swath of new legislation, Parliament extended the term of patent protection from 17 years from the issue of a patent to 20 years from the filing of

a patent application, explicitly recognized product patents in the pharmaceutical field, established the Patented Medicine Prices Review Board to ensure that prices charged by patentees are not excessive, abolished the compulsory licensing of pharmaceuticals, and allowed the Governor in Council to make the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 ("*PMNOC Regulations*"), to provide guidance on marketing authorizations of generic drugs upon the expiry of patents for brand-name products (Library of Parliament, at pp. 5-8).

[244] In repealing s. 41(1), it is evident that Parliament did not intend to preserve a blanket prohibition on "substances prepared or produced by, or significantly derived from, microbiological processes and intended for . . . medicine", as the provision read at the time of its repeal. On the contrary, the repeal of s. 41(1) signalled Parliament's intention to rid the *Patent Act* of such a prohibition, as the amendments came at a time when Canada's pharmaceutical industry was on life support (R. A. Wilkes, "The New Canadian Patent Act" (1989), 71 *J.P.T.O.S.* 202, at p. 226). In analyzing s. 41, Robert A. Wilkes explained the political context informing the large-scale statutory amendments:

> The net result of these provisions . . . was that the Canadian pharmaceutical industry very nearly died. Similarly, the amount of pharmaceutical research being done in Canada in both the public and the private sectors became minimal. It was industry generated pressure to reverse this situation, and to remove this handicap to seeking and keeping adequate patent rights for pharmaceuticals in Canada, that generated the political will to make these changes. The changes now made are not needed at all in order to get "better" pharmaceutical patents: quite explicitly they were made with the political intent of helping to recreate a climate in which

> pharmaceutical research and an innovative pharmaceutical industry can exist once again in Canada. [p. 226]

[245] In instituting these changes to the *Patent Act* throughout the late 1980s and early 1990s, Parliament liberalized the Canadian pharmaceutical industry and rebalanced the patent scheme to be more technical rather than guided by public policy. This marked a shift where Parliament signalled its intent to cultivate Canada's pharmaceutical economy at a time when it was facing external pressures from the United States amidst free-trade negotiations, notably in the context of the *North American Free Trade Agreement*, Can. T.S. 1994 No. 2 ("*NAFTA*") (see M. Bourassa Forcier and J.-F. Morin, "Canadian pharmaceutical patent policy: international constraints and domestic priorities", in Y. Gendreau, ed., *An Emerging Intellectual Property Paradigm: Perspectives from Canada* (2008), 81, at pp. 85-86). In addition to Canada's obligations under *NAFTA*, Parliament's amendments flowed from international obligations under the *Agreement on Trade-Related Aspects of Intellectual Property Rights*, 1869 U.N.T.S. 299 ("*TRIPS*") (see *Bristol-Myers Squibb*, at para. 10).

(ii) The Broader Regulatory Regime

[246] The broader regulatory context is also relevant, as the practical function of the *PMNOC Regulations* and the Health Canada approval regime logically point to the potential patentability of MMTs in Canada.

[247] In 1993, the *Patent Act Amendment Act, 1992*, came into force. It enacted s. 55.2(1) of the *Patent Act*, which provides for an exception to infringement, known as the "early working exception", such that generic drug companies can develop generic equivalents and prepare regulatory submissions to Health Canada while patents for the reference products are still in force (MacOdrum, McIntosh and Szweras, at § 1:56).

[248] After the abolition of the compulsory licensing scheme in 1993, the Governor in Council made the *PMNOC Regulations* to prevent generic manufacturers from marketing their products until the expiry of all relevant patents (*Bristol-Myers Squibb*, at para. 46; Regulatory Impact Analysis Statement, SOR/93-133, *Canada Gazette*, Part II, vol. 127, No. 6, March 24, 1993, at p. 1388; *Merck & Co. v. Canada (Attorney General)* (1999), 176 F.T.R. 21, at para. 51). This Court has previously accepted that Parliament's intention in enacting the 1993 amendments was to "thwar[t] the possible appropriation by generic drug companies . . . of the research and development initiatives of innovators" (*Bristol-Myers Squibb*, at para. 45 (emphasis deleted), citing *Apotex Inc. v. Canada (Attorney General)*, [1994] 1 F.C. 742 (C.A.), at p. 752, aff'd [1994] 3 S.C.R. 1100).

[249] Under the *PMNOC Regulations*, the Minister of Health must maintain a register of eligible patents (s. 3(2); MacOdrum, McIntosh and Szweras, at § 1:56). Under s. 4(2) of the *PMNOC Regulations*, a patent in relation to a new drug submission is eligible to be added to the patent register if the patent contains a claim for the

medicinal ingredient, the formulation that contains the medicinal ingredient, the dosage form, or the use of the medicinal ingredient. Moreover, the Regulatory Impact Analysis Statement that accompanied amendments to the *PMNOC Regulations* specifically refers to dosing regimens as an example of a "use patent" that exists in the pharmaceutical realm (SOR/2006-242, *Canada Gazette*, Part II, vol. 140, No. 21, October 18, 2006, at p. 1517).

[250] Finally, in order to obtain approval from Health Canada to market a drug, the drug's manufacturer must provide information regarding the recommended dosage of the drug and "adequate directions for use of the drug", which is interpreted to include the recommended single and daily dose of the drug (see *Food and Drug Regulations*, C.R.C., c. 870, ss. C.01.004(1)(c)(iii), C.01.014.1(2)(j) and C.08.002(2)(k)(ii); Health Canada, *Guidance document: Labelling of pharmaceutical drugs for human use* (2024), at s. 3.5.4).

[251] Looking at the regulatory environments holistically compels a practical conclusion: a commercial offering in the context of drugs and pharmaceuticals is usually a package of both the medicine itself and the instructions for its use. On the facts of this case, Janssen was only able to obtain market authorization for INVEGA SUSTENNA after having developed *both* the paliperidone palmitate formulation and the effective dosing regimen. The manner in which the regulatory framework was crafted points to the recognition that the way in which a drug is used, specifically through a dosing regimen, is not inherently unpatentable as an MMT. Indeed, dosing

regimens are recognized in the *PMNOC Regulations*, Regulatory Impact Analysis Statement (2006), and Health Canada authorization requirements. Not only is the prohibition against patenting MMTs resting on a shaky jurisprudential foundation, but its application ignores the surrounding regulatory context.

(iii) Parliament Expressly Excludes Unpatentable Subject Matter in the *Patent Act*

[252] Where Parliament intends to exclude potential subject matter from patentability, it does so expressly. For example, s. 27(8) of the *Patent Act* specifically states that a "mere scientific principle or abstract theorem" is unsuitable for patentability. This signals that prohibitions on patentable subject matter are the concern of Parliament, not the courts.

[253] Of course, the common law may develop to restrict some subject matter from patentability when courts engage in their proper role in interpreting the *Patent Act*. For example, this Court in *Harvard College* determined that higher life forms are unsuitable for patentability. In doing so, it recognized that the courts are ill suited to create an exception from subject matter patentability (para. 181). Rather, the Court engaged in a rigorous statutory interpretation exercise, concluding that higher life forms are not patentable because they do not fall within the enumerated subject matters within the meaning of "invention" as per s. 2 of the *Patent Act*.

[254] Courts must be alive to the reality that Parliament is best suited to determine what should and should not constitute patentable subject matter. As exemplified by the application of the MMT doctrine, courts do not have the resources or expertise to make case-by-case determinations on what should constitute prohibited subject matter without any underlying statutory guidance. Now that the original statutory foundation of the MMT doctrine has been repealed, courts are using a results-oriented, patchwork approach to making sense of the MMT doctrine. This departs from the approach in *Harvard College*, as this Court rooted its analysis in the principles of statutory interpretation to reach its ultimate conclusion. Coming to principled conclusions on the interpretation of a statute is squarely within the realm of the courts — determining what constitutes patentable subject matter without statutory foundation is not.

(iv) The International Context

[255] Surveying the law of similar jurisdictions may be helpful in conducting a statutory interpretation analysis (see generally *Westmount (City) v. Rossy*, 2012 SCC 30, [2012] 2 S.C.R. 136, at para. 31; *Godbout v. Pagé*, 2017 SCC 18, [2017] 1 S.C.R. 283, at para. 64). Recourse to comparative law reveals that other similar legal systems that have chosen to prohibit the patenting of MMTs do so expressly, without relying on antiquated common law doctrine or previously repealed statutory provisions. Similarly, jurisdictions that have not opted for an express prohibition on patenting MMTs have developed practical tests for determining their patentability.

[256] Article 27(3)(a) of *TRIPS*, to which Canada is a signatory, expressly allows, but does not require, signatories to exclude "diagnostic, therapeutic and surgical methods for the treatment of humans" from patentability. Several signatories, such as the United Kingdom, New Zealand, the European Union, India, Brazil, Argentina, South Africa, and Indonesia, explicitly exclude MMTs from patentability under their patent legislation (see, e.g., *Patents Act 1977* (U.K.), 1977, c. 37, s. 4A(1); *Patents Act 2013* (N.Z.), s. 16(2); *Convention on the Grant of European Patents (European Patent Convention)*, Article 53(c); *Patents Act, 1970* (India), s. 3(*i*); Law No. 9.279 (Brazil), May 14, 1996, s. 10(VIII); Law No. 24.481 (Argentina), May 23, 1995, s. 6e); *Patents Act, 1978* (South Africa), s. 25(11); Law No. 13 of 2016 (Indonesia), s. 9(b)).

[257] While Canada has made other amendments to the *Patent Act* in light of *TRIPS*, the exclusion of MMTs has not been incorporated. For example, Bill S-17, *An Act to amend the Patent Act*, S.C. 2001, c. 10, was introduced to implement two World Trade Organization decisions that related to Canada's obligations under *TRIPS* (Library of Parliament, *Bill S-17: An Act to amend the Patent Act*, Legislative Summary LS-390E, March 1, 2001). It is evident that Parliament turned its mind to amending the *Patent Act* with a view to the express guidance in *TRIPS*. Had Parliament wished to firmly prohibit patenting MMTs, then it could have integrated a prohibition, as many other signatories have done. While it is arguable that Parliament did not see the need for such an amendment given the existence of the common law prohibition, we do not find this persuasive. The broader legislative context, and the lack of express guidance in the statute, strongly suggest otherwise.

[258] In other *TRIPS* jurisdictions where, as in Canada, no statutory exclusion of MMTs from patentable subject matter exists, MMTs are not regarded as inherently unpatentable. For example, in the United States, MMTs are generally considered patentable. Section 101 of the U.S. *Patent Act of 1952* provides: "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title" (35 U.S.C. § 101 (2024)). Excluded from this definition are "[l]aws of nature, natural phenomena, and abstract ideas" (see *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576 (2013), at p. 589).

[259] The Supreme Court of the United States has been cautious in the application of these excluded subject matters. The court balances concerns of pre-empting the monopolization of basic scientific principles, which may impede innovation rather than promote it, against the recognition that, at some level, all inventions build upon laws of nature, natural phenomena, or abstract ideas (see *Bilski v. Kappos*, 561 U.S. 593 (2010), at pp. 611-12; *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. 66 (2012), at p. 71). In this regard, the court "tread[s] carefully in construing this exclusionary principle lest it swallow all of patent law" (*Alice Corp. v. CLS Bank Int'l*, 573 U.S. 208 (2014), at p. 217).

[260] The patent scheme in the United States represents a balancing exercise that is analogous to that which exists within the Canadian patent bargain. Precedent in the

United States, however, does not rely on nebulous principles such as skill and judgment or vendible products. Rather, the question is whether a patent claims the building blocks of human ingenuity or whether it integrates those building blocks into something more (*Alice Corp.*, at p. 217; *Mayo*, at p. 89). The Supreme Court of the United States has confirmed that "a new drug or a new way of using an existing drug" is patentable subject matter per s. 101 of the U.S. *Patent Act of 1952* (*Mayo*, at p. 87). Based on this framework, U.S. federal appellate courts have "been reasonably consistent in holding that methods of medical treatment are eligible for patenting" (*INO Therapeutics LLC v. Praxair Distribution Inc.*, 782 Fed. Appx. 1001 (Fed. Cir. 2019), at p. 1015, per Newman J., concurring in part, dissenting in part, citing *Athena Diagnostics, Inc. v. Mayo Collaborative Services, LLC*, 927 F.3d 1333 (Fed. Cir. 2019), at pp. 1367-68, per Newman J., dissenting from denial of rehearing *en banc*).

[261] We referred to Australia's approach to the patentability of MMTs. Relevant to our statutory interpretation analysis is the High Court of Australia's decision in *Apotex Pty. Ltd*. Despite Australian patent legislation having been amended over 20 times since *TRIPS* came into force, there is no express statutory prohibition against patenting MMTs (see *Apotex Pty. Ltd.*, at para. 280). The High Court recognized this as a persuasive point in rejecting the proposition that MMTs are inherently unpatentable.

[262] Similarly to Canada's legislative scheme, Australia's patent legislation "contains no specific exclusion from patentability of methods of medical treatment of

the human body, nor can any be implied" (*Apotex Pty. Ltd.*, at para. 279 (emphasis added)). In noting the lack of statutory basis to prohibit MMTs from patentability, the court stated that "to construe s 18(1)(a) of the [*Patents Act 1990* (Cth.)] as excluding methods of medical treatment of the human body would be to introduce a lack of harmony between Australia and its major trading partners, where none exists at present" (para. 280). The High Court confirmed that a method of treating the human body can qualify as a patentable invention if it satisfies all ordinary patentability criteria, including being "a contribution to a useful art having economic utility" (*Apotex Pty. Ltd.*, at para. 286; see also *National Research Development*, at p. 275).

[263] In sum, it is instructive that jurisdictions outside Canada that have not opted for an express prohibition on patenting MMTs have developed practical tests for determining their patentability. In our view, in the absence of an express statutory prohibition against MMTs, a similar path commends itself in Canada.

(c) *Purpose*

[264] The central purpose of the *Patent Act* is to incentivize innovation and invention through the promise of a temporally limited monopoly (see *Nova Chemicals*, at para. 43; *Sanofi-Synthelabo*, at para. 64; *Teva Canada Ltd. v. Pfizer Canada Inc.*, 2012 SCC 60, [2012] 3 S.C.R. 625, at para. 32; *Wellcome*, at para. 37; Perry and Currier, at ¶3-1; Clarizio et al., at §1). The patent bargain is mutually beneficial: "The public benefits by receiving innovations in science and technology", and "[t]he inventor benefits because they receive a time-limited market monopoly. The inventor

can use the monopoly to generate profits and compensate themselves for the time, effort, and risk associated with making the invention" (*Nova Chemicals*, at para. 43).

[265] The *Patent Act* must be interpreted in a manner consistent with the patent bargain. Recognizing that MMTs can qualify as patentable subject matter is compatible with the patent bargain. Put inversely, a blanket prohibition on patent protection for MMTs undermines the patent bargain by creating a chilling effect on invention and innovation. Since Parliament repealed s. 41(1) of the *Patent Act*, pharmaceuticals and medicine are no longer treated differently through legislation. It follows that Parliament intended these fields to obtain the full benefit of the patent bargain. Inventing new medical methods warrants the same patent protection as other discoveries that meet the requirements of the *Patent Act*. As Janssen points out, a dosing regimen that ameliorates non-adherence with schizophrenia treatments is the type of invention that the *Patent Act* was meant to encourage and that the patent bargain was meant to incentivize (R.F., at para. 55).

[266] Unquestionably, other objectives outside of the patent bargain, such as fairness and the promotion of Canada's universal healthcare system, have formed part of Parliament's patent calculus. However, the recognition that MMTs are not inherently unpatentable, and must be scrutinized in the same manner as other scientific inventions, does not undercut Parliament's objective to promote Canada's healthcare system. Not only does the regulatory scheme include careful measures to prevent excessive drug prices — through the Patented Medicine Prices Review Board, for example —, but

there is also a lack of persuasive evidence demonstrating that removing the prohibition on MMTs would create fractures in the healthcare system. With the shift in liberalizing the pharmaceutical landscape through the *Patent Act*, Parliament signalled a concomitant shift in the way pharmaceutical patents should be treated. Perplexingly, Canadian jurisprudence does not demonstrate that same shift.

[267] For all of the foregoing reasons, we conclude that a modern interpretation of the *Patent Act* compels the conclusion that MMTs are not inherently unpatentable. We now turn to the future direction of MMT patenting.

C. *Clarifying the Future Direction of Patenting MMTs*

(1) Patenting MMTs Should Be Assessed in the Same Manner as Any Other Claimed Invention

[268] As outlined in the above analysis, there is no principled basis to institute a blanket prohibition against patenting MMTs. Instead, MMTs should be subject to the same rigorous analysis as other inventions: if the subject matter comes within the definition of "invention" in s. 2 of the *Patent Act* and is novel, useful, and non-obvious, then a patent "shall" be issued (see s. 27(1)). In other words, the patent regime, as it currently operates in Canada, is well equipped to filter out subject matter that should not be protected through patent. As Mark S. Wilke asserts:

> . . . methods of medical treatment ought to be assessed for patentability on a case-by-case basis to prevent patentable methods from being unjustly

> rejected. Banning all medical methods merely changes the question from "what fits the definition of 'invention'" to "what fits the category of a 'medical method'?" [Emphasis added; p. 234.]

[269] To be clear, these reasons are not asserting that all MMTs are now patentable in Canada. By removing the blanket prohibition on patenting MMTs, we simply propose to reframe the analysis around whether the subject matter fits the definition of "invention", rather than whether it fits the unclear and impractical definition of an MMT (see Wilke, at p. 234). In so doing, we are not proposing a "new framework" that will significantly disrupt the current legal and regulatory landscapes (see reasons of Jamal J., at para. 114). To the contrary, we are simply proposing to use the well-established requirements that shape the contours of the definition of "invention" to assess the patentability of MMTs.

(2) Many MMTs Will Fail to Meet the Utility Criterion for Patentability

[270] Our reasons do not have the effect of opening the floodgates. The *Patent Act* already contains safeguards, in particular the utility requirement, that will prevent patenting certain MMTs and incidentally alleviate the policy concerns against patenting MMTs. There is no evidence that our suggested approach will "unsettle commercial expectations and risk significant disruption" in Canada's pharmaceutical industry (reasons of Jamal J., at para. 115). Our approach merely represents a recalibration with the intention of centering the patentability analysis for MMTs within the governing statutory framework.

[271] As we have seen, the MMT doctrine is generally understood as flowing from the doctrine of patentable subject matter: courts and commentators alike have repeatedly stated that an MMT is not patentable subject matter in that it constitutes neither an "art" nor a "process". Upon closer examination, however, it becomes apparent that the current MMT doctrine, because of its reliance on skill and judgment, is in fact grounded in considerations that are more closely associated with the utility requirement for patentability (see Lipkus and Albanese, at p. 96). Accordingly, we offer some general observations below on the interaction of the utility requirement and the patentability of MMTs.

[272] A claimed invention will lack utility if it is incapable of "practical purpose", i.e., if it cannot produce an "actual result" (*AstraZeneca*, at para. 54). This "practical purpose" or "result" must be "demonstrated or soundly predicted at the time of application" (*AstraZeneca*, at para. 56; see also *Wellcome*, at para. 70), meaning that it must be established "that an embodiment falling within the claim works as described in the patent" (Clarizio et al., at § 11). Therefore, "inoperable" inventions, which cannot fulfill the purpose for which they were designed, are not "useful" within the meaning of the *Patent Act* (*AstraZeneca*, at para. 57; see also *Northern Electric Co. v. Brown's Theatres Ltd.*, [1940] Ex. C.R. 36, at p. 56, aff'd [1941] S.C.R. 224).

[273] Inventions that depend upon a person's skill, judgment, or reasoning will likely be deemed inoperable. Inventions of this nature lack utility because the "actual result" for which they were designed is uncontrollable or irreproducible (see *President*

and Fellows of Harvard College v. Canada (Commissioner of Patents), [2000] 4 F.C. 528 (C.A.), at paras. 150-52, rev'd on other grounds 2002 SCC 76, [2002] 4 S.C.R. 45; *Re Application of Itek Corp.* (1981), 68 C.P.R. (2d) 94 (Pat. App. Bd.), at p. 98; MacOdrum, McIntosh and Szweras, at § 6:5; Perry and Currier, at ¶7-18; Canadian Intellectual Property Office, *Manual of Patent Office Practice* ("*MPOP*"), at s. 19.01.01). In other words, due to the significant subjective human contribution necessary for the operation of the invention, the "actual result" of the claimed invention cannot be demonstrated at the time of the patent application. Therefore, a process or an art will not be granted protection under the *Patent Act* if it "comprises or is dependent upon a judgmental or interpretive mental step, depending on the intelligence and reasoning of the human mind" (MacOdrum, McIntosh and Szweras, at § 3:29).

[274] This is why "[a] way of doing something in a professional field . . . that is characterized by human interaction, communication, and subjective interpretation" (E. F. Judge and D. J. Gervais, *Intellectual Property: The Law in Canada* (2nd ed. 2011), at p. 658) will likely not meet the utility requirement for patentability.

[275] As we have seen, the Exchequer Court's decision in *Lawson* stated, without clear explanation, that professional skills are not patentable for lack of subject matter. In other words, they cannot qualify as an "art" or a "process" within the meaning of s. 2 of the *Patent Act*. In the editorial note accompanying the *Lawson* ruling reproduced in the Canadian Patent Reporter, it was suggested that the Exchequer Court conflated the notions of patentable subject matter and utility:

> . . . professional skill is an art. The art of advocacy, the skill of the surgeon, the artistry of the painter fall within the ordinary dictionary meaning of the word art as the application of skill in the sense of knowledge and practice.
>
> In Canada, each of such "arts" would not be patentable because they lack "utility" not because they are outside the scope of categories included in invention. They lack utility because the result following the practice of these arts no matter how skilfully practised is not reproducible. The variables arising from the human element in the practice of such skills make success unpredictable. [Emphasis added; p. 103.]

[276] We agree. For example, to draw on the analogy explored in *Lawson*, a method of advocacy or cross-examination cannot be patented because such a method depends on the lawyer's experience, adaptability, and judgment, among other factors. It cannot, therefore, be demonstrated that the method works as described in the patent. It is inoperable, irreproducible, and uncontrollable. These three concepts relate to the fundamental principle that the patentee must be able to establish that the invention will fulfill the claimed practical purpose, or to demonstrate the claimed utility of the invention (*AstraZeneca*, at paras. 49 and 55-56; *Wellcome*, at para. 70; Clarizio et al., at § 11).

[277] In the context of MMTs, the correct application of the utility requirement is, in our view, aptly illustrated in *Re Application No. 016,962* (1973), 17 C.P.R. (2d) 177 (Pat. App. Bd.). This case concerned a patent application for a method designed to assess the capacity and strength of human lungs, which had been rejected by the patent examiner. Drawing from *Lawson* and *Tennessee Eastman* (Ex. Ct.), the patent examiner stated that the claims were directed at a diagnostic method that was performed on a

non-industrial product (the human body) and that the method was non-economic and did not produce a result associated with trade, commerce or industry (pp. 178-80).

[278] The Patent Appeal Board rejected this argument and concluded that the method was an "art" within the meaning of the *Patent Act*. It also noted that the prerequisite for the utility requirement for patentability was the following:

> . . . the subject-matter is controllable and reproducible by the means disclosed so that the desired result inevitably follows whenever it is worked, and . . . the subject-matter has utility in the field of practical application (as that in relation to trade, commerce or industry) which is beneficial to the public. [p. 180]

[279] The Patent Appeal Board further concluded that the method had utility since "achieving the desired result of the process d[id] not depend on professional skills" (p. 180) and "since no professional judgment or manual expertise [was] involved in working the process" (p. 181). It was thus demonstrated that the desired result would inevitably follow whenever the invention was used for its stated purpose (p. 181).

[280] A process that relies on human skill, judgment, interpretation, and reasoning is unpatentable not because it falls outside of patentable subject matter, but because it lacks utility. As such, it is more than likely that a new and complex surgical method, or any other complex medical method, is unpatentable by virtue of its irreproducibility flowing from its heavy reliance on the skill and judgment of a professional, honed through years of practice. In these cases, demonstrating that a claimed invention will achieve its practical purpose — in other words, its utility — will

be impossible because of the necessity of subjective human involvement in operating the claimed invention.

[281] This approach does not endorse a *de facto* "skill and judgment" test that currently exists under the MMT doctrine and that our colleague endorses. On the contrary, in placing reliance on the utility framework, the focus rightly remains on the demonstration or sound prediction of utility and on the related principles of operability, reproducibility, and control, which roots the analysis in a principled and consistent approach. In order to be useful, the subject matter must be "controllable and be reliably reproducible", and "the desired result must inevitably follow when the invention is put into practice and may not be left up to chance" (*MPOP*, at s. 19.01.01, citing *Re Application No. 003,389 of N.V. Organon* (1973), 15 C.P.R. (2d) 253 (Pat. App. Bd.), at p. 258). As a corollary, "[a]n invention that relies upon the judgment or reasoning of an operator is considered to lack reproducibility and thus, lacks utility" (*MPOP*, at s. 19.01.01, citing *Re Application for Patent Containing Claims That Read on Mental Steps Performed by a Human Operator in Deciding to Transmit a Signal* (1972), 23 C.P.R. (2d) 93 (Pat. App. Bd.), and *Re Application of Itek Corp.*). When a medical professional is required to make subjective judgment calls based on experience, relying on intuition, creativity, conjecture, and approximation to give effect to the invention, then the subject matter is not objectively controllable or reproducible (*MPOP*, at s. 19.01.01) and, therefore, it is unpatentable.

[282] It is true that an assessment of utility in this context will often lead to results that overlap with our colleague's suggested skill and judgment test. But anchoring the analysis in established doctrine, rather than a hindsight assessment of whether a medical decision involves varying degrees of skill and judgment, provides a consistent framework for determining the patentability of MMTs.

[283] In sum, the patentability of MMTs, including dosing regimens, can be resolved within the framework of the *Patent Act*. Our approach will not open the floodgates to allow every medical innovation to obtain patent protection. The ordinary patentability analysis, which requires an invention to be novel, non-obvious, useful, and fall within the relevant subject matter, is rigorous enough to offer protection against claims that demand ingenuity from physicians.

D. *Application*

[284] In light of our analysis, the application to this case becomes straightforward. As the Federal Court of Appeal stated in *Sanofi-Aventis*, the starting point for any patentability analysis is the *Patent Act* (para. 34; see also *Harvard College*, at para. 145). The onus rests on Pharmascience to show that Janssen's patent is invalid. Since there is no general prohibition on patenting MMTs, Pharmascience's arguments are ultimately unavailing. Indeed, apart from the contention that the 335 Patent is invalid on the ground that it constitutes a prohibited MMT, we were not asked to disturb the trial judge's findings that the patent is otherwise valid because it is non-obvious and is squarely within the subject matter contemplated by the *Patent Act*. We

note that utility and novelty were not at issue before the Federal Court. The patent for Janssen's dosing regimen is valid.

VI. Disposition

[285] For the foregoing reasons, we would dismiss the appeal and award costs to Janssen.

Appeal dismissed without costs.

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