mccarthy tetrault

Methods of Medical Treatment

Steven Tanner

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Patentable Subject Matter

Section 2 of the *Patent Act* (R.S.C. 1985, c. P-4)

2. ***invention*** means 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.

Old Statutory Prohibition on Methods of Medical Treatment

Subsection 41(1) of the *Patent Act* (R.S.C. 1952, c. 203)

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.

Tennessee Eastman Co. et al. v. Commissioner of Patents, [1974] S.C.R. 111

Subject of patent application – A surgical method for joining living animal tissues by applying certain compounds: "the 'invention' essentially consists in the discovery that a known adhesive substance is adaptable to surgical use" (pg. 117). The compounds claimed were old but their application to binding human tissue was new, useful and non-obvious (pg. 112).

Question for the SCC – Is a method for surgical bonding of body tissues by applying the compounds described in the claims patentable subject matter?

Answer – "**I do not think so**, and it appears to me that s. 41 definitely indicates that it is not so" (pg. 118).

> [119] In my view, [section 41] necessarily implies that, with respect to [substances intended for food or medicine], **the therapeutic use cannot be claimed by a process claim apart from the substance itself**. Otherwise, it would mean that while the substance could not be claimed except when prepared by the patented process, its use *however prepared* could be claimed as a method of treatment. In other words, if a method of treatment consisting in the application of a new drug could be claimed as a process apart from the drug itself, then the inventor, by making such a process claim, would have an easy way out of the restriction in s. 41(1).

***Tennessee Eastman Co. et al. v. Commissioner of Patents*, [1974] S.C.R. 111**

Methods of Medical Treatment are not Patentable:

> Having come to the conclusion that methods of **medical treatment are not contemplated in the definition of "invention"** as a kind of "process", the same must, on the same basis, be true of a method of surgical treatment. (pg. 119)

- The Court held that the breadth of section 2 can be circumscribed by other sections in the *Patent Act,* and other statutes. (pg. 116)
- Section 2 was construed in light of section 41 of the *Patent Act*.

Repeal of s. 41 of the *Patent Act*

- In 1993, the *Patent Act* was substantially amended and section 41 was repealed.
- Question remained as to whether *Tennessee Eastman* and cases that followed were good law since they had been based on section 41 of the *Patent Act*.

Apotex Inc. v. Wellcome Foundation Ltd., [2001] 1 F.C. 495 (FCA)

Subject of patent – The use of AZT for HIV/AIDS treatment and prophylaxis.

Key claims of Canadian Patent No. 1,238,277 upheld by the FCA and SCC included:

— 22. A pharmaceutical formulation for use in the treatment or prophylaxis of AIDS comprising an effective amount of 3'-azido-3'-deoxythymidine in association with a pharmaceutically acceptable carrier.

— 28. A formulation according to claim 22, wherein said 3'-azido-3'-deoxythymidine is present in an amount effective to provide a unit dose of 10 to 1500 mg.

— 29. A formulation according to claim 22 or 28, wherein said 3'-azido-3'-deoxythymidine is present in an amount effective to achieve a peak plasma concentration on administration of from about 1 to about 75 µm.

— 65. A formulation according to claim 21, 22 or 23, in a capsule form.

The claims upheld by the FCA and SCC did not include method, process, or use claims.

Apotex Inc. v. Wellcome Foundation Ltd., [2001] 1 FC 495 (FCA)

Justice Rothstein for the FCA held that the pharmaceutical formulations claimed were vendible products and not methods of medical treatment:

— [74] What is at issue in this case is the use of a **pharmaceutical formulation**—**a vendible product**, clearly related to trade, industry and commerce. Wetston J. found, and I agree, that what was invented was a new use for a known compound and not a method of medical treatment.

— [75] Novopharm suggests that Wetston J. erred in not following *Imperial Chemical Industries Ltd. v. Commissioner of Patents*.[64] In *Imperial Chemical*, this Court, in applying *Tennessee*, upheld the Commissioner's decision to refuse a patent application that described its invention as "a method of cleaning teeth"[65] (emphasis added). There, this court agreed with the Commissioner that one of the main purposes of the patent was a method of medical treatment. However, since Wetston J., following *Shell Oil*, found that the subject of the patent here is the use of an old compound as a vendible product and not a method of medical treatment, *Imperial Chemical* does not apply to the facts of this case. I would also observe that *Imperial Chemical* was decided without reference to the Supreme Court of Canada decision in *Shell Oil.*

Apotex Inc. v. Wellcome Foundation Ltd., 2002 SCC 77

The Supreme Court of Canada dismissed the generics' appeal. Justice Binnie noted the repeal of section 41, but held:

> [49] … *Tennessee Eastman* was concerned with the patentability of a surgical method for joining incisions or wounds by applying certain compounds. The decision was based on the former s. 41 of the *Patent Act*, now repealed. The Court concluded that the method (apart from the compounds) was not patentable. The policy rationale, as explained by Wilson J. in *Shell Oil*, *supra*, at p. 554, was that the unpatentable claim was essentially non-economic and unrelated to trade, industry, or commerce. It was related rather to the area of professional skills.
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> [50] 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**.**

The FCA and SCC decisions suggest that a commercial offering (a pharmaceutical formulation) is a vendible product and therefore not a method of medical treatment.

AbbVie Biotechnology Ltd. v. Canada (Attorney General), 2014 FC 1251

Subject of patent application – The use of Humira in the treatment of autoimmune diseases, using a fixed dosage amount (40 mg) on a fixed schedule (bi-weekly).

Claim 1 of Canadian Patent Application No. 2,385,745:

> A preloaded syringe comprising a syringe, **40 mg of an isolated human anti-TNF-alpha antibody** wherein said antibody [comprises amino acid sequences]; and at least one pharmaceutically acceptable carrier, for treating an arthritic disease or an inflammatory bowel disease in a human subject, said preloaded syringe being (i) adapted for subcutaneous administration of its contents to the human subject in need thereof and (ii) for use on a continuous schedule **having an every other week dosing interval of 14 days**.

AbbVie Biotechnology Ltd. v. Canada (Attorney General), 2014 FC 1251

Patentable subject matter – The claims do not encompass a physician's skill and are therefore not "methods of medical treatment" (at paras. 114-115, 121):

> [114] … the Courts have consistently found that a claim directed to the exercise of professional skill or judgment is not patentable. However, a claim which does not restrict, or interfere with, or otherwise engage professional skill or judgment – including a claim for a fixed dosage and or a fixed dosage schedule or interval - is not impermissible subject matter where there is no evidence to contradict that claimed dosage.
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> [115] The present claim is for a vendible product. It does not restrict the physician's choice or skill that would be relied on at the outset to determine whether that vendible product should or should not be prescribed. The case law has established that a use claim may be a vendible product.
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> …
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> [121] In the present case, the physician's skill is not expected to be exercised within the claim. The prescribing practices are not restricted. The physician must exercise skill and judgment to determine if the claimed use is appropriate for the patient. The physician decides to prescribe it as is or not at all. If prescribed, there would be no restriction on the exercise of skill or judgment. The evidence is that this dosage with the bi-weekly interval is appropriate for all those to whom it is administered.

Janssen Inc. v. Pharmascience Inc., 2022 FC 1218

Decision: Justice Manson held that the asserted claims of Canadian Patent No. 2,655,335 were not invalid as claiming methods of medical treatment. Pharmascience's appeal of that order is scheduled to be heard on December 5, 2023.

Patent:

— 335 Patent includes claims to prefilled syringes (e.g. claim 1) and claims to the use of a dosage form (e.g. claim 17) that are useful for treating schizophrenia.

— The treatment regimen includes the following steps (e.g. claims 1, 17, 33 and 49):

- A first loading dose of 150 mg-eq. of paliperidone palmitate administered into the deltoid muscle on Day 1 of treatment;
- A second loading dose of 100 mg-eq. of paliperidone palmitate administered into the deltoid on Day 8 ± 2 days; and
- Maintenance doses of 75 mg-eq. of paliperidone palmitate administered into the deltoid or gluteal muscle monthly ± 7 days after the second injection.

Janssen Inc. v. Pharmascience Inc., 2022 FC 1218

The product claims (e.g. prefilled syringes) were not methods of medical treatment because they were vendible products:

> [163] However, there appears to be no question in the case law that claims to a vendible product are patentable as not being methods of medical treatment. … claims 1 to 16, and 33 to 64 are "product claims" … and are not "methods" of medical treatment. Therefore, the method of medical treatment analysis is only relevant in respect of… "use" claims…

In addressing the "use" claims, the Court highlighted inconsistencies in Canadian law:

> [165] While this dichotomy, between specific dosages and administration intervals contrasted with ranges of dosages and schedules, has led to a series of cases wherein the former has been held to be patentable, vendible products and the latter, at least in some cases, as being unpatentable as requiring skill and judgment amounting to methods of medical treatment, **seems to have a questionable underpinning in resulting judgments based on this dichotomy**, nevertheless that is where we are under the current state of decisions up to and including decisions in the Federal Court of Appeal.

Janssen Inc. v. Pharmascience Inc., 2022 FC 1218

Patentable subject matter – Although the use claims provide for two possible dosing regimens and a range of administration techniques, the claims are not directed at subject matter that requires the exercise of skill and judgment (at paras. 169-170):

> [169] The use claims provide for two possible dosing regimens, one for non-renally impaired patients and another for renally impaired patients. **Once 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.**
>
> [170] While there are elements where there are choices (dosing windows around the Day 8 and monthly doses, and injection sites for the maintenance dose), **those choices do not have clinical implications**. The 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**. Therefore, no skill and judgment is required that would interfere with or restrict a physician's skill or judgment in deciding to prescribe the dosing regiment within the claimed invention.

Calls for Reconsideration by the FCA

***Cobalt Pharmaceuticals Company v. Bayer Inc.*, 2015 FCA 116** at para. 101:

The current law in this Court is that methods of medical treatment are not patentable: *Novartis Pharmaceuticals Canada Inc v. Cobalt Pharmaceuticals Company*, 2013 FC 985, 440 F.T.R. 1 at paragraphs 70-101, endorsed by this Court at 2014 FCA 17, 459 N.R. 17, in very brief reasons based on the particular arguments made. The provenance of this is *Tennessee Eastman Co. et al. v. Commissioner of Patents*, 1972 CanLII 167 (SCC), [1974] S.C.R. 111, 33 D.L.R. (3d) 459, a decision based on former subsection 41(1) of the *Patent Act*, now repealed. In his blog, "Sufficient Description," Professor Norman Siebrasse has forcefully advanced arguments of policy and logic against the current position. **In my view, this calls for full consideration by this Court or the Supreme Court in a case where the issue is squarely raised on the facts.**

***Hospira Healthcare Corporation v. Kennedy Trust for Rheumatology Research*, 2020 FCA 30** at paras. 52-53:

[I]t 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… **I agree that this issue deserves deep analysis**.

Should the restriction on “methods of medical treatment” remain?

— Any policy desire to protect physicians from patent infringement can be addressed in other ways. In the US, physicians are protected by statute:

  — **35 U.S.C. § 287(c)(1)** With respect to a medical practitioner’s performance of a medical activity that constitutes an infringement under section 271(a) or (b) of this title, the provisions of sections 281, 283, 284, and 285 of this title shall not apply against the medical practitioner or against a related health care entity with respect to such medical activity.

— Should the Courts do away with the prohibition on methods of medical treatment and instead create an exception to infringement for physicians, similar to the US? [e.g. s. 42 or 55.3(1) of the *Patent Act*]

— Is there a policy reason to treat a physician’s skill and judgment different from that of other professionals, e.g. mechanics, engineers, teachers?

— Should Canada do the opposite, and encourage patent protection on methods of medical treatment to increase investment and innovation?

— If the restriction on methods of medical treatment remains, does a distinction between a fixed dosage (or interval) and a range of doses (or intervals) make sense? Should product claims be exempt from the complaint that they are to methods of medical treatment?