



PATENTABILITY INELIGIBILITY IN CANADA

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In many jurisdictions, the notion of statutory subject matter or patentable inventions is evolving. Arguably, there are a number of factors influencing this evolution, including the increase in litigation in the United States fuelled in part by “non-practicing entities”. Canada has been an active participant in this evolution, evidenced by a number of notable causes and the changing practice adopted by the Canadian Intellectual Property Office (CIPO). Though perhaps inspired by developments in foreign jurisdictions, Canada’s position on patentable inventions has been centered on interpreting the meaning of “invention” as defined in the Canadian *Patent Act*¹.

Section 2 of the *Act* sets out that a patent eligible “invention” is any new or useful art, process, machine, manufacture or composition of matter, or any improvement thereon. This must be read in conjunction with section 27(8) of the *Act* which excludes from patentability any mere scientific principle or abstract theorem. Although the statutory definition of “invention” has remained unchanged since 1923², developments in the Canadian requirements for patent eligibility have involved reconsidering the notions of “art, process, machine, manufacture or composition of matter” in light of new types of technologies.

Computer Implemented Inventions and Software

In Canada, computer implemented inventions may be claimed in terms of hardware components and in terms of a method.

The patent eligibility of a computer implemented method essentially hinges on whether or not it falls within the definition of “art”. A case that still provides guidance today notwithstanding its age is *Lawson v. Canada (Commissioner of Patents)*³, where it was held that “art is an act or series of acts performed by some physical

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¹ RSC, 1985, c. P-4 [Act]

² S.C. 1923, c. 23, s. 2(c)

³ *Lawson v. Canada (Commissioner of Patents)*, (1970) 62 CPR 101 (Ex Ct) [Lawson]

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agent upon some physical object and producing in such object some change of either character or condition". In the landmark Federal Court of Appeal decision regarding Amazon.com's "one-click" online ordering technology⁴, 40 years later, the Court affirmed that the definition of "art" must meet three important elements outlined in *Progressive Games, Inc. v. Canada (Commissioner of Patents)*⁵: "i) it must not be a disembodied idea but have a method of practical application; ii) it must be a new and inventive method of applying skill and knowledge; and iii) it must have a commercially useful result." This definition does not require an impact on the physical world, as *Lawson* did.

In order to evaluate whether or not a claimed invention falls within the definition of "art", one first has to identify what the invention actually is. In *Amazon.com*, the Court stated that the proper approach is to perform a purposive construction of the claims. The notion of purposive construction was discussed in the Supreme Court decisions *Free World Trust*⁶ and *Whirlpool*⁷ in 2000. Purposive construction involves determining what a person of reasonable skill in the art would understand the claimed invention to be, upon reading the disclosure in the patent application using general knowledge available to him at the time the patent application was published. According to *Free World Trust* and *Whirlpool*, one must identify the essential elements of a claim by assessing the nature of the claimed invention in light of what is described in the disclosure of the patent application. There is a presumption that the elements in a claim are essential, so in order for an element to be considered non-essential, it must be shown that upon purposive construction of the claims, the element was clearly not intended to be essential, or that the element could be substituted without affecting the function of the invention. As noted in *Amazon.com*, such an approach allows looking beyond the literal language of the claim in order to assess whether or not the underlying invention is in fact directed to patentable subject matter.⁸

Two years after the *Amazon.com* decision was rendered, CIPO issued two practice notices to guide Examiners in assessing the patentability of computer implemented inventions.⁹ Although not binding, these practice notices provide insight into how Examiners are currently handling applications relating to computer implemented inventions.

⁴ *Amazon.com v. Attorney General of Canada et al*, 2011 FCA 328, 97 C.P.R. (4th) 171 (F.C.A.) [Amazon.com]

⁵ *Progressive Games, Inc. v. Canada (Commissioner of Patents)*, 1999 CanLII 8921 (FC), 177 F.T.R. 241 (T.D.) at para. 16, aff'd (2000), 2000 CanLII 16519 (FCA), 9 C.P.R. (4th) 479 (F.C.A.).

⁶ *Free World Trust v. Électro Santé Inc.*, 2000 SCC 66 [Free World Trust]

⁷ *Whirlpool Corp. v. Camco Inc.*, 2000 SCC 67 [Whirlpool]

⁸ Paragraph 44 Amazon.

⁹ Canada, Canadian Intellectual Property Office, Examination Practice Respecting Purposive Construction - PN2013-02, (Ottawa: CIPO 2013); Examination Practice Respecting Computer-Implemented Inventions - PN 2013-03, (Ottawa: CIPO 2013), online: CIPO <http://www.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/wr03628.html>.

In following with the *Amazon.com* decision, the practice notices explain that the combination of essential elements of a claim, as determined by purposive construction, must be directed to patentable subject matter. However, seemingly contrary to the principles of purposive construction outlined in *Free World Trust* and *Whirpool*, the practice notices essentially instruct Examiners to perform a purposive construction of the claims by taking a problem-solution approach. Examiners are directed to look not only at the language in the claims, but also in the application as a whole in order to identify the problem and the essential elements of the solution. Accordingly, not every element having a material effect on operation is necessarily essential to an identified solution. Some elements can be considered to be superfluous, or merely define the context or environment of a specific working embodiment notwithstanding the limitations appearing in the claim. Conversely, some essential elements of the identified solution can be missing from the claim, in which case the claims can be rejected for lack of utility.

According to the practice notices, a good indication that a claim is directed to statutory subject matter is if a computer is found to be an essential element of a construed claim. In assessing whether a computer is essential, the Examiner will have to determine whether the computer is in fact essential to carry out the solution, or if it is merely a convenience or afterthought.

The practice notices further explain that one possible approach to determine the essentiality of hardware is to consider whether the computer can be varied or substituted without having a material effect on the operation of the invention. For example, if an invention teaches using a computer to perform certain calculations according to an equation, the calculations could feasibly be performed by a human instead. Although the use of a computer would expedite the calculations, the same results would be achieved if performed by a human. In such a scenario, the computer would not be considered essential.

Still according to the practice notices, another good indication that the invention is directed to patentable subject matter is if it is a technical solution to a technical problem. For example, if the problem is a computer problem (e.g. a problem with the operation of a computer), the solution cannot be carried out without the presence of a computer, and therefore, the claimed computer or hardware components would be considered essential.

Thus, the current trend of Canadian Examiners is to evaluate whether the computer hardware in a claim is essential to the operation of the invention. Otherwise, the computer can be thought of as an arbitrary vehicle for carrying out an abstract or disembodied idea which would otherwise be prohibited subject-matter under the Canadian *Patent Act*.

According to CIPO's 2013-2014 Annual Report, in the years following the 2011 *Amazon.com* decision, the number of computer-related patents granted by the Canadian Patent Office has increased.¹⁰ However, trends in recent decisions from the Patent Appeal Board (PAB) seem to indicate that the courts are taking a more restrictive approach. In fact, between 2006 and 2009, the Amazon patent application was only 1 out of 7 applications in the domain of computer-related inventions brought before the PAB in which the Examiner's rejection for lack of patentable subject matter was upheld¹¹. Between 2012 and 2014 (i.e. the years following the *Amazon.com* decision) the Examiner's rejection was upheld in 5 out of 12 cases.¹²

Business Methods

The patent eligibility of business methods is still a gray area in Canadian patent law as there is very little relevant jurisprudence. The subject was, however, discussed recently in *Amazon.com*, where the Court confirmed that there is no Canadian case that supports the proposition that business methods are not patent eligible, nor is there any statutory or regulatory prohibition. While this opens the door to the possibility of business methods being patent eligible in Canada, it is not an unequivocal confirmation that they are indeed patent eligible.

The principles established in *Amazon.com* do, however, bring some clarity to the requirements of a patent eligible business method claim. Although the courts have yet to define a "business method", any method claim, whether qualified as a business method or not, must meet the criteria of a patentable "art" in order to be patent eligible. The Court's discussion on the notion of patentable "art" in *Amazon.com* can thus serve as guidance for understanding the requirements for a business method claim.

¹⁰ <http://www.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/wr03865.html>

¹¹ Examiner's rejection upheld in *Amazon.com's Application* (2009), CD 1290 (P.A.B., Commr.); Examiner's rejection reversed in *Index Systems, Inc.'s Application* (2006), CD 1266 (P.A.B., Commr.); *Northern Light Technology Group Inc.'s Application* (2006), CD 1265 (P.A.B., Commr.); *Diamonds.net LLC's Application* (2006), CD 1272 (P.A.B., Commr.); *Sydney H. Belzberg's Application* (2007), CD 1274 (P.A.B., Commr.); *Orange Personal Communications Services Ltd.'s Application* (2007), CD 1277 (P.A.B., Commr.); *Toyota Jidosha Kabushiki Kaisha's Application* (2008), CD 1286 (P.A.B., Commr.).

¹² Examiner's rejection upheld in *Deroyal Business Systems, LLC's Application* (2013), CD 1338 (P.A.B., Commr.); *Fair Isaac Corporation's Application* (2013), CD 1339 (P.A.B., Commr.); *IGT's Application* (2013), CD 1346 (P.A.B., Commr.); *Cantor Fitzgerald, L.P.'s Application* (2013), CD 1355 (P.A.B., Commr.); *Financial Engines, Inc.'s Application* (2014), CD 1373 (P.A.B., Commr.); Examiner's rejection reversed in *Navigation Technologies Corporation's Application* (2012), CD 1332 (P.A.B., Commr.); *Pitney Bowes Inc.'s Application* (2013), CD 1334 (P.A.B., Commr.); *Progressive Casualty Insurance Company's Application* (2013), CD 1336 (P.A.B., Commr.); *Pitney Bowes Inc.'s Application* (2013), CD 1337 (P.A.B., Commr.); *RPX Corporation's Application* (2013), CD 1341 (P.A.B., Commr.); *Weyerhaeuser's Application* (2013), CD 1345 (P.A.B., Commr.); *Progressive Casualty Insurance Company's Application* (2013), CD 1349 (P.A.B., Commr.).

As discussed above, the Court stated that a method claim must meet the practical application requirement for it to meet the requirements of a patentable “art”. The method must satisfy a “physicality” requirement in that it includes something with a physical existence or something that manifests a discernable effect or change. An involvement of a computer may not satisfy the physicality requirement if the only inventive and essential element is an algorithm or formula. However, if the algorithm or formula is one of a number of essential elements in a novel combination, the practical application requirement may be satisfied.

Gene Patents

In the domain of biotechnology, it is a well-established principle in Canada that lower life forms are patentable, while higher life forms are not (although the courts have shied away from providing definitions to “lower” and “higher” life forms). This principle was discussed in the Supreme Court’s *Harvard College*¹³ decision, which concerned Harvard College’s patent application for a genetically-modified cancer-prone mouse (“oncomouse”). The Court affirmed that claims to a genetically modified gene in the mouse were allowable. Claims to the mouse itself, however, were patent-ineligible because a mammal does not fall under the categories of “manufacture” or “composition of matter” in the statutory definition of “invention”. Implicitly, several other types of claims present in Harvard College’s patent application can be understood as being patent-eligible because they were neither contested nor rejected by the Court. These claims include claims to: a transgenic cell culture, a somatic cell culture derived from a transgenic mammal, a method of producing a transgenic mammal, a method of testing using such mammal, and the use of such mammal in a method of testing.

The patentability of genes and cells established in Harvard was further confirmed in *Monsanto v. Schmeiser*¹⁴, where the Supreme Court held that claims to an herbicide resistant gene and cell were patentable. The plants which contained the gene and cell were themselves unpatentable, because plants fall under the definition of a higher life form. However, claims to the gene or cell were sufficient to protect the plant. This is because claims to a gene or cell can be infringed even if their use occurs within a higher life form. This means that cultivating plants containing a patented gene or cell could result in infringement, even though the plant is not itself patented.

Though the court established that higher and lower life forms differ in patent eligibility, it was left up to the Patent Office to determine the distinction between a

¹³ *Harvard college v. Canada (Commissioner of Patents)* 2002 SCC 76, [2002] 4 SCR 45, 21 CPR (4th) 417.

¹⁴ *Monsanto Canada Inc v Schmeiser*, [2004] 1 SCR 902, 2004 SCC 34, 31 C.P.R. (4th) 161 (S.C.C.)

higher life form and a lower life form. According to the Manual of Patent Office Practice (MOPOP), the Patent Office generally considers lower life forms to be unicellular, while higher life forms are multicellular. However, multicellular life forms are considered to be higher life forms at any stage of their development.¹⁵ This means that any cell which has the potential to develop into a multicellular life form (such as a fertilized egg or a totipotent cell, for example) is also considered by the Patent Office to be a higher life form and thus patent ineligible.

Methods of Medical Treatment and Pharmaceutical Compositions

Methods of medical treatment are not patentable in Canada. Although not explicitly prohibited by the Canadian *Patent Act*, the courts are clear that such claims are directed to non-statutory subject matter and thus cannot be protected. Meaningful protection can be obtained, however, if the claims are directed to medical uses or pharmaceutical compositions, inasmuch as they cannot be equated to methods of medical treatment. Protection can also be obtained for diagnostic methods, as long as the claims fall within the definition of a patentable “art”

In *Lawson*¹⁶, it was established that one cannot obtain an exclusive property or privilege in a professional skill. Essentially, professional skill does not relate to trade, industry, or commerce and should therefore not be subject to a monopoly under the *Patent Act*. This principle was applied in the context of a surgical method in *Tennessee Eastman Co. v. Commissioner of patents*¹⁷, where the Supreme Court took the position that a method of medical treatment is neither an “art” nor a “process” and therefore does not satisfy the statutory definition of “invention”.

In discussing the prohibition of methods of medical treatment, the courts have been clear that this prohibition is not intended to cover substances used in these methods, nor is it intended to cover processes for creating said substances.¹⁸ As such, medical use claims and pharmaceutical compositions do fall under the statutory definition of invention and are patentable, inasmuch as they cannot be equated to medical methods, and as long as they meet the other requirements of patentability.

There is a fine line between a medical use claim and method of medical treatment. In order for a claim to be treated as a patentable medical use, the professional skill and judgement of a medical practitioner cannot be essential to the claim. As was

¹⁵ Canadian Intellectual Property Office, Patent Office: Manual of Patent Office Practice (1998 Edition: last updated July 2015) at 17.02.01 [MOPOP]

¹⁶ *Lawson* at 111

¹⁷ *Tennessee Eastman Co. v commissioner of patents* [1974] SCR 111 [Tennessee Eastman]; affirmed by *Shell Oil and Apotex v. Wellcome* 2002 21 C.p.r. 4th 499 (s.c.c.) and *Novartis Pharmaceuticals Canada Inc v. Cobalt Pharmaceuticals Company*, 2013 FC 985, 440 FTR 1 at para 70-101, endorsed by this Court at 2014 FCA 17, 459 N.R. 17

¹⁸ *Tennessee Eastman*, *supra* note 14 at para 118.

discussed in *Merck & Co. v. Apotex*¹⁹, if the claims are directed to the use of a vendible product and can be distinguished from the work of a physician which requires the exercise of skill and judgement, *Tennessee Eastman* does not apply. Justice Hughes in *Novartis Pharmaceuticals Canada inc. v. Cobalt Pharmaceuticals Co.*²⁰ also confirmed that a proper claim should be directed to a vendible product including a substance which is intended for the treatment of a medical condition.

Practically speaking, claims to the use of a capsule or tablet in specific dosages for treating a condition are generally considered patent eligible. These types of claims relate to a vendible product, and do not require the exercise of skill and judgement of physicians. Conversely, the patent eligibility of claims directed to the use of a range of dosages or a dosage regimen for treating a condition is less clear. In general, claims defining specific dosages or a specific dosage regimen (such as a specific administration schedule) are patentable since the claims do not require the exercise of skill and judgement of physicians. However, claims directed to the use of a medication in a range of dosages for treating a condition may be considered patent ineligible because professional skill and judgement may be required in order to select the appropriate dosage from the range. What's more, such claims could interfere with a physician's professional judgement or skill and could therefore be ethically questionable and a hazard to public health. As was noted in *Janssen Inc. v. Mylan Pharmaceuticals*, "the concern with patenting a dosage regimen is that the physician may be prevented from exercising skill and judgment in using a known compound for an established purpose absent a licence from the patentee."²¹

As such, a proper claim could be structured as: "the substance X for the treatment of Y", "the substance X in the form of a 5 mg tablet for the treatment of Y", "use of the substance X for 4 weeks at 8 mg/day for the treatment of Y" or "use of a dosage formulation of 70 mg of the substance X, once a week, to treat Y". An improper claim could be structured as: "the use of substance X in a dosage range between 5 mg and 10 mg for the treatment of Y" or "use of a 10 mg dosage unit of the substance X to treat Y for about 3 to 5 weeks".

It should be noted, however, that the mere inclusion of a dosage range or regimen in a medical use claim does not necessarily equate the claim to a method of medical treatment. A more thorough analysis is required in order to determine whether or not the claim interferes with or requires the professional skill of a physician.²²

In an effort to guide examiners in examining claims containing dosage regimens or dosage ranges, CIPO issued a practice notice respecting medical uses in 2013,

¹⁹ *Merck & Co. v. Apotex* (2005), 2005 FC 755, 41 CPR (4th) 35 (FC)

²⁰ *Novartis Pharmaceuticals Canada inc. v. Cobalt Pharmaceuticals Co.* (2005), 43 CPR (4th) 81 (F.C.)

²¹ *Janssen Inc. v Mylan Pharmaceuticals ULC*, 2010 FC 1123, 376 FTR 311 at paras 51 [Janssen]

²² *AbbVie Biotechnology Ltd. v. Canada (Attorney General)* 2014 FC 1251

followed by revised practice notice in 2015.²³ Examiners are directed to apply a purposive construction of the claims using a problem-solution approach. As discussed earlier in the context of computer-implemented inventions, this exercise is generally carried out by considering the specification as a whole to identify the problem faced by the inventor, and the essential elements required for the successful resolution of the problem.

The revised practice notice essentially directs examiners to look for situations where dosage ranges or regimens are essential to a claim. When a dosage range or regimen is not present or is not essential to a claim, the claim will generally be considered a medical use claim and thus patent eligible. According to the practice notice, such claims teach a practitioner “what” to use to treat a medical condition, rather than “how” to treat the medical condition.

When it is found that a dosage range or regimen is an essential element in a claim, the claim *may* be directed to unpatentable subject matter. In following *Janssen*, the revised practice notice states that if the dosage range or regimen is essential to a claim encompassing the use of a known compound in an established treatment, then the claim may cover a method of medical treatment. Following *Apotex Inc. v. Wellcome Foundation Ltd.*²⁴, the revised practice notice states that if the essential element only instructs a medical professional “how” (i.e. how and when) to treat a patient rather than “what” to use to treat the patient, there is an implication that the claim must encompass the use of a known compound in an established treatment. In such a scenario, in order to determine whether the claim equates to a method of medical treatment, it must be determined that the essential element prevents, interferes with or requires the professional skill of a physician.

The revised practice notice goes on to provide two examples of elements that point to a limitation of a physician’s professional skill or judgement: (1) detailed dosage schedules encompassing a range; and (2) a range of potential dosages that a patient may receive. In contrast, the following elements are provided as examples of elements which do not limit a physician’s professional skill: a fixed dosage; a fixed dosage regimen; a patient sub-population; and a particular administration site.

According to the MOPOP, methods for diagnosing disease are not considered to be methods of medical treatment because they do not involve a step of surgery or provide a practical therapeutic benefit.²⁵ Medical diagnostic methods are therefore not subject to the same prohibition as methods of medical treatment, however diagnostic methods raise their own patentability issues, particularly in view of the *Amazon.com* decision. As is the case with computer-implemented inventions, the

²³ PN 2013-04 *Examination Practice Respecting Medical Uses* published on June 10, 2013, revised by PN 2015-01 *Revised Examination Practice Respecting Medical Uses* published March 18, 2015.

²⁴ *Apotex Inc. v Wellcome Foundation Ltd.*, [2002] 4 SCR 153, 2002 SCC 77, 21 CPR (4th) 499.

²⁵ MOPOP at 12.05.02 and 17.02.03

patent eligibility of a medical diagnostic method essentially hinges on whether the essential elements of a claim fall within the statutory definition of “art”.

A practice notice issued by CIPO in 2015 guides examiners in assessing the patent eligibility of medical diagnostic methods.²⁶ As with computer-implemented inventions and medical uses, examiners are directed to take a problem-solution approach to construe the claims and identify its essential elements. The problem can be generally identified as a “data acquisition problem” (i.e. how to identify, detect, or measure the presence or quantity of X in a sample) or a “data analysis problem” (i.e. how X correlates to a condition Y). The solution can be identified as the elements or set of elements essential to resolve the identified problem.

According to the practice notice, if a physical step of data acquisition is found to be an essential element of the construed claim, the claim is likely directed to statutory subject matter. However, if the essential elements are disembodied, such as if they simply involve a mental process, lack physicality, or have no practical application, then the claim is likely unpatentable. Therefore, if the essential elements of a claim are merely associated with the analysis or significance of acquired data, then the claim is likely unpatentable.

Conclusion

As is the case in many other jurisdictions, the Canadian position on patentable subject matter is still in a state of change. Several important causes have prompted CIPO to update its practice, but it's likely that this practice will continue to change as the evolution in patentable subject matter progresses. In the meantime, the MOPOP and the practice notices provide valuable insight into how Canadian examiners treat inventions that border on patentable subject matter, and should aid practitioners in preparing applications accordingly.



²⁶ PN 2015-02 *Patent Notice: Examination Practice Respecting Medical Diagnostic Methods* published on June 29, 2015

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