CHAPTER 8 — VALIDITY: LATENT DEFECTS

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[1] Acknowledge assistance of Megan Paterson, articling student, Baker &McKenzie LLP. May 2018

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8.1 INTRODUCTION

The present chapter addresses a "grab-bag" of patent validity issues, often referred to as "latent defects". They are "latent" in the sense that they remain hidden until the Court is invited to scrutinize them. Latent defects are most often addressed after consideration of anticipation and obviousness.They relate generally to the patentee's conduct in dealing with the Patent Office (misrepresentation, small entity fee, disclaimer, dedication to the public, re-issue) or the manner in which the patent was drafted (adequacy of the disclosure, over-claiming, double patenting, sound prediction).

8.2 DISCLOSURE REQUIREMENT

The *Patent Act* requires that the applicant file a "specification" comprised of a description ("the disclosure") and claims.[2] The Supreme Court of Canada has held, "[a]dequate disclosure in the specification is a precondition for the granting of a patent".[3] Failure to make adequate disclosure as required under the *Patent Act* is a latent defect that can render the patent invalid.[4]

Subsection 27(3) of the *Patent Act* sets out the requirements for a proper disclosure.[5] The specification must:

(a) correctly and fully describe the invention and its operation or use as contemplated by the inventor;

(b) set out clearly the various steps in a process, or the method of constructing, making, compounding or using a machine, manufacture or composition of matter, in such full, clear, concise and exact terms as to enable any person skilled in the art or science to which it pertains, or with which it is most closely connected, to make, construct, compound or use it;

(c) in the case of a machine, explain the principle of the machine and the best mode in which the inventor has contemplated the application of that principle; and

(d) in the case of a process, explain the necessary sequence, if any, of the various steps, so as to distinguish the invention from other inventions.

The Supreme Court has noted that the disclosure requirements captured in this section lie "at the heart of the whole patent system. The description of the invention therein provided for is the quid pro quo for which the inventor is given a monopoly for a limited term of years on the invention."[6]

Courts have repeatedly endorsed the proposition that consideration for the grant is twofold: first, there must be a new and useful invention, and second, the inventor must, in return for the grant of a patent, give to the public an adequate description of the invention with sufficiently complete and accurate details as will enable a workman, skilled in the art to which the invention relates, to construct or use that invention when the period of the monopoly has expired.

Adequate disclosure is required to enable the construction and use of the devices claimed after the expiry of the patent, and to allow others to ascertain, with a measure of exactness, the boundaries of the claims during the life of the grant.[7]

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[2] *Patent Act*, R.S.C. 1985, c. P4, as amended. All references to the *Patent Act* in this chapter refer to R.S.C. 1985, c. P-4 unless otherwise noted. See also *Consolboard Inc. v. MacMillan Bloedel (Saskatchewan) Ltd.*, [1981] 1 S.C.R. 504 at 520.

[3] *Teva Canada Ltd. v Pfizer Canada Inc.*, 2012 SCC 60, [2012] 3 S.C.R. 625 at para 34 ["*Sildenafil"*].

[4] *Teva Canada Ltd. v Pfizer Canada Inc.*, 2012 SCC 60, [2012] 3 S.C.R. 625 at paras 82–87, noting that s. 27 of the *Patent Act* does not specify a remedy for inadequate disclosure but finding that invalidity of the patent is the logical remedy, as cited in *Pioneer Hi-Bred Ltd. v. Canada (Commissioner of Patents)*, [1989] 1 S.C.R. 1623, [1989] S.C.J. No. 72 (S.C.C.) at para. 29 (a patent must define the nature of the invention and how to put it into operation, failing which the patent is invalid for ambiguity or insufficiency). It should be noted that subsequent to the Court's decision in *Sildenafil* (2012), the Supreme Court varied its order to find that the patent was invalid only as between parties, since the issue was decided in the course of a proceeding under the *Patented Medicines (Notice of Compliance)* ("*PM(NOC)"*) *Regulations*. Notwithstanding the variation, the same patent was subsequently found invalid in an infringement action heard by the Federal Court in *Apotex Inc. v. Pfizer Ireland Pharmaceuticals*, 2012 FC 1339 affirmed 2014 FCA 13.

[5] The requirements captured in section 27(3) were formerly found in section 34(1), and before that, in section 36(1). In assessing a latent defect, the patent is to be governed by the provisions of the *Patent Act* in force at the time. That said, the substance of the provision has not changed in the various re-numberings. Moreover, as noted in Harold G. Fox, *Canadian Patent Law and Practice*, 4th ed. (Toronto: Carswell, 1969) at 166–167, "the provision of the statute does not alter the requirements of the law, as laid down in the cases; it merely puts them into statutory form. The public was entitled at common law to a full, clear and exact description of the nature of an invention and the manner in which it was to be performed." See also *Consolboard Inc. v. MacMillan Bloedel (Saskatchewan) Ltd.*, [1981] 1 S.C.R. 504 (S.C.C.) at 518–519; *Teva Canada Ltd. v Pfizer Canada Inc.*, 2012 SCC 60, [2012] 3 S.C.R. 625 at para. 50; and the *Patent Rules*, SOR/96-423, s. 80(1).

[6] *Consolboard Inc. v. MacMillan Bloedel (Saskatchewan) Ltd.*, [1981] 1 S.C.R. 504 (S.C.C.) at 517, referring to then s. 36(1) of the *Patent Act.* See also *Teva Canada Ltd. v Pfizer Canada Inc.*, 2012 SCC 60, [2012] 3 S.C.R. 625 at para 3; *Whirlpool Corp. v. Camco Inc.*, 2000 SCC 67, [2000] S.C.J. No. 68 at para 42, reconsideration / rehearing refused 2001 CarswellNat 283 (S.C.C.).

[7] *Pioneer Hi-Bred Ltd. v. Canada (Commissioner of Patents)*, [1989] 1 S.C.R. 1623, [1989] S.C.J. No. 72 (S.C.C.) at para 23, citing with approval Harold G. Fox, *Canadian Patent Law and Practice*, 4th ed. (Toronto: Carswell, 1969) at 163. The Court further noted, at para 25, that the disclosure also facilitates the work of the examiner, the Commissioner of Patents, and appellate courts in distinguishing between discovery of a theoretical principle or a product occurring in nature, and an invention which

The applicant must disclose everything that is essential for the invention to function properly. It has been stated that, to be complete, disclosure must meet two conditions: 1) describe the invention and 2) define the way it is produced or built.[8] However, the Supreme Court has clarified that it is equally critical that, with respect to each condition, the description be "correct and full" so as to enable a person skilled in the art or the field of the invention to produce it using only the instructions contained in the disclosure; and, to use the invention as successfully as the inventor could at the time of his application.[9]

Following the Supreme Court's *Sildenafil* decision, courts now use the following analytical framework to assess sufficiency: (i) What is your invention? (ii) How does it work? (iii) Having only the specification, can the person of ordinary skill in the art produce the invention using only the instructions contained in the disclosure?[10]

In the seminal decision of the Supreme Court of Canada in *Consolboard*, Dickson J. (as he then was) stated that the language of section 36 of the *Patent Act* (as it then was) does not lend itself to a tight, literal interpretation. It is and should be treated as a parliamentary pronouncement, in general terms, of what must be disclosed by the patentee before being qualified to receive a patent.[11]

It is a question of fact whether the disclosure is sufficient to enable a skilled person to understand how to work the subject matter of the patent.[12] In the case of patents of a highly technical and scientific nature, the person skilled in the art may be someone possessing a high degree of expert scientific knowledge and skill in the particular branch of science to which the patent relates.[13]

Although the relevant date for assessing insufficiency has been debated in the case law, the date on which sufficiency is to be assessed now seems to be established as (i) the date on which the patent was issued for applications prior to October 1, 1989 under the old *Patent Act*, and (ii) the date of filing for applications under the new *Patent Act*.[14]

If the invention lies in a novel compound, it is proper to claim the new compound without reference to its use, but the use for the new compound must be disclosed in the specification. If the invention lies in a new use for an old compound, the utility must be included in the claim.[15]

8.2.1. The Sufficiency of Disclosure

To ascertain the adequacy of disclosure, the Court must first define the nature of the invention and how it works, and then determine whether disclosure is sufficient to allow the public, having only the specification, to make the same

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requires human activity for its development. See also *Teva Canada Ltd. v Pfizer Canada Inc.*, 2012 SCC 60, [2012] 3 S.C.R. 625 at para 70 (the specification "must define the 'precise and exact extent' of the privilege being claimed").

[8] *Pioneer Hi-Bred Ltd. v. Canada (Commissioner of Patents)*, [1989] 1 S.C.R. 1623, [1989] S.C.J. No. 72 (S.C.C.) at para 27.

[9] *Teva Canada Ltd. v Pfizer Canada Inc.*, 2012 SCC 60, [2012] 3 S.C.R. 625 at paras 70-71, citing with approval *Consolboard Inc. v. MacMillan Bloedel (Saskatchewan) Ltd.*, [1981] 1 S.C.R. 504 (S.C.C.) at 520, *Minerals Separation North American Corp. v. Noranda Mines Ltd.* (1949), 12 C.P.R. 99 (S.C.C.) at 102, affirmed 1952 CarswellNat 2 (Canada P.C.), and *Pioneer Hi-Bred Ltd. v. Canada (Commissioner of Patents)*, [1989] 1 S.C.R. 1623 (S.C.C.) at 1638.

[10] See *Teva Canada Ltd. v. Novartis AG*, 2013 FC 141 at para. 344, referring to the new framework suggested by *Teva Canada Ltd. v Pfizer Canada Inc.*, 2012 SCC 60, [2012] 3 S.C.R. 625 at para 70.

[11] *Consolboard Inc. v. MacMillan Bloedel (Saskatchewan) Ltd.*, [1981] 1 S.C.R. 504 (S.C.C.) at 518, referring to then s. 36(1) of the *Patent Act.* See also *Whirlpool Corp. v. Camco Inc.*, 2000 SCC 67, [2000] S.C.J. No. 68, reconsideration / rehearing refused 2001 CarswellNat 283 (S.C.C.).

[12] *Visx Inc. v. Nidek Co.*, 1999 CarswellNat 2773, [1999] F.C.J. No. 1971 (Fed. T.D.) at para 144, affirmed 2001 CarswellNat 1435 (Fed. C.A.).

[13] *Consolboard Inc. v. MacMillan Bloedel (Saskatchewan) Ltd.*, [1981] 1 S.C.R. 504 (S.C.C.) at 517, referring to then s. 36(1) of the *Patent Act.* See also *Whirlpool Corp. v. Camco Inc.*, 2000 SCC 67, [2000] S.C.J. No. 68 at para. 42, reconsideration / rehearing refused 2001 CarswellNat 283 (S.C.C.).

[14] *Teva Canada Ltd. v Pfizer Canada Inc.*, 2012 SCC 60, [2012] 3 S.C.R. 625 at para. 90. See also *Teledyne Industries Inc. v. Lido Industrial Products Ltd.*, 1981 CarswellNat 561, [1981] F.C.J. No. 703 (Fed. C.A.) at paras. 45–47, leave to appeal refused 1981 CarswellNat 813 (S.C.C.); *TRW Inc. v. Walbar of Canada Inc.* (1991), 39 C.P.R. (3d) 176 (Fed. C.A.) at 195, leave to appeal refused 1992 CarswellNat 1626 (S.C.C.); *Whirlpool Corp. v. Camco Inc.*, 2000 SCC 67, [2000] S.C.J. No. 68 note 4 at paras. 55–56, reconsideration / rehearing refused 2001 CarswellNat 283 (S.C.C.); *Free World Trust c. Électro Santé Inc.*, 2000 SCC 66, [2000] 2 S.C.R. 1024 at paras. 52–54; *Hughes & Woodley on Patents*, 2 ed., looseleaf (Canada: Butterworth, 2005) at para. 31; *Idenix Pharmaceuticals Inc. v Gilead Pharmasset LLC*, 2017 FCA 161 at para 46.

[15] *Pfizer Canada Inc. v. Mylan Pharmaceuticals ULC*, 2011 FC 547, 93 C.P.R. (4th) 81 at 130 [C.P.R.], affirmed 2012 FCA 103 at para 192.

successful use of the invention.[16]

What is the invention is a question of law.[17] In that regard, the issue may arise as to whether the invention is defined by the patent as a whole or whether the claim at issue is to be considered as a stand-alone invention. The answer is that the patent as a whole defines the invention. The Supreme Court of Canada in *Teva Canada Ltd. v Pfizer Canada Inc.* held:

> … [W]hat the Act requires is that the courts consider the specification as a whole to determine whether the disclosure of the invention is sufficient.[18]

The Court rejected the proposition that separate claims disclose separate inventions. However, the Court recognized that, in the event that each claim in a patent does disclose a separate invention, it will consider the issue on a case-by-case basis having regard first to the specification as a whole.[19]

Taken in its entirety, the sufficiency of disclosure is a question of mixed fact and law, as the Judge is required to assess the evidence before him or her against a legal standard of sufficiency.[20] Whether or not a specification is sufficient depends on the evidence of what a person skilled in the art would consider sufficient to put the invention into practice.[21] Courts have held that a skilled person may have to conduct certain experiments on a patent specification, short of requiring any inventive faculty in arriving at the result.[22] However, if a skilled person is required to undertake a "minor research project" to determine the true invention, a court may find disclosure to be inadequate.[23]

8.2.2 Sufficiency of Disclosure and Utility

For purposes of sufficiency of disclosure, there is no requirement for a patentee to disclose the utility of the invention in the patent specification. However, the patentee must establish utility if challenged at a trial. Having regard to subsection 27(3), the disclosure requirement, the Federal Court of Appeal has held:

> [56]….Whether or not a patentee has obtained enough data to substantiate its invention is, in my view, an irrelevant consideration with respect to the application of subsection 27(3). An analysis thereunder is concerned with the sufficiency of the disclosure, not the sufficiency of the data underlying the invention. Allowing Ranbaxy to attack the utility, novelty and/or obviousness of the 546 patent through the disclosure requirement unduly broadens the scope of an inventor's obligation under subsection 27(3) and disregards the purpose of this provision.
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> [57] While it is true that subsection 27(3) requires that an inventor "correctly and fully describe" his invention, this provision is concerned with ensuring the patentee provide the information needed by the person skilled in the art to use the invention as successfully as the patentee.[24]

There is a tendency to confuse the utility requirement in section 2 (an invention must be new and useful) with the disclosure requirement under subsection 27(3). In *Consolboard*, the Supreme Court had to decide whether a patentee was required to disclose the utility (i.e., the commercial application in the specification). Dickson J (as he then was) held in respect of the disclosure obligation that "practical usefulness of the invention does not matter, nor does its commercial utility…" and that the inventor "is not obliged to extol the effect or advantage of his discovery, if he describes his invention so as to produce it".[25]

The Supreme Court of Canada in *Sildenafil* confirmed that there is no obligation on the patentee to demonstrate or prove utility in the patent disclosure. To comply with subsection 27(3), the patentee must provide enough

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[16] *Teva Canada Ltd. v Pfizer Canada Inc.*, 2012 SCC 60, [2012] 3 S.C.R. 625 at para 70.
[17] *Pfizer Canada Inc. v. Canada (Minister of Health)*, 2011 FCA 236 at para 17, leave to appeal to SCC refused 2012 CarswellNat 193; *Apotex Inc. v. Pfizer Ireland Pharmaceuticals*, 2012 FC 1339 at para 31.
[18] *Teva Canada Ltd. v Pfizer Canada Inc.*, 2012 SCC 60, [2012] 3 S.C.R. 625 at para 55.
[19] *Teva Canada Ltd. v Pfizer Canada Inc.*, 2012 SCC 60, [2012] 3 S.C.R. 625 at para 64.
[20] *Teva Canada Ltd. v Pfizer Canada Inc.*, (2010), 88 C.P.R. (4th) 405 (F.C.A.) at para. 75, reversed on other grounds 2012 SCC 60.
[21] *Teva Canada Ltd. v Pfizer Canada Inc.*, 2012 SCC 60, [2012] 3 S.C.R. 625 at paras 75, 79.
[22] *Teva Canada Ltd. v Pfizer Canada Inc.*, 2012 SCC 60, [2012] 3 S.C.R. 625 at paras 74, 75.
[23] See *Teva Canada Ltd. v Pfizer Canada Inc.*, 2012 SCC 60, [2012] 3 S.C.R. 625 at paras 74–80 (the Court found Pfizer's disclosure inadequate because a skilled reader would have had to undertake a minor research project to determine the true invention).
[24] *Pfizer Canada Inc. v. Canada (Minister of Health)*, 2008 FCA 108, 67 C.P.R. (4th) 23 at paras 56–57.
[25] *Consolboard Inc. v. MacMillan Bloedel (Saskatchewan) Ltd.*, [1981] 1 S.C.R. 504 (S.C.C.) at 525–26.

information to enable someone to practice the invention; it does not require the patentee to demonstrate or prove utility in the disclosure of the patent.[26]

> Nothing in this passage suggests that utility is a disclosure requirement; all it says is that "the utility required for patentability (s. 2) must, as of the priority date, either be demonstrated or be a sound prediction". Utility can be demonstrated by, for example, conducting tests, but this does not mean that there is a separate requirement for the disclosure of utility. In fact, there is no requirement whatsoever in s. 27(3) to disclose the utility of the invention: see, e.g., *Consolboard*, at p. 521, *per* Dickson J.: "I am further of the opinion that s. 36(1) [now s. 27(3)] does not impose upon a patentee the obligation of establishing the utility of the invention".

As to the measure of utility, that previously depended on whether or not the specification made a promise of a specific result and to what extent that promise, should it be unfulfilled, impacted the individual claims in a patent to such an extent as to render the entire patent invalid.[27] The "promise doctrine" was described by the Federal Court of Appeal as follows:

> [76] Where the specification does not promise a specific result, no particular level of utility is required; a "mere scintilla" of utility will suffice. However, where the specification sets out an explicit "promise", utility will be measured against that promise. [citation omitted]. The question is whether the invention does what the patent promises it will do.[28]

The "promise doctrine" became almost a standalone ground of invalidity, resulting in a number of patents being invalidated. This led Eli Lilly to advance a NAFTA Chapter 11 claim against the Canadian Government, which was ultimately dismissed.

In 2017, the Supreme Court of Canada struck down the Promise Doctrine.[29] It was held that the doctrine is unsound and incongruent with the words and the scheme of the *Patent Act*. The doctrine was considered excessively onerous because it determined the standard of utility by reference to the promises in the patent and where multiple promises were made, all had to be fulfilled in order for a patent to be valid.[30]

The Court set out a new two-part test for utility: (i) identify the subject-matter of the invention as claimed in the patent; and (ii) ask whether that subject-matter is useful, in that it is capable of even a scintilla of any practical purpose related to the nature of the subject-matter of the invention.[31]

Prior to the 2017 decision, the leading cases from the Supreme Court of Canada regarding adequacy of disclosure were *Consolboard*, *Pioneer Hi-Bred*, and *Sildenafil*. *Sildenafil*, released in 2012, upheld the reasoning in the two earlier Supreme Court decisions:

> In *Consolboard* and in *Pioneer Hi-Bred*, the Court correctly analysed the disclosure requirements set out in s. 27(3) of the Act. The reasoning in those cases should be reaffirmed and applied in the case at bar.[32]

These three cases set out the relevant considerations for a court when faced with an allegation that the patent is invalid for inadequate disclosure.[33]

In *Consolboard*, the Supreme Court of Canada found that the Federal Court of Appeal had erred in two respects in holding that the patent was invalid pursuant to (then) section 36(1) of the *Patent Act*. In reversing the holding that the patent was invalid because it did not make the utility of the invention clear to the public, the Supreme Court held that the only test under that section was whether the specification adequately described the invention "for a person

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[26] *Teva Canada Ltd. v Pfizer Canada Inc.*, 2012 SCC 60, [2012] 3 S.C.R. 625 at para 40.

[27] See *Amgen Canada Inc v Apotex Inc.*, 2015 FC 1261 at para 111 where it was held that "…some promises may affect some claims of the patent but not others; an unfulfilled promise does not necessarily mean that the whole patent, or every claim, is invalid", affirmed 2016 FCA 196.

[28] *Eli Lilly Canada Inc. v. Novopharm Ltd.*, 2010 FCA 197, 85 C.P.R. (4th) 413 at para 76, reconsideration / rehearing refused 2010 CarswellNat 3183 (F.C.A.), leave to appeal refused 2011 CarswellNat 215 (S.C.C.).

[29] *AstraZeneca Canada Inc v Apotex Inc.*, 2017 SCC 36.

[30] *AstraZeneca Canada Inc v Apotex Inc.*, 2017 SCC 36 at paras 36-37.

[31] *AstraZeneca Canada Inc v Apotex Inc.*, 2017 SCC 36 at paras 54-55.

[32] *Teva Canada Ltd. v Pfizer Canada Inc.*, 2012 SCC 60, [2012] 3 S.C.R. 625 at para 52.

[33] *See also Patent Act*, s. 53(1), note 1, as amended, which provides that "A patent is void if any material allegation in the petition of the applicant in respect of the patent is untrue, or if the specification and drawings contain more or less than is necessary for obtaining the end for which they purport to be made, and the omission or addition is wilfully made for the purpose of misleading."

skilled in the art."[34] The Supreme Court found that the Federal Court of Appeal had erred in holding that section 36(1) required the distinct indication of the real utility of the invention. The Supreme Court further held that section 36(1) did not oblige the inventor, in the disclosure or claims, to describe in what respect the invention is new or in what way it is useful.[35]

Pioneer Hi-Bred was an appeal from the Patent Commissioner's refusal to grant a patent for the creation of a new plant variety: a high-yielding soybean with certain desirable characteristics. The specification disclosed that the application was a plant line cultivated naturally but resulting from the artificial cross-breeding of three known varieties to produce a new variety combining the desirable characteristics of each one. The applicant had deposited seeds with U.S. and Canadian governmental agencies.

The Supreme Court considered whether the patent applicant had made sufficient disclosure of its invention in the description and whether depositing samples of seeds constituted disclosure under the *Patent Act*.[36] After setting out the principles informing the analysis of sufficiency, the Court reviewed the specification and found it was limited to describing the materials used for cross-breeding. The patentee had submitted an affidavit to the Patent Appeal Board admitting that "unique controlled plant breeding techniques were employed, which resulted in ... a completely different and new genetic background." The Supreme Court was persuaded that even a person skilled in the science of the invention could not arrive at the same result as the inventor without further explanation.[37]

In *Sildenafil*, the Supreme Court addressed sufficiency of disclosure in the context of a *Patended Medicines Notice of Compliance* ("*PM(NOC)*") proceeding for the Viagra patent, a drug currently on the market for treating erectile dysfunction. The Court found that Pfizer failed to adequately disclose its invention by not specifying which of the seven cascading claims related to sildenafil, the active compound in Viagra. The Court held that a skilled person in the art would be unable to put the invention into practice without first undertaking a minor research project to determine which of the claims contained the true invention. At the time of its application, Pfizer knew which claim contained the active compound but chose not to disclose it specifically.

In reaching its decision in *Sildenafil*, the Supreme Court held that the lower courts erred in considering the disclosure requirements with respect to each individual claim. Instead, adequacy of disclosure must be assessed according to the specification as a whole. There was nothing in Pfizer's specification that suggested that sildenafil was a separate invention to be regarded apart from the other claims. In fact, the patent application used the language "this invention", underscoring that there was only one invention in the patent. The invention was the use of sildenafil for the treatment of erectile dysfunction, and according to the Supreme Court, this had to be disclosed in order to meet the requirements set out in section 27 (3) of the Act.[38]

8.2.3 The "Best Mode" Requirement

For patents claiming a machine, paragraph 27(3)(c) of the *Patent Act* requires the specification "[to] explain the principle of the machine and the best mode in which the inventor has contemplated the application of that principle." Paragraph 80(1)(f) of the *Patent Rules* provides that the description shall "set forth at least one mode contemplated by the inventor for carrying out the invention in terms of examples, where appropriate, and with reference to the drawings, if any."[39]

There is no express statutory duty to disclose the "best mode" of applying the invention *per se*, where the invention is not a machine. However, it has been said that the duty to act *uberrima fides* requires that nothing useful in respect of carrying out the invention may be withheld, and so requires the applicant to disclose the best mode where applicable.[40] Arguably, the obligation may be implied by subsection 27(3)(a) to "correctly and fully describe the

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[34] *Consolboard Inc. v. MacMillan Bloedel (Saskatchewan) Ltd.*, [1981] 1 S.C.R. 504 (S.C.C.) at 521–523. The Federal Court of Appeal was found to have erred in holding that the test with respect to the claims, which are now dealt with under section 27(4), was whether a member of the public would understand them.

[35] *Consolboard Inc. v. MacMillan Bloedel (Saskatchewan) Ltd.*, [1981] 1 S.C.R. 504 (S.C.C.) at 525–527.

[36] *Pioneer Hi-Bred Ltd. v. Canada (Commissioner of Patents)*, [1989] 1 S.C.R. 1623 (S.C.C.) at para 22. See now *Patent Act*, s. 38.1(1) regarding the deposit of biological material.

[37] *Pioneer Hi-Bred Ltd. v. Canada (Commissioner of Patents)*, [1989] 1 S.C.R. 1623, [1989] S.C.J. No. 72 (S.C.C.) at para 29.

[38] *Teva Canada Ltd. v Pfizer Canada Inc.*, 2012 SCC 60, [2012] 3 S.C.R. 625 at para 72.

[39] SOR/96-423. SOR/2007-90, s. 19, effective June 2, 2007 (Can. Gaz. Pt. II, Vol. 141, No. 10, at 838).

[40] See *Teledyne Industries Inc. v. Lido Industrial Products Ltd.* (1981), 57 C.P.R. (2d) 29, [1981] F.C.J. No. 703 (Fed. C.A.) at para 41, leave to appeal refused 1981 CarswellNat 813 (S.C.C.); *Hughes & Woodley on Patents*, 2d ed., loose-leaf (Canada: Butterworth's, 2005) at para 31.

invention".[41]

A statement of the principle informing the necessity of disclosure of the best mode was articulated by the Federal Court of Appeal in *Teledyne Industries Inc. v. Lido Industrial Products Ltd.*:

> As Thorson P. observed ... 'The inventor must act uberrima fide and give all information known to him that will enable the invention to be carried out to its best effect as contemplated by him.' On this principle, the statute provides that in case of a machine an applicant must explain the 'best mode' in which he has contemplated the application of the principle of the machine. That is, after all, the only logical application of the principle because any attempt to prove lack of disclosure of all knowledge relating to the invention would involve the difficult, if not impossible, task of proving a negative with respect to a state of mind, and for the further reason that, if a patentee discloses his best knowledge — his best means and method — the public is little interested in second and third-rate alternatives. ... He must put the public in possession of the invention in as full and ample a manner as he himself possesses it and give to them the opportunity of deriving benefits therefrom equal to the benefits accruing to him. ...
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> If, however, the patentee is not in possession of the most efficient manner in which his invention may be put into practice, he cannot be penalized if he does not give it to the public, for he is only required to give the best knowledge that he himself possesses."[42]

The Court in *Teledyne Industries* went on to hold that the duty of the patentee to state the best mode for the application of the principle of its device would not include a duty to state modifications devised to save manufacturing costs.[43]

8.2.4 Ambiguity

Ambiguity is a distinct latent validity attack that is directed to the claims. It is the duty of the patentee to state clearly and distinctly, either in direct words or by clear and distinct reference, the nature and limits of what is claimed. Where the claims, properly construed, are capable of more than one meaning, are vague or obscure, the claims are said to be bad for ambiguity. For example, the Patent Appeal Board rejected a patent application because of the ambiguous use of the term "compact characteristics" in a claim describing the traits of a plant. The Commissioner characterized the term as an "avoidable ambiguity" and stated that "nothing can excuse the use of ambiguous language when simple language can be easily employed".[44]

"Insufficiency" is a separate ground of invalidity from "ambiguity". "Insufficiency" is directed to the issue of whether the description is sufficient to enable those persons to whom the specification is addressed to understand how the subject matter of the patent has to be made or put into operation. "Ambiguity" is directed to the issue of whether the invention is sufficiently described and ascertained in the claims so as to enable the public to understand the scope of the monopoly granted by the Letters Patent.

In dismissing a motion for summary judgment on grounds that the patent was invalid for ambiguity, Mr. Justice Mosley held:

> A claim is not invalid simply because it is not a model of concision and lucidity. Very few patent claims are. Claims are drafted to be understood by people with practical knowledge and experience in the specific field of the invention: *Risi Stone Ltd.* supra, at 20. If a term can be interpreted using grammatical rules and common sense, it cannot be ambiguous: *Mobil Oil Corp. v. Hercules Canada Inc.* (1995), 63 C.P.R. (3d) 473 at 484, 188 N.R. 382 (F.C.A.).[45]

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[41] *Bauer Nike Hockey Inc. v. Regan*, 2001 CarswellNat 2919, [2001] F.C.J. No. 1839 (Fed. T.D.) (Prothonotary) at paras 11–13 (dismissing a motion to strike a paragraph in the plaintiffs statement of claim alleging that the defendant failed to specify the best method of creating an invention that was not a machine) citing Harold G. Fox, *Canadian Patent Law and Practice*, 4th ed. (Toronto: Carswell, 1969) at 180.

[42] *Teledyne Industries Inc. v. Lido Industrial Products Ltd.* (1981), 57 C.P.R. (2d) 29, [1981] F.C.J. No. 703 (Fed. C.A.) at para 41, leave to appeal refused 1981 CarswellNat 813 (S.C.C.), citing Harold G. Fox, *Canadian Patent Law and Practice*, 4th ed. (Toronto: Carswell, 1969) at 180.

[43] *Teledyne Industries Inc. v. Lido Industrial Products Ltd.* (1981), 57 C.P.R. (2d) 29, [1981] F.C.J. No. 703 (Fed. C.A.) at para. 50, leave to appeal refused 1981 CarswellNat 813 (S.C.C.). See *TRW Inc. v. Walbar of Canada Inc.*, 1991 CarswellNat 1122, [1991] F.C.J. No. 1075 (Fed. C.A.), wherein the court held that because the teaching in the patent was to the contrary, a person skilled in the art would not be expected to "clamp on the root" and, accordingly, the disclosure failed to comply with (then) subsection 36(1) of the *Patent Act.*

[44] *Nunhems, Re* 2015 CarsewellNat 5143 at para 43.

[45] *Letourneau v. Clearbrook Iron Works Ltd.*, 2005 FC 1229, 44 C.P.R. (4th) 345 at para 37, affirmed 2006 FCA 42.

There is a dearth of cases in the Federal Court in which an issued patent has been held invalid for ambiguity.[46] As repeatedly noted by the Court, "ambiguity is truly a last resort, rarely, if ever, to be used."[47]

8.2.5 "Selection Patents"

The sufficiency of disclosure often arises in the context of "selection patents". A selection patent is a patent whose subject matter is a fraction of a larger known class which was the subject matter of a prior patent.[48] In *Sanofi-Synthelabo Canada Inc. v. Apotex Inc.*, the Supreme Court of Canada upheld the permissibility of selection patents in principle.[49] For a selection patent to be valid, it should disclose a "substantial advantage to be secured or disadvantage to be avoided by the use of the selected members" not disclosed in the prior genus patent.[50] "There must be a special advantage arising from the selected substances and any advantage, novel property, or use must be fully characterized in the description."[51] Hence the importance of the disclosure in the specification.

The Federal Court considered the sufficiency of disclosure with respect to selection patents.[52] The price to be paid by a patentee who has already enjoyed a monopoly from a prior patent is clear and explicit disclosure of the invention in the selection patent. Mr. Justice Hughes concluded that a "statement that the selected group possesses advantages or lack of disadvantages is not in itself sufficient"; rather, the advantage or disadvantage "must be plainly and fully set out in sufficient detail in the specification so as to enable a person skilled in the art to know and appreciate what they are."[53] In refusing to hear an appeal from this decision on grounds of mootness, the majority of the Federal Court of Appeal noted that it cannot necessarily be assumed that Hughes J. meant that comparative data must always be provided in order for a selection patent to be valid, and declined to further consider this issue.[54]

The fact that the compound was one of a number of claimed compounds in an earlier patent does not render the later patent a selection patent if its claims are limited to the discovery of a new use for the old compound. Had the later patent re-claimed the old compound, a selection would have been made requiring additional disclosure of the surprising and unexpected advantages over the other compounds claimed in the older patent.[55]

8.3 MISREPRESENTATION IN THE PATENT APPLICATION

A distinct challenge to a patent's validity is an assertion the patentee made a material misrepresentation in the prosecution of the patent. Section 53 of the *Patent Act* provides, in part,

> 53. (1) A patent is void if any material allegation in the petition of the applicant in respect of the patent is untrue, or if the specification and drawings contain more or less than is necessary for obtaining the end for which they purport to be made, and the omission or addition is wilfully made for the purpose of misleading. [underlining added]
>
> (2) Where it appears to a court that the omission or addition referred to in subsection (1) was an involuntary error and it is proved that the patentee is entitled to the remainder of his patent, the court shall render a judgment in accordance with the facts, and shall determine the costs, and the patent shall be held valid for that part of the invention described to which the

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[46] *Pfizer Canada Inc. v. Canada (Minister of Health)*, 2005 FC 1725, [2005] F.C.J. No. 2155 at para 51, affirmed 2007 CarswellNat 6.
[47] *Pfizer Canada Inc. v. Canada (Minister of Health)*, 2005 FC 1725, [2005] F.C.J. No. 2155 at para 53, affirmed 2007 CarswellNat 6.
[48] *Sanofi-Synthelabo Canada Inc. v. Apotex Inc.*, 2008 SCC 61, 69 C.P.R. (4th) 251 at paras 10, 32.
[49] *Sanofi-Synthelabo Canada Inc. v. Apotex Inc.*, 2008 SCC 61, 69 C.P.R. (4th) 251 at para 19.
[50] *Sanofi-Synthelabo Canada Inc. v. Apotex Inc.*, 2008 SCC 61, 69 C.P.R. (4th) 251 at paras 10, 32.
[51] *Pfizer Canada Inc. v. Canada (Minister of Health)* (2008), 2008 FCA 108, [2009] 1 F.C.R. 253 at para 41.
[52] *Eli Lilly Canada Inc. v. Novopharm Ltd.*, 2007 FC 596, [2007] F.C.J. No. 800 at paras. 128–165, additional reasons 2007 CarswellNat 1894 (F.C.), appeal dismissed as moot 2007 FCA 359, [2007] F.C.J. No. 809, leave to appeal refused 2008 CarswellNat 746, [2008] S.C.C.A. No. 9 (S.C.C.). See also Harold G. Fox, *Canadian Patent Law and Practice*, 4th ed. (Toronto: Carswell, 1969) at 193.
[53] *Eli Lilly Canada Inc. v. Novopharm Ltd.*, 2007 FC 596, [2007] F.C.J. No. 800 at para 139, additional reasons 2007 CarswellNat 1894 (F.C.), appeal dismissed as moot 2007 FCA 359, [2007] F.C.J. No. 809, leave to appeal refused 2008 CarswellNat 746, [2008] S.C.C.A. No. 9 (S.C.C.).
[54] *Eli Lilly Canada Inc. v. Novopharm Ltd.*, 2007 FC 596, [2007] F.C.J. No. 800 at para 30, additional reasons 2007 CarswellNat 1894 (F.C.), appeal dismissed as moot 2007 FCA 359, [2007] F.C.J. No. 809, leave to appeal refused 2008 CarswellNat 746, [2008] S.C.C.A. No. 9 (S.C.C.).
[55] *Novopharm Ltd. v. Eli Lilly & Co.* (2010), 87 C.P.R. (4th) 301 (F.C.) at 337–338, paras 88–89, additional reasons 2010 CarswellNat 4371 (F.C.), affirmed without comment (2011), 94 C.P.R. (4th) 95 (F.C.A.), leave to appeal refused 2011 CarswellNat 5075, [2011] S.C.C.A. No. 362 (S.C.C.).

patentee is so found to be entitled.

The presumption of patent validity presumes that the patent contains no misrepresentations within the meaning of section 53.[56] The party challenging the validity of the patent under section 53 should lead direct evidence of knowledge or an intention to mislead, or such evidence by which the court may infer such knowledge or intent.[57] It is the addressee of the patent, the person skilled in the art, that must be misled by the alleged misrepresentation.[58] The relevant date for assessing subsection 53(1) is the date of issue, although untrue allegations made prior to issue and not corrected as of the date of issue may also be considered.[59]

The party making the allegation of invalidity under section 53 must prove the allegation, notwithstanding that knowledge may lie with the patentee. The alleging party must lead evidence or take steps to obtain evidence from the patentee by request or appropriate Court Order.[60] There is no obligation on the patentee to lead evidence.[61]

Arguably, Section 53 gives rise to the spectre of fraud. It is commonly thought that a party should not speculate or make imputations as to motive in a reckless manner or without sufficient evidence. To raise a section 53 allegation and not follow through with the matter, or fail to prove it, may give rise to serious cost consequences.[62]

It was once thought that under subsection 53(1), a material allegation that was untrue would render a patent void regardless of whether or not it was made wilfully.[63] However Stone J.A., for a unanimous court in *671905 Alberta Inc. v. Q'Max Solutions Inc.*, held that "an untrue 'material allegation' that consists of a failure to name co-inventors in a petition for a patent will not render the patent void if the allegation was not 'wilfully made for the purpose of misleading'."[64] Furthermore, the Federal Court of Appeal has held that the failure of an inventor to disclose his public servant status, pursuant to the *Public Servants Inventions Act*, was not a material obligation imposed by the *Patent Act* and thus did not render the patent invalid.[65]

Where the patent contains an omission or addition not made wilfully for the purpose of misleading, the patentee is "entitled to the remainder of his patent [and] the court shall render a judgment in accordance with the facts".[66]

Whether a misrepresentation is material under subsection 53(1) is a question of mixed fact and law.[67]

Relying on *Jules R. Gilbert Ltd. v. Sandoz Patents Ltd.*,[68] Mr. Justice Wetston held in *Apotex Inc. v. Wellcome Foundation Ltd.* that "the only allegations which are material to a patent are those which relate to the subject-matter of the patent".[69] Allegations concerning subject-matter outside the patent claims are immaterial.[70] For example, the

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[56] *Eli Lilly Canada Inc. v. Apotex Inc.*, 2007 FC 455 at para 245, affirmed 2008 FCA 44.
[57] *Eli Lilly Canada Inc. v. Apotex Inc.*, 2007 FC 455 at para 381, affirmed 2008 FCA 44.
[58] *Corning Glass Works v. Canada Wire & Cable Ltd.* (1984), 81 C.P.R. (2d) 39 (Fed. T.D.) at 74–76.
[59] *Weatherford Canada Ltd. v. Corlac Inc.*, 2011 FCA 228, 95 C.P.R. (4th) 101 at para 330, leave to appeal refused 2012 CarswellNat 846 (S.C.C.), referring to *Jules R. Gilbert Ltd. v. Sandoz Patents Ltd.* (1970), 64 C.P.R. 14 (Can. Ex. Ct.), reversed in part on other grounds (1972), [1974] S.C.R. 1336 (S.C.C.).
[60] *Eli Lilly Canada Inc. v. Novopharm Ltd.* (2007), 58 C.P.R. (4th) 214 at para 169, additional reasons 2007 CarswellNat 1894 (F.C.), appeal dismissed as moot 2007 CarswellNat 3771 (F.C.A.), leave to appeal refused 2008 CarswellNat 746 (S.C.C.).
[61] *Eli Lilly Canada Inc. v. Novopharm Ltd.* (2007), 58 C.P.R. (4th) 214 at para 172, additional reasons 2007 CarswellNat 1894 (F.C.), appeal dismissed as moot 2007 CarswellNat 3771 (F.C.A.), leave to appeal refused 2008 CarswellNat 746 (S.C.C.).
[62] *Eli Lilly Canada Inc. v. Apotex Inc.*, 2009 FCA 97 at paras 62–63, leave to appeal refused 2009 CarswellNat 3235 (S.C.C.). See however *Johnson & Johnson Inc. v. Boston Scientific Ltd. / Boston Scientifique Ltée*, 2008 FC 817 at para 9, per Layden-Stevenson J..
[63] See, for example, the discussion by Hansen J. in *Zambon Group S.p.A. v. Teva Pharmaceutical Industries Ltd.*, 2005 FC 1585 where at para 31 she concludes that it is not settled law that "willfulness is an essential element on the first ground of invalidity under subsection 53(1)."
[64] 2003 FCA 241, [2003] 4 F.C. 713, 27 C.P.R. (4th) 385 (Fed. C.A.), leave to appeal refused 2004 CarswellNat 1207 (S.C.C.), recently applied in *Weatherford Canada Ltd. v. Corlac Inc.*, 2011 FCA 228, 95 C.P.R. (4th) 101 (Fed. C.A.) at 140 [C.P.R.], para. 116, leave to appeal refused 2012 CarswellNat 846 (S.C.C.).
[65] *Brown v Canada* 2016 FCA 37 at para 49-50, reversing *Brown v Canada* 2014 FC 831.
[66] *Patent Act*, s. 53(2).
[67] *Weatherford Canada Ltd. v. Corlac Inc.*, 2011 FCA 228, 95 C.P.R. (4th) 10 at para 115, leave to appeal refused 2012 CarswellNat 846 (S.C.C.).
[68] *Jules R. Gilbert Ltd. v. Sandoz Patents Ltd.* (1970), 64 C.P.R. 14 (Can. Ex. Ct.), reversed in part 1972 CarswellNat 438 (S.C.C.); see also *Rothmans, Benson & Hedges Inc. v. Imperial Tobacco Ltd./Ltée* (1991), 35 C.P.R. (3d) 417 (Fed. T.D.) at para. 28, affirmed 1993 CarswellNat 1393 (Fed. C.A.).
[69] *Apotex Inc. v. Wellcome Foundation Ltd.* (1998), 79 C.P.R. (3d) 193 (Fed. T.D.), reversed in part 2000 CarswellNat 2643 (Fed. C.A.), affirmed 2002 CarswellNat 3436 (S.C.C.).

failure to include the name of a co-inventor in the petition does not constitute a material allegation that would result in the invalidity of the patent.[71] Conversely, where the wrong inventor is named, the patent will be invalid if that untrue material allegation was made wilfully for the purpose of misleading.[72] The Federal Court of Appeal in *Q'Max* characterized the remedy in subsection 53(1) as "draconian". In practice, Courts are reluctant to invoke it absent compelling evidence of wrong-doing.[73] That said, the Federal Court of Appeal has advised that the materiality of a failure to name the proper inventor depends on the specific circumstances of the case.[74]

In the past, Courts have held that an improper claim to a priority date[75] and an applicant's failure to disclose all prior applications are not material allegations.[76] An applicant's failure to cite relevant prior art during the petition of the patent will not result in the patent's invalidity. There is no obligation under the *Patent Act* for an applicant to disclose and describe all prior art.[77]

Alleged missteps in the application for, or prosecution of, a patent are sometimes framed by those who seek to invalidate a patent as a breach of section 73 of the *Patent Act*. The issue is whether paragraph 73(1) (a) can be invoked to invalidate a patent once it has been issued. Paragraph 73(1) (a) provides:

> 73. (1) An application for a patent in Canada shall be deemed to be abandoned if the applicant does not
>
> (*a*) reply in good faith to any requisition made by an examiner in connection with an examination, within six months after the requisition is made or within any shorter period established by the Commissioner;

In *Weatherford Canada Ltd. v. Corlac Inc.,* the Federal Court of Appeal rejected the argument that "if it is established (at any time) that an applicant did not respond in good faith to a requisition during the prosecution of the application, then by operation of law, the application is deemed abandoned if not reinstated within the requisite time."[78] The Court held:

> [149] In my view, subsection 53(1) of the Act speaks to misrepresentations in relation to patents, that is, issued patents. Paragraph 73(1) (a) speaks to good faith in the prosecution of the patent application. The provisions are mutually exclusive….
>
> [150] To be clear, the concept of abandonment in paragraph 73(1) (a) operates during the prosecution of the application for a patent. Its operation is extinguished once the patent issues. Post issuance, the provisions of subsection 53(1) must be utilized with respect to allegations of misrepresentation. To conclude otherwise would be an absurdity. An issued patent would be subject to retroactive scrutiny by the courts in relation to the submissions made by an applicant to the Patent Office during prosecution (generally many years prior), judged against unknown criteria. It is for the Commissioner to determine whether an applicant's response to a requisition from an Examiner is made in good faith, not for the courts. The courts do not issue patents.[79] [underlining added]

The Court expressly held that two earlier decisions of the Federal Court that could be interpreted as standing for the proposition that paragraph 73(1)(a) can be relied upon for the purpose of attacking the validity of a patent, should

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[70] *Jules R. Gilbert Ltd. v. Sandoz Patents Ltd.* (1970), 64 C.P.R. 14 (Can. Ex. Ct.), reversed in part 1972 CarswellNat 438 (S.C.C.).
[71] *Eli Lilly & Co. v. Apotex Inc.* (1998), 80 C.P.R. (3d) 80 (Fed. T.D.) at para 27, affirmed 2000 CarswellNat 1343 (Fed. C.A.).
[72] *671905 Alberta Inc. v. Q'Max Solutions Inc.* (2003), 27 C.P.R. (4th) 385 (Fed. C.A.) at paras 23–32, leave to appeal refused 2004 CarswellNat 1207, [2003] S.C.C.A. No. 381 (S.C.C.)
[73] *Weatherford Canada Ltd. v. Corlac Inc.*, 2011 FCA 228, 95 C.P.R. (4th) 101 at para 123, leave to appeal refused 2012 CarswellNat 846 (S.C.C.), referencing *671905 Alberta Inc. v. Q'Max Solutions Inc.* (2003), 27 C.P.R. (4th) 385 (Fed. C.A.) at para. 32, leave to appeal refused 2004 CarswellNat 1207 (S.C.C.).
[74] *Weatherford Canada Ltd. v. Corlac Inc.*, 2011 FCA 228, 95 C.P.R. (4th) 101 at para 128, leave to appeal refused 2012 CarswellNat 846 (S.C.C.), and see discussion of cases at paras 126–127 at 143–144.
[75] *Canadian Marconi Co. v. Vera Prinzen Enterprises Ltd.* (1964), 46 C.P.R. 97 (Can. Ex. Ct.).
[76] *Bayer AG v. Apotex Inc.* (1998), 84 C.P.R. (3d) 23 (Fed. T.D.) at paras 19–23, affirmed 2001 CarswellNat 2031 (Fed. C.A.), leave to appeal refused 2002 CarswellNat 1323 (S.C.C.)
[77] *Bourgault Industries Ltd. v. Flexi-Coil Ltd.* (1998), 80 C.P.R. (3d) 1 (Fed. T.D.) at 87–92, affirmed 1998 CarswellNat 554 (Fed. T.D.), affirmed (1999), 86 C.P.R. (3d) 221 (Fed. C.A.), leave to appeal refused 2000 CarswellNat 393 (S.C.C.); see also *Eli Lilly & Co. v. Apotex Inc.* (1998), 80 C.P.R. (3d) 80 (Fed. T.D.) at paras 27–29, affirmed (2000), 259 N.R. 225 (Fed. C.A.).
[78] *Weatherford Canada Ltd. v. Corlac Inc.*, 2011 FCA 228, 95 C.P.R. (4th) 101 at para 139, leave to appeal refused 2012 CarswellNat 846 (S.C.C.).
[79] *Weatherford Canada Ltd. v. Corlac Inc.*, 2011 FCA 228, 95 C.P.R. (4th) 101 at para 150, leave to appeal refused 2012 CarswellNat 846 (S.C.C.).

not be followed.[80]

8.4 OVER-CLAIMING OR "CLAIMS BROADER"

The proper scope of claims drafting is a common ground for patent invalidity in Canada. Subsection 27(4) of the *Patent Act* requires:

> (4) Claims – The specification must end with a claim or claims defining distinctly and in explicit terms the subject-matter of the invention for which an exclusive privilege or property is claimed.

Rule 84 of the *Patent Rules* provides:

> The claims shall be clear and concise and shall be fully supported by the description independently of any document referred to in the description.[81]

The challenge was well expressed by Thorson P. in *Minerals Separation North American Corp. v. Noranda Mines Ltd.*[82]

> By his claims the inventor puts fences around the fields of his monopoly and warns the public against trespassing on his property. His fences must be clearly placed in order to give the necessary warning and he must not fence in any property that is not his own. The terms of a claim must be free from ambiguity or obscurity and must not be flexible; they must be clear and precise so that the public will be able to know not only where it must not trespass but also where it may safely go.

There has been little jurisprudential guidance as to the meaning of Rule 84. The Patent Appeal Board noted that the Commissioner of Patents has held that it may be possible for a single sentence in the disclosure to provide sufficient support to warrant claims to some inventions, subject to the overriding principle that an inventor may not validly claim what he has not described.[83]

A somewhat related invalidity allegation to "insufficiency" is the issue of over-claiming. This is an issue of claim construction to be determined by the court, as informed by evidence from inventors and experts where available and applicable.[84] A claim will be invalid as overly broad where it fails to include an essential element of the invention as disclosed in the specification.[85] The definition of essential elements is a matter of claim construction to be performed by the Court. If an omitted element is found by the Court to be non-essential, it will not render the claim invalid for over-claiming.[86]

Over-claiming may render a claim invalid on the basis that the scope of the claims granted to the inventor is broader than the invention made and disclosed in the patent. Valid claims must not be broader than either: (i) the new and useful invention as invented by the inventor; or (ii) the invention as described in the specification of the patent.[87] Simply stated, "a patent claim must not exceed either the invention made or the invention disclosed."[88]

The Federal Court of Appeal in *Pfizer Canada Inc. v. Canada (Minister of Health)* confirmed: "It is now settled law

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[80] *Weatherford Canada Ltd. v. Corlac Inc.*, 2011 FCA 228, 95 C.P.R. (4th) 101 at para 151, leave to appeal refused 2012 CarswellNat 846 (S.C.C.), referring to *G.D. Searle & Co. v. Novopharm Ltd.*, 2007 FC 81, reversed 2007 FCA 173, leave to appeal refused 2007 CarswellNat 3623, [2007] S.C.C.A. No. 340 (S.C.C.) and *Lundbeck Canada Inc. v. Ratiopharm Inc.*, 2009 FC 1102.

[81] *Patent Rules*, SOR/96-423, s. 84. All references to the *Patent Rules* in this chapter refer to SOR/1996-423 unless otherwise noted.

[82] [1947] Ex. C.R. 306 (Can. Ex. Ct.) at 352, reversed 1949 CarswellNat 19 (S.C.C.), affirmed 1952 CarswellNat 2 (Canada P.C.).

[83] *Geron Corp., Re* (2011), 93 C.P.R. (4th) 384 (Can. Pat. App. Bd. & Pat. Commr.) at para 52.

[84] *Pfizer Canada Inc. v. Canada (Minister of Health)*, 2007 FCA 209 (F.C.A.) at para 39, leave to appeal refused 2007 CarswellNat 3850 (S.C.C.); See also *Cobalt Pharmaceuticals Co. v Bayer Inc.*, 2015 FCA 116 at para 14-25.

[85] *Amfac Foods Inc. v. Irving Pulp & Paper Ltd.* (1986), 12 C.P.R. (3d) 193 (Fed. C.A.); *Visx Inc. v. Nidek Co.*, 1999 CarswellNat 2773, [1999] F.C.J. No. 1971 (Fed. T.D.) at para 145, affirmed 2001 CarswellNat 1435 (Fed. C.A.).

[86] *Stonehouse v. Batco Manufacturing Ltd.*, 2004 FC 1767 at para 174.

[87] *Leithiser v. Pengo Hydra-Pull of Canada Ltd.*, [1974] 2 F.C. 954, 17 C.P.R. (2d) 110 (Fed. C.A.) at para 21 [C.P.R.].

[88] *Farbwerke Hoechst A.G. vormals Meister Lucius & Bruning v. Canada (Commissioner of Patents)* (1965), [1966] Ex. C.R. 91 (Can. Ex. Ct.), affirmed [1966] S.C.R. 604 (S.C.C.); *Pfizer Canada Inc. v. Canada (Minister of Health)*, 2007 FCA 209 at para 115, leave to appeal refused 2007 CarswellNat 3850 (S.C.C.); *Eli Lilly Canada Inc. v. Apotex Inc.*, 2008 FC 142, 63 C.P.R. (4th) 406 at para 180, affirmed 2009 FCA 97, leave to appeal refused 2009 CarswellNat 3235 (S.C.C.).

that a patent which claims more than what was invented or disclosed can be found invalid for being overly broad."[89] The test is "a claim will be considered overly broad and accordingly, invalid, if it asserts an exclusive property or privilege in something the inventor did not actually invent; or something that the inventor did not fully disclose in the patent."[90] The Federal Court of Appeal decision in *Amfac Foods Inc. v. Irving Pulp & Paper Ltd.* summarized the earlier case law.[91]

8.4.1 Claims Broader Than Invention Made

A patent is granted for a new and useful invention that was actually discovered by the inventor. It is a question of fact as to what the inventor(s) actually invented.[92] If the evidence establishes that the inventor did not invent what is claimed, or the claims are broader than what was invented, the claims are invalid (as poosed to the entire patent). This general principle is subject to the doctrine of sound prediction, discussed in 8.6 below.

The issue may be tied to an allegation that the patent is invalid for lack of utility; that is, whether at the time of filing the application, did the inventor have sufficient evidence to demonstrate that the invention would work, or if not, the utility could be soundly predicted.

8.4.2 Claims Broader Than Invention Disclosed

A claim is invalid if it purports to monopolize more than what is disclosed in the specification.[93] This is sometimes referred to as "covetous claiming".

This cardinal principle of Canadian patent law is reflected in the following:

> The question to be determined by the Court when dealing with the argument that a claim is covetous is whether the claim at issue exceeds the scope of the disclosure on which this claim is based.
>
> It is a cardinal principle of patent law that an inventor may not validly claim what he has not described. In the patent law jargon, it is said that the disclosures of the specification must support the claims. If they do not, the claims are invalid.[94]

8.4.3 Remedial Efforts

To remedy the risk of over-claiming, and to achieve a better balance between a broad claim which risks being invalidated and a narrow claim which may not be effective in preventing infringement, alternatives for narrowing the patent claims include the use of disclaimer or reissue procedures, addressed in 8.8 and 8.10 below.

8.5 DOUBLE PATENTING

Double patenting refers to judge-made rules that are intended to prohibit a patent from being granted where a patent has previously been issued for the same invention. The theory is that a person should not enjoy an extended monopoly in the same invention by having separate patents issued to it when in reality only one invention is involved.[95] The prohibition against double patenting relates to the "ever greening" problem described by the Supreme Court of Canada in *Whirlpool Corp. v. Camco Inc.*, [96] namely, that a patentee must not be allowed to prolong its monopoly by filing a new patent that does not offer a new invention to the public. [97] The *Patent Act*

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[89] *Pfizer Canada Inc. v. Canada (Minister of Health)*, 2007 FCA 209, 60 C.P.R. (4th) 81 at para 115, leave to appeal refused 2007 CarswellNat 3850, [2007] S.C.C.A. No. 377 (S.C.C.); See *Arctic Cat Inc. v Bombardier Recreational Products Inc.*, 2016 FC 1047, 161 CPR (4th) at para 311.
[90] *Pfizer Canada Inc. v. Canada (Minister of Health)*, 2007 FCA 209, 60 C.P.R. (4th) 81 at para 115, leave to appeal refused 2007 CarswellNat 3850, [2007] S.C.C.A. No. 377 (S.C.C.) at para. 116.
[91] *Amfac Foods Inc. v. Irving Pulp & Paper Ltd.* (1986), 12 C.P.R. (3d) 193 (Fed. C.A.).
[92] *Pfizer Canada Inc. v. Canada (Minister of Health)*, 2008 FC 11 at para 46.
[93] *Unilever PLC v. Procter & Gamble Inc.* (1995), 61 C.P.R. (3d) 499 (Fed. C.A.).
[94] *Radio Corp. of America v. Raytheon Manufacturing Co.* (1957), 27 C.P.R. 1 (Can. Ex. Ct.) at 12, as cited in *Leithiser v. Pengo Hydra-Pull of Canada Ltd.*, [1974] 2 F.C. 954, 17 C.P.R. (2d) 110 (Fed. C.A.) at 112 [C.P.R.].
[95] *Merck & Co. v. Apotex Inc.*, 2006 FC 524 at para 207, additional reasons 2006 CarswellNat 1407 (F.C.), reversed in part 2006 CarswellNat 3315 (F.C.A.), reversed in part 2006 CarswellNat 3206 (F.C.A.), leave to appeal refused 2007 CarswellNat 1097 (S.C.C.).
[96] *Whirlpool Corp. v. Camco Inc.*, 2000 SCC 67, [2000] S.C.J. No. 68, reconsideration / rehearing refused 2001 CarswellNat 283 (S.C.C.).
[97] *Mylan Pharmaceuticals ULC v Eli Lilly Canada Inc.*, 2016 FCA 119, 136 CPR (4th) 1, at para 26.

provides that an inventor is only entitled to one patent for each invention,[98] to allow otherwise would violate "the bargain at the heart of the patent system".[99]

There are two branches of double patenting: "same invention" (identical or coterminous claims) and "obviousness" double patenting (claims not patentably distinct).[100] For patents filed before October 1, 1989, obviousness double patenting is determined with reference to the date of the invention and not the date of the patent.[101] For patents filed on or after October 1, 1989, the date of issuance is relevant.

The prohibition on double patenting does not require identical language in the two patents' claims. The claims may claim the same invention regardless of the words used.[102] For example, a patent claiming a medicine with an inert pharmaceutical carrier (i.e. a simple dilution of a medicine) was held invalid for double patenting where there was already a patent for the medicine itself.[103] In addition, the Federal Court of Appeal confirmed that the Commissioner of Patents was correct in refusing to grant a patent for a compound because a patent had already been issued for the same compound made by a particular process.[104] More recently, the Federal Court of Appeal affirmed that the substance of the obviousness double patenting inquiry is that set out by the Supreme Court in *Whirlpool Corp., v Camco Inc.*, namely, whether the issuance of the second patent contains claims that are not "patentably distinct" from those of the earlier patent.[105]

Whether a patent is invalid for double patenting necessarily involves a comparison of the claims rather than the disclosure, because it is the claims that define the monopoly.[106] Historically, double patenting was not limited to patents issued to the same inventors or patentees.[107] However, in a more recent decision Justice Hughes held that double patenting "only applies when dealing with the same person getting two or more patents."[108]

Patents applied for after October 1, 1989 and granted based on divisional applications may be declared invalid based on an allegation of double patenting even where the patents share the same expiry date.[109] This was said to prevent the "sin of double patenting" in which multiple patents are listed on the patent register to obtain successive stays under the *PM(NOC) Regulations*.[110] Conversely, with respect to old *Patent Act* patents, it has been held that double patenting is not applicable to claims found within two patents that are issued on the same day.[111]

Where a patent has been found to be a proper selection patent, and therefore not obvious, the claims will not be invalid for double patenting.[112] A selection patent that claims a compound that is patentably distinct from the prior genus patent will not be invalid for obviousness double patenting.[113]

[NOTE: re: 8.6 SOUND PREDICTION - THIS ENTIRE SECTION NEEDS TO BE MOVED UP TO BECOME 8.5]

8.6 SOUND PREDICTION -

There is no requirement for a patentee to prove utility in the patent disclosure so long as the court finds utility to

[98] *Patent Act*, s. 36(1).
[99] *Mylan Pharmaceuticals ULC v Eli Lilly Canada Inc.*, 2016 FCA 119, 136 CPR (4th) 1, at para 26.
[100] *Whirlpool Corp. v. Camco Inc.*, 2000 SCC 67, [2000] S.C.J. No. 68, paras 65–66, reconsideration / rehearing refused 2001 CarswellNat 283 (S.C.C.).
[101] *Aventis Pharma Inc. v. Pharmascience Inc.* (2005), 38 C.P.R. (4th) 441 (F.C.) at para. 85, affirmed 2006 CarswellNat 1731 (F.C.A.), leave to appeal refused 2007 CarswellNat 859 (S.C.C.).
[102] *Sanofi-Synthelabo Canada Inc. v. Apotex Inc.*, 2008 SCC 61 at para 109.
[103] *Farbwerke Hoechst A.G. vormals Meister Lucius & Bruning v. Canada (Commissioner of Patents)* (1963), [1964] S.C.R. 49 (S.C.C.) at para 5; *Consolboard Inc. v. MacMillan Bloedel (Saskatchewan) Ltd.*, [1981] 1 S.C.R. 504 (S.C.C.) at 536.
[104] *Bayer Schering Pharma AG v. Canada (Attorney General)*, 2010 FCA 275, 90 C.P.R. (4th) 313 at 325 [C.P.R.], para 49.
[105] *Mylan Pharmaceuticals ULC v Eli Lilly Canada Inc.*, 2016 FCA 119, 136 CPR (4th) 1, at para 36.
[106] *Whirlpool Corp. v. Camco Inc.*, 2000 SCC 67, [2000] S.C.J. No. 68 at para 63, reconsideration / rehearing refused 2001 CarswellNat 283 (S.C.C.).
[107] *Aventis Pharma Inc. v. Pharmascience Inc.* (2005), 38 C.P.R. (4th) 441 (F.C.) at para. 59, affirmed 2006 CarswellNat 1731 (F.C.A.), leave to appeal refused 2007 CarswellNat 859 (S.C.C.).
[108] *Bristol-Myers Squibb Co. v. Apotex Inc.*, 2009 FC 137 at para. 174.
[109] *GlaxoSmithKline Inc. v. Apotex Inc.* (2003), 27 C.P.R. (4th) 114 (Fed. T.D.) at paras. 85-91.
[110] *GlaxoSmithKline Inc. v. Apotex Inc.* (2003), 27 C.P.R. (4th) 114 (Fed. T.D.) at paras. 90-91.
[111] *Xerox of Canada Ltd. v. IBM Canada Ltd.* (1977), 33 C.P.R. (2d) 24 (F.C.A) at 57.
[112] *Pfizer Canada Inc. v. Canada (Minister of Health)* (2008), 67 C.P.R. (4th) 23 (F.C.A.) at para 77.
[113] *Sanofi-Synthelabo Canada Inc. v. Apotex Inc.*, 2008 SCC 61, 69 C.P.R. (4th) 251 at para 113.

have been established as at the date of filing upon a challenge to the patent's validity. Alternatively, if the inventor has not established the utility of the invention at the date of filing, she may still be entitled to a patent if the inventor had a basis for a "sound prediction" that the elements of the claim, if made, would be useful for the purpose claimed by the patent.[114] It has been held that "sound prediction is not a free-standing statutory requirement [but rather] is a way of showing that an invention is useful when the invention has not been directly demonstrated to work [prior to the filing date]".[115]

The Supreme Court of Canada has articulated a three part test to determine whether a claim is valid on the basis of a sound prediction.[116]

(a) there must be a factual basis for the prediction. The factual basis may be supplied by tested compounds or other factual underpinnings, depending on the nature of the invention. The factual basis must be disclosed in the patent and any underlying data supporting a sound prediction must be disclosed in the patent. When a patent is based on a sound prediction, the disclosure must include the prediction;[117]

(b) the inventor must have had an articulable and "sound" line of reasoning from which the desired result could be inferred from the factual basis. The inventor must have possessed this reasoning at the date of filing the patent application; and

(c) there must be proper disclosure within the patent. It is generally sufficient if the specification provides a full, clear and exact description of the nature of the invention and the manner in which it can be practised. Subsection 27(3) of the *Patent Act* requires an inventor to indicate and distinctly claim the part, improvement or combination which is the invention. It does not obligate the inventor to describe in what respect the invention is new or in what way useful. The disclosure must show enough to enable the person skilled in the art to work the invention, or to soundly predict the invention.'[118]

If all three criteria of the test for sound prediction have been satisfied but the prediction has been shown to be incorrect, the patent will be invalidated as a result of inutility.[119] Conversely, where a prediction is based on speculation that subsequently turns out to be accurate, the patent may nonetheless be invalidated for a failure to sufficiently disclose the invention.[120]

> The doctrine of 'sound prediction' balances the public interest in early disclosure of new and useful inventions, even before their utility has been verified by tests (which in the case of pharmaceutical products may take years), and the public interest in avoiding cluttering the public domain with useless patents and granting monopoly rights in exchange for misinformation.[121]

The doctrine of sound prediction is applicable to patents claiming new uses for old compounds as well as patents claiming new compounds, however the disclosure requirements arguably differ.[122] An inventor is not required to disclose test results in the patent application in support of every claim to prove utility if the inventor had sufficient information and expertise that would enable him to soundly predict the utility of the claims. However, if the utility of a claim is not demonstrated in the disclosure and the inventor could not have soundly predicted that "something he claimed to have invented, but had not actually made or shown to be useful, would be useful, the claim will be invalid."[123] The Commissioner of Patents must reject a patent application if the inventor is unable to establish utility,

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[114] *Aventis Pharma Inc. v. Apotex Inc.*, 2006 FCA 64 at para 24, leave to appeal refused 2006 CarswellNat 2316 (S.C.C.).
[115] *Cobalt Pharmaceuticals Co. v Bayer Inc.*, 2015 FCA 116 at para 56 citing *Teva Canada Ltd. v Novartis* AG 2013 FC 141 at para 164.
[116] *Apotex Inc. v. Wellcome Foundation Ltd.*, [2002] 4 S.C.R. 153 (S.C.C.) at para. 70.
[117] *Eli Lilly Canada Inc. v. Apotex Inc.* (2008), 63 C.P.R. (4th) 406 (F.C.) at para. 164, affirmed 2009 FCA 97 (F.C.A.) at para. 15, leave to appeal refused 2009 CarswellNat 3235 (S.C.C.).
[118] *Eli Lilly Canada Inc. v. Apotex Inc.*, 2009 FCA 97 at para 18, leave to appeal refused 2009 CarswellNat 3235, [2009] S.C.C.A. No. 219 (S.C.C.).
[119] *Apotex Inc. v. Wellcome Foundation Ltd.*, [2002] 4 S.C.R. 153 (S.C.C.) at para. 76; *Goldfarb v. W.L. Gore & Associates Inc.*, 2001 FCT 45 (Fed. T.D.) at para. 114, affirmed 2002 CarswellNat 4205 (Fed. C.A.), leave to appeal refused 2003 CarswellNat 2038 (S.C.C.), referring to *Monsanto Co. v. Canada (Commissioner of Patents)* (1979), 42 C.P.R. (2d) 161 (S.C.C.), additional reasons 1979 CarswellNat 814 (S.C.C.).
[120] *Apotex Inc. v. Wellcome Foundation Ltd.*, [2002] 4 S.C.R. 153 (S.C.C.) at para 84.
[121] *Apotex Inc. v. Wellcome Foundation Ltd.*, [2002] 4 S.C.R. 153 (S.C.C.) at para 66.
[122] *Pfizer Canada Inc. v. Apotex Inc.*, 2007 FC 26 at para 36, affirmed 2007 FCA 195 at para 3, leave to appeal refused 2007 CarswellNat 3627 (S.C.C.).
[123] *Aventis Pharma Inc. v. Apotex Inc.*, 2006 FCA 64 at paras 25–26, leave to appeal refused 2006 CarswellNat 2316 (S.C.C.).

either on the basis of actual results or sound prediction, at the relevant date.[124]

Whether a prediction was based on an articulable and "sound" line of reasoning is a question of fact and must be assessed based upon available information and expertise at the Canadian filing date of the patent application.[125] While the prediction must be sound, it need not be certain.[126] "[T]esting is not an absolute requirement for a patent based on sound prediction."[127]

The Federal Court of Appeal, applying the *Wellcome* decision, upheld the dismissal of an NOC application because the patentee failed to disclose in the patent a Hong Kong study that was required to make the prediction of utility sound, even though the study was publicly available.[128] In a subsequent decision, the Court of Appeal confirmed a patentee must disclose in the patent a study that provides the factual basis of the sound prediction.[129] As a legal commentator has noted:

> Patentees must include [in the disclosure] the facts or data underlying the line of reasoning even where those facts are otherwise publicly known. Given the clear and unrestricted language employed by the Federal Court of Appeal, this heightened disclosure requirement is fundamental and applies to all patents that rely on a sound prediction of utility, whatever their nature or subject matter.[130]

To date, the Supreme Court of Canada has declined to address whether there is a heightened disclosure requirement for patents relying upon sound prediction.[131] The Federal Court addressed this issue and held that sound prediction of utility does not require heightened disclosure of the underlying facts and line of reasoning, unless it is in the context of a "new use" patent.[132] The rationale for the distinction is derived from the Supreme Court's comments in *obiter dicta* in the *Wellcome* decision, where the exception to heightened disclosure was discussed as relevant to "new use" patents given that utility is essentially the only quid pro quo for the monopoly since the compound itself has previously been disclosed.[133] **[NOTE: re: 8.6 SOUND PREDICTION - THIS ENTIRE SECTION NEEDS TO BE MOVED UP TO BECOME 8.5]**

8.7 MAINTENANCE FEES

8.7.1 Maintenance Fees Generally

Under the *Patent Act*, a patent applicant and patentee must pay prescribed annual fees, referred to as "maintenance fees", to keep a patent application and patent in good standing.[134] If the correct maintenance fee is not paid in a timely manner, the patent is deemed to be abandoned and irrevocably lapses unless the proper steps to reinstate the patent are taken.[135] Where a deadline was missed by inadvertence, a letter requesting that a regular payment be accepted is not a "request" for reinstatement.[136] However, an application will be reinstated pursuant to a clear request and the payment of the reinstatement fee within one-year of the original due date.[137] Annual maintenance

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[124] *Apotex Inc. v. Wellcome Foundation Ltd.*, [2002] 4 S.C.R. 153 (S.C.C.) at para. 46; *Patent Act*, s. 40.
[125] *Aventis Pharma Inc. v. Apotex Inc.*, 2005 FC 1283 at paras. 92–93, affirmed 2006 CarswellNat 404 (F.C.A.), leave to appeal refused 2006 CarswellNat 2316 (S.C.C.).
[126] *Aventis Pharma Inc. v. Apotex Inc.*, 2005 FC 1283 at para 87, affirmed 2006 CarswellNat 404 (F.C.A.), leave to appeal refused 2006 CarswellNat 2316 (S.C.C.).
[127] *Aventis Pharma Inc. v. Apotex Inc.*, 2006 FCA 64 at paras 25–26, leave to appeal refused 2006 CarswellNat 2316 (S.C.C.).
[128] *Eli Lilly Canada Inc. v. Apotex Inc.*, 2009 CarswellNat 833, [2009] F.C.J. No. 404 (F.C.A.), leave to appeal refused 2009 CarswellNat 3235 (S.C.C.).
[129] *Novopharm Ltd. v. Eli Lilly & Co.* (2011), 94 C.P.R. (4th) 95 (F.C.A.) at 107, para. 47, leave to appeal refused 2011 CarswellNat 5075 (S.C.C.).
[130] Jonathan Stainsby, "Appeal Court Clarifies Utility Tests for Patents", *The Lawyers Weekly*, 8 May 2009, 9–10.
[131] *Pfizer Canada Inc. v. Novopharm Ltd.*, 2012 SCC 60 (S.C.C.) at para 43.
[132] *AstraZeneca Canada Inc v Apotex Inc.*, 2014 FC 638 at paras 141-152, affirmed 2015 FCA 158, leave to appeal allowed 2016 CarswellNat 603 (SCC); See also *Gilead Sciences Inc v Idenix Pharmaceuticals.*, 2015 FC 1156 at para 248 affirmed 2017 FCA 161 leave to appeal to SCC requested 2017 CarswellNat 5890 (S.C.C.)
[133] *Apotex Inc. v. Wellcome Foundation Ltd.*, [2002] 4 S.C.R. 153 (S.C.C.) at paras 70–72.
[134] *Patent Act*, s. 27.1(1), as amended S.C. 1993, c. 15; Patent Rules, ss. 99(1) or 154(1), item 30, Schedule II.
[135] *Patent Act*, s. 73(1) (c), as amended S.C. 1993, c. 15.
[136] *Actelion Pharmaceuticals Ltd. v. Canada (Attorney General)* (2008), 64 C.P.R. (4th) 381 (F.C.A.) at para 9.
[137] see Chapter 24.01.02 of the Manual of Patent Office Practice available online at < http://www.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/wr01084.html>

fees are designed to "discourage the proliferation of deadwood patents and patent applications."[138] The fees may only come from persons authorized under subsection 6(1) of the *Patent Act* to correspond with CIPO.[139] However, this should not be read so restrictively as to prohibit a principal or a principal's agent from engaging in matters so routine and clerical in nature as paying maintenance fees.[140]

The patent maintenance fees are divided into standard fees, i.e., "large entity" fees, and lower "small entity" fees as defined by the *Patent Rules*.[141] The small entity fees are half the amount of the large entity fees.[142] For example, a small entity must pay $50.00 each year while the large entity fee is $100.00 per year until the fifth anniversary of the patent application filing date, at which point the fees double.[143] This regime of different maintenance fees provides "modest monetary relief to inventors who are presumed to be of limited means."[144]

Under subsection 3.01(3) of the *Patent Rules*, a small entity means an entity that employs 50 or fewer employees or that is a university, but does not include an entity that:

(a) is controlled directly or indirectly by an entity, other than a university, that employs more than 50 employees; or

(b) has transferred or licensed or has an obligation, other than a contingent obligation, to transfer or license any right in the invention to an entity, other than a university, that employs more than 50 employees.[145]

To qualify as a small entity, the applicant must file a declaration with the Commissioner indicating qualification as a small entity on the filing date of the patent application.[146]

8.7.2 Dutch Industries

This seemingly uncontroversial regime of maintenance fees entered the spotlight through the *Dutch Industries* decision. Before addressing *Dutch Industries* and the resulting legislative changes, it is important to briefly step back to outline the state of affairs before *Dutch Industries*.

Before *Dutch Industries*, a practice had developed whereby the Commissioner allowed large entities to pay the differential between the small entity and large entity fees if the applicant/patentee had incorrectly paid the small entity fee in the past.[147] This differential payment was commonly referred to as a "top-up" payment. The Commissioner's acceptance of top-up payments was an informal practice that was never provided for in the *Patent Act* or *Rules*.[148]

In *Dutch Industries*, the alleged infringer ("Dutch Industries") claimed that an asserted patent and a pending patent application had lapsed because the patentee, Barton No-Till Disk ("Barton"), had improperly paid the small entity fee and the Commissioner was not entitled to accept the corrective top-up payments made by Barton.[149]

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[138] *Dutch Industries Ltd. v. Barton No-Till Disk Inc.*, [2003] 4 F.C. 67, [2003] F.C.J. No. 396 (Fed. C.A.) at para 30, leave to appeal refused 2003 CarswellNat 3903, [2003] S.C.C.A. No. 204 (S.C.C.). See also *Actelion Pharmaceuticals Ltd. v. Canada (Attorney General)* (2008), 64 C.P.R. (4th) 381 (F.C.A.) at para 13.
[139] *Rendina v. Canada (Attorney General)* (2007), 60 C.P.R. (4th) 436 (F.C.) at para 20.
[140] *Sarnoff Corp. v. Canada (Attorney General)* (2008), 66 C.P.R. (4th) 167 (F.C.) at para 27, affirmed 2009 CarswellNat 1236 (F.C.A.).
[141] *Patent Rules*, s. 3(2).
[142] *Patent Rules*, item 30, Schedule II.
[143] *Patent Rules*, item 30, Schedule II.
[144] *Dutch Industries Ltd. v. Barton No-Till Disk Inc.*, [2003] 4 F.C. 67, [2003] F.C.J. No. 396 (Fed. C.A.) at para 30, leave to appeal refused 2003 CarswellNat 3903, [2003] S.C.C.A. No. 204 (S.C.C.).
[145] *Patent Rules*, s. 3.01(3).
[146] *Patent Rules*, s. 3.01(1).
[147] *Dutch Industries Ltd. v. Barton No-Till Disk Inc.*, [2003] 4 F.C. 67, [2003] F.C.J. No. 396 (Fed. C.A.) at para 2, leave to appeal refused 2003 CarswellNat 3903, [2003] S.C.C.A. No. 204 (S.C.C.); *Johnson & Johnson Inc. v. Boston Scientific Ltd. / Boston Scientifique Ltée*, 2004 FC 1672, [2004] F.C.J. No. 2040 at para 10, reversed on other grounds *Johnson & Johnson Inc. v. Arterial Vascular Engineering Canada Inc.*, 2006 CarswellNat 1379, [2006] F.C.J. No. 785 (F.C.A.), leave to appeal refused *Johnson & Johnson Inc. v. Arterial Vascular Engineering Canada Inc.*, 2007 CarswellNat 68 (S.C.C.).
[148] *Dutch Industries Ltd. v. Barton No-Till Disk Inc.*, [2003] 4 F.C. 67, [2003] F.C.J. No. 396 (Fed. C.A.) at para 25, leave to appeal refused 2003 CarswellNat 3903, [2003] S.C.C.A. No. 204 (S.C.C.).
[149] *Dutch Industries Ltd. v. Barton No-Till Disk Inc.*, [2003] 4 F.C. 67, [2003] F.C.J. No. 396 (Fed. C.A.) at paras 12–20, leave to appeal refused 2003 CarswellNat 3903, [2003] S.C.C.A. No. 204 (S.C.C.).

In response, Barton asserted that the Commissioner had the jurisdiction to accept the top-up payments.[150] Barton argued that it would be manifestly unfair for the Court to stop the practice of top-up payments as the public had relied on the existing practice of the Commissioner to accept such payments in the past.[151]

The Trial Court held that because nothing in the *Patent Act* or *Rules* provided the Commissioner with the jurisdiction to accept top-up payments, the patent and patent application at issue had lapsed.[152] The Federal Court of Appeal affirmed the Commissioner's lack of jurisdiction to accept top-up payments.[153] The Court held that entity size is determined only once when the patent regime is first engaged–i.e., when the patentee applies for a patent in Canada.[154] Thus, the applicant maintains the same status throughout the patent's term. Because Barton was a small entity when it applied for the first patent, that patent had not lapsed. However, the pending patent application had lapsed due to failure to pay the "large entity fee" because Barton was a large entity when it applied for that patent.[155]

The applicable date for determining the status of the entity is the filing date of the Canadian patent application and not a priority filing date based on a non-Canadian filing.[156]

8.7.3 Section 78.6 of the Patent Act

The *Dutch Industries* decision unleashed a maelstrom by threatening the validity of several hundred patents for which informal top-up payments had been made in the past. In response to *Dutch Industries*, the Government brought section 78.6 of the *Patent Act* into force on February 1, 2006.[157] Section 78.6(1) provided a 12-month grace period (i.e., until February 1, 2007) for patent owners and applicants to make any necessary corrective payments in situations where a fee was incorrectly paid at the lower small entity fee level.[158]

The Federal Court of Appeal has interpreted the remedial effects of section 78.6(1) broadly by holding that it retroactively affirmed the validity of all top-up payments made in the past.[159] The Court held that the legislation must have a retroactive effect to achieve the desired result of alleviating the harshness of *Dutch Industries*. Most recently, the Federal Court made a clear distinction between a patent application and an issued patent with respect to the failure to pay such fees. In *Apotex Inc. v Pfizer Inc.*, it was held that the past failure of Apotex to top up a "small entity" fee when they were in fact a "large entity" did not render the already issued patent invalid. It was stated that "breaches which go to the heart of the patent, namely those which require the inventor to pay figurative hard coinage, can be fatal to issued patents. Administrative breaches, on the other hand, which can invalidate a patent application, will not invalidate issued patents."[160]

As a practical matter, the primary outcome of *Dutch Industries* and section 78.6 may be that patent applicants will simply choose to pay the large entity fee to avoid any potential headaches from a *Dutch Industries* challenge, but the

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[150] *Dutch Industries Ltd. v. Barton No-Till Disk Inc.* (2001), [2002] 1 F.C. 325, 14 C.P.R. (4th) 499 (Fed. T.D.) at para 39, reversed in part on other grounds 2003 CarswellNat 582, [2003] F.C.J. No. 396 (Fed. C.A.), leave to appeal refused 2003 CarswellNat 3903, [2003] S.C.C.A. No. 204 (S.C.C.).
[151] *Dutch Industries Ltd. v. Barton No-Till Disk Inc.*, [2003] 4 F.C. 67, [2003] F.C.J. No. 396 (Fed. C.A.) at para 48, leave to appeal refused 2003 CarswellNat 3903, [2003] S.C.C.A. No. 204 (S.C.C.).
[152] *Dutch Industries Ltd. v. Barton No-Till Disk Inc.* (2001), [2002] 1 F.C. 325, 14 C.P.R. (4th) 499 (Fed. T.D.) at paras 42–47, reversed in part on other grounds 2003 CarswellNat 582, [2003] F.C.J. No. 396 (Fed. C.A.), leave to appeal refused 2003 CarswellNat 3903, [2003] S.C.C.A. No. 204 (S.C.C.).
[153] *Dutch Industries Ltd. v. Barton No-Till Disk Inc.*, [2003] 4 F.C. 67, [2003] F.C.J. No. 396 (Fed. C.A.) at para 48, leave to appeal refused 2003 CarswellNat 3903, [2003] S.C.C.A. No. 204 (S.C.C.).
[154] *Dutch Industries Ltd. v. Barton No-Till Disk Inc.*, [2003] 4 F.C. 67, [2003] F.C.J. No. 396 (Fed. C.A.) at para 46, leave to appeal refused 2003 CarswellNat 3903, [2003] S.C.C.A. No. 204 (S.C.C.).
[155] *Dutch Industries Ltd. v. Barton No-Till Disk Inc.*, [2003] 4 F.C. 67, [2003] F.C.J. No. 396 (Fed. C.A.) at paras 46–48, leave to appeal refused 2003 CarswellNat 3903, [2003] S.C.C.A. No. 204 (S.C.C.).
[156] *Johnson & Johnson Inc. v. Boston Scientific Ltd. / Boston Scientifique Ltée*, 2004 FC 1672 (F.C.) at paras 78, 83, reversed on other grounds *Johnson & Johnson Inc. v. Arterial Vascular Engineering Canada Inc.*, 2006 CarswellNat 1379, [2006] F.C.J. No. 785 (F.C.A.), leave to appeal refused *Johnson & Johnson Inc. v. Arterial Vascular Engineering Canada Inc.*, 2007 CarswellNat 68 (S.C.C.), leave to appeal refused 2007 CarswellNat 70 (S.C.C.).
[157] *Johnson & Johnson Inc. v. Arterial Vascular Engineering Canada Inc.* (2006), 53 C.P.R. (4th) 182, [2006] F.C.J. No. 785 (F.C.A.) at para 6, leave to appeal refused 2007 CarswellNat 68 (S.C.C.), leave to appeal refused 2007 CarswellNat 70 (S.C.C.); "The Clock is Ticking: Coming into Force of Section 78.6 of the *Patent Act* (Bill C-29)", CIPO News Updates, February 1, 2006.
[158] *Patent Act*, 2005, c. 18, s. 78.6.
[159] *Johnson & Johnson Inc. v. Arterial Vascular Engineering Canada Inc.* (2006), 53 C.P.R. (4th) 182, [2006] F.C.J. No. 785 (F.C.A.) at para 5, leave to appeal refused 2007 CarswellNat 68 (S.C.C.), leave to appeal refused 2007 CarswellNat 70 (S.C.C.).
[160] *Apotex Inc. v. Pfizer Inc.*, 2016 FC 136, 263 A.C.W.S. (3d) 1023 at para 87, affirmed 2017 FCA 201, 150 CPR (4th) 211.

pressures to qualify as a small entity could increase if maintenance fees rise. One aspect of the maintenance fee regime that bears watching is the factual determination in qualifying as a small entity. As Madam Justice Sharlow noted in *Dutch Industries*, ascertaining whether an applicant qualifies as a small entity may involve complex questions, such as the meaning of "employee" in determining whether an applicant has 50 or fewer employees, but this issue has yet to be addressed by the Courts.[161]

8.7.4 Failure to Pay Maintenance Fees

Two Federal Court decisions deal with the failure of patent applicants to make timely maintenance fee payments and the Commissioner's refusal to reinstate the applications.

In *Repligen Corp. v. Canada (Attorney General),*[162] the patent applicant submitted second and third maintenance fee payments incorrectly identifying the patent number. Repligen requested correction of the patent number pursuant to section 8 of the *Patent Act*. The Commissioner denied the request. Upon judicial review, the Federal Court found that the Commissioner had failed to properly exercise her discretion in this case. In regards to section 8, the Court observed:

> [57] The purpose of section 8 of the Act is clear. It is a remedial section which enables the Commissioner *in limited cases of clerical errors in any instrument of record* to be corrected under the authority of the Commissioner taking into account *all* relevant considerations which, as the jurisprudence established, included delay in seeking correction and the impact on third parties. [emphasis in original]

Particularly, the Court found that the Commissioner failed to have regard to the following list of relevant factors, namely: (i) the impact of the decision on the applicant (losing its patent); (ii) the Commissioner took the applicant's payments and used them elsewhere; (iii) the payments were made by the due date; (iv) the proper scope of the remedial power under section 8; (v) the purpose and object of the maintenance fee provision; (vi) the lack of hard evidence that third party rights would be impaired; and (vii) a failure to weigh and balance the relevant factors before exercising her discretion. The Commissioner's decision was set aside and the applicant's request was sent back for reconsideration by a different official in the Patent Office.[163]

Repligen's case came before the Federal Court for a second time two years later, after the Commissioner once again refused to reinstate the patent.[164] The Federal Court's finding was identical to its prior decision, holding that the Commissioner failed to properly exercise its discretion under section 8 taking into account the unique situation that the applicant had in fact paid fees. The court set aside the Commissioner's decision and sent the matter back to the Commissioner to be reconsidered for a third time.

A second decision, *Excelsior Medical Corp. v. Canada (Attorney General)*, dealt with the payment of maintenance fees in respect of a Canadian patent application where the fees were paid within the relevant time period but by a firm other than the patent agent of record.[165] The Patent Office initially accepted the fees and sent a notice indicating that the application had been reinstated. A few days later, the Patent Office sent a further letter seeking to retract its earlier letter and offering to refund the fees. Several months later, the firm tendering the fees requested and received a refund. Two years later the same firm submitted a request for an appointment of an associate agent to the Patent Office, following which the Patent Office advised that the application could not be reinstated. The applicant brought an application for judicial review, seeking a declaration that the application was not dead.

The Court dismissed the application, in part due to the fact that there was an absence of evidence by the applicant of any detrimental reliance with respect to the Patent Office's initial notice of reinstatement. In regards to *Patent Rule* 6(1) which specifies that the Commissioner shall only communicate with and have regard to communications from the authorized correspondent, the Court determined:

> I have found Rule 6(1) to be in harmony with the *Patent Act* and the other pertinent *Patent Rules*. The Commissioner may safely ignore communications respecting an application or maintenance fees which do not come from an authorized

[161] *Dutch Industries Ltd. v. Barton No-Till Disk Inc.*, [2003] 4 F.C. 67, [2003] F.C.J. No. 396 (Fed. C.A.) at paras 31–32, leave to appeal refused 2003 CarswellNat 3903, [2003] S.C.C.A. No. 204 (S.C.C.).
[162] *Repligen Corp. v. Canada (Attorney General),* 2010 FC 1288, 90 C.P.R. (4th) 409 at para 60.
[163] *Repligen Corp. v. Canada (Attorney General),* 2010 FC 1288, 90 C.P.R. (4th) 409 at para 60.
[164] *Repligen Corp. v. Canada (Attorney General),* 2012 FC 931.
[165] *Excelsior Medical Corp. v. Canada (Attorney General)* (2011), 92 C.P.R. (4th) 220 (F.C.), affirmed 2011 FCA 303.

representative.[166]

The difficulty in this case was that prior to the expiration of time for reinstatement, the Patent Office gave notification it had accepted the maintenance fees. Only after the time for reinstatement had expired, did the Patent Office notify the applicant that it would not accept the fees. By then, it was too late for the applicant to make amends. Ultimately, the Court concluded that the passage of time *and* the return of the maintenance fees to the applicant at the request of the applicant's agent caused the application to be truly dead and the Court was unable to revive it under law or equity.[167]

Excelsior was recently heard and dismissed by the Federal Court of Appeal, which held,

> The acceptance of maintenance fees, whether within or outside the reinstatement period, from someone other than the applicant's authorized correspondent does not reinstate a patent application. Contrary to the application judge's view, the Patent office's acceptance of those fees did not create rights and its return of those fees did not extinguish rights. To hold otherwise would be to create a situation in which the Patent office's administrative errors created or extinguished rights independently of the statutory scheme.[168]

8.8 DISCLAIMER

8.8.1 Definition

Disclaimer is a statutory mechanism by which a patentee may amend an issued patent to claim less than what was claimed in the original patent.[169] A disclaimer is available when a patentee, by mistake, accident, or inadvertence, and without any wilful intent to defraud or mislead the public,

(a) made a specification too broad, claiming more than what the patentee invented, or

(b) in the specification claimed that the patentee was the inventor of any material or substantial part of the invention that the patentee was not the inventor.[170]

The patentee can disclaim all or part of a patent claim, or part of the patent specification, so long as the disclaimer does not extend the monopoly of the patent.[171]

Disclaimers cannot be used to claim an invention that is substantially different from the invention claimed in the original patent or to introduce a new inventive idea.[172] Disclaimers cannot widen the scope or change the character of the invention.[173]

The patent that remains after the disclaimer retains the prima facie presumption of validity that existed before the disclaimer.[174] The patentee can maintain an action based on the remaining patent claims.[175] If the disclaimer is entered during the course of litigation, only the validity of the patent in its disclaimed form is considered.[176]

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[166] *Excelsior Medical Corp. v. Canada (Attorney General)* (2011), 92 C.P.R. (4th) 220 (F.C.) at 234–235, para 34, affirmed 2011 FCA 303.
[167] *Excelsior Medical Corp. v. Canada (Attorney General)* (2011), 92 C.P.R. (4th) 220 (F.C.) at 238–240, paras 44 and 50, affirmed 2011 FCA 303 (F.C.A.). See also *Unicrop Ltd. v. Canada (Attorney General)* (2011), 91 C.P.R. (4th) 289 (F.C.A.), where the Court denied an appeal from a judicial review refusing to overturn the Commissioner of Patent's decision that an application could not be reinstated and had been abandoned on a similar basis under Rule 6(1).
[168] *Excelsior Medical Corp. v. Canada (Attorney General)*, 2011 FCA 303 (F.C.A.) at para. 5.
[169] *Patent Act*, R.S.C. 1985, c. P-4, s. 48, as amended by R.S.C. 1985, c. 33 (3rd Supp.), s. 17; *Richards Packaging Inc. v. Canada (Attorney General)*, 2007 FC 11, 2007 CarswellNat 36 (F.C.) at para. 1, affirmed 2008 FCA 4 (F.C.A.).
[170] *Patent Act*, as amended, s. 48(1).
[171] *Monsanto Co. v. Canada (Commissioner of Patents)*, [1975] F.C. 197 (Fed. T.D.) at para 24, reversed on other grounds [1976] 2 F.C. 476 (Fed. C.A.).
[172] *AMP Inc. v. Hellermann Ltd.*, [1961] R.P.C. 160 (Eng. C.A.) at 178, (1961), reversed on other grounds [1962] R.P.C. 55 (Eng. H.L.) at 71.
[173] *Chain Bar Mill Co. Ltd.'s Application* (1941), 58 R.P.C. 200 at 205; *White's Patent*, [1958] R.P.C. 287.
[174] *Patent Act*, s. 48(6); *Richards Packaging Inc. v. Canada (Attorney General)*, 2007 FC 11, 2007 CarswellNat 36 at para 9, affirmed (2008) 66 C.P.R. (4th) 1 (F.C.A.); *Cooper & Beatty v. Alpha Graphics Ltd.* (1980), 49 C.P.R. (2d) 145 (Fed. T.D.) at para 58; *Canadian Celanese Ltd. v. B.V.D. Co.*, [1939] 2 D.L.R. 289, [1939] 1 All E.R. 410 (Canada P.C.) at para 12.
[175] *Richards Packaging Inc. v. Canada (Attorney General)*, 2007 FC 11, 2007 CarswellNat 36, affirmed (2008) 66 C.P.R. (4th) 1 (F.C.A.).
[176] *Canadian Celanese Ltd. v. B.V.D. Co.*, [1939] 2 D.L.R. 289, [1939] 1 All E.R. 410 (Canada P.C.); *Cooper & Beatty v. Alpha Graphics Ltd.* (1980), 49 C.P.R. (2d) 145 (Fed. T.D.) at paras 52–55.

Subsection 48(1) of the *Patent Act* mandates that the disclaimed language must have been included in the original patent by mistake, accident, or inadvertence.[177] The mistake, accident, or inadvertence — and the absence of the intent to defraud must occur when the patentee made the specification.[178] The onus of showing mistake, accident or inadvertence, and the lack of intent to defraud, is on the patentee if the disclaimer is challenged.[179] Where the patentee does not discharge this burden, the disclaimer will be held to be invalid and the patent will remain in its original form.[180] The validity of the disclaimer depends solely upon the state of mind of the patentee at the time the specification was made.[181] The Commissioner's acceptance of the disclaimer is not determinative of whether the disclaimed language was included by mistake, accident or inadvertence.[182] A disclaimer may be permissible even if it is made in response to the decision of a Court on a related patent.[183]

In a Federal Court of Appeal decision, the Court confirmed that the determination of whether there was "mistake, accident or inadvertence" is one of mixed fact and law, subject to the usual balance of probabilities standard, reviewable on an appellate standard of "palpable and overriding error".[184]

8.8.2 Patent Office Role in Accepting Disclaimers

To obtain a disclaimer, the patentee, or an assignee or legal representative of the patentee, must file in duplicate with the Patent Office a witnessed petition in the appropriate form with the required fee requesting that parts of the patent be disclaimed.[185]

As long as the required formalities for filing a disclaimer are satisfied, the Patent Office does not have any discretion to reject a disclaimer.[186] The propriety or validity of a disclaimer can only be reviewed by the courts.[187] In *Richards Packaging Inc. v. Canada (Attorney General)*, the Court held that the Commissioner lacked the jurisdiction to reject a disclaimer on the grounds that it rendered the patent claim broader than what was originally allowed:[188] Justice Martineau emphasized that:

> The Commissioner and the examiners have simply no authority under the Act and the Rules to make a decision on the validity of a disclaimer filed by a patentee. This is a power that therefore belongs to the courts and that may be exercised by them in the context of an action or proceeding under the Act respecting the patent in issue.[189]

8.8.3 Disclaimers in Pending Actions

The use of a disclaimer to avoid jurisdiction in an ongoing proceeding has been rejected. In *ICN Pharmaceuticals Inc. v. Canada (Patented Medicine Prices Review Board)*, the Federal Court of Appeal found that the patentee's motivation to avoid the jurisdiction of the Patented Medicine Prices Review Board was improper.[190] The Court held that the patentee does not have free reign to avoid jurisdiction in an ongoing proceeding through disclaimers or by

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[177] *Patent Act*, s. 48(1).
[178] *Trubenizing Process Corp. v. John Forsyth Ltd.*, 1941 CarswellOnt 44, 2 Fox Pat. C. 11 (Ont. S.C.) at para 39, affirmed 1942 CarswellOnt 72 (Ont. C.A.), reversed on other grounds [1943] S.C.R. 422 (S.C.C.).
[179] *Trubenizing Process Corp. v. John Forsyth Ltd.*, 1941 CarswellOnt 44, 2 Fox Pat. C. 11 (Ont. S.C.) at para 46, affirmed 1942 CarswellOnt 72 (Ont. C.A.), reversed on other grounds [1943] S.C.R. 422 (S.C.C.).
[180] *Pfizer Canada Inc. v. Apotex Inc.* (2007), 61 C.P.R. (4th) 305 (F.C.) at para 38, affirmed 2009 FCA 8.
[181] *Pfizer Canada Inc. v. Apotex Inc.* (2007), 61 C.P.R. (4th) 305 (F.C.) at para 38, affirmed 2009 FCA 8.
[182] *ICN Pharmaceuticals Inc. v. Canada (Patented Medicine Prices Review Board)* (1996), 68 C.P.R. (3d) 417 (Fed. C.A.) at para 70.
[183] *Pfizer Canada Inc. v. Apotex Inc.* (2007), 61 C.P.R. (4th) 305 (F.C.) at paras 39–43, affirmed 2009 FCA 8.
[184] *Hershkovitz v. Tyco Safety Products Canada Ltd.* (2010), 89 C.P.R. (4th) 101 (F.C.A.) at paras 39–42.
[185] *Patent Act*, s. 48(2)–(3).
[186] *Richards Packaging Inc. v. Canada (Attorney General)*, 2007 FC 11, 2007 CarswellNat 36 at paras 10, 25-25, 28, 30-31, affirmed 2008 FCA 4; *Monsanto Co. v. Canada (Commissioner of Patents)*, [1976] 2 F.C. 476, 28 C.P.R. (2d) 118 (Fed. C.A.) at para 3.
[187] *Richards Packaging Inc. v. Canada (Attorney General)*, 2007 FC 11, 2007 CarswellNat 36 at paras 10, 28, affirmed 2008 FCA 4; see also *Distrimedic Inc. v Dispill Inc.*, 2013 FC 1043, F.C.J. No. 1093, at paras 49-50.
[188] *Richards Packaging Inc. v. Canada (Attorney General)*, 2007 FC 11, 2007 CarswellNat 36 at paras 21, 30–31, affirmed 2008 FCA 4.
[189] *Richards Packaging Inc. v. Canada (Attorney General)*, 2007 FC 11, 2007 CarswellNat 36 at para 28, affirmed 2008 FCA 4.
[190] *ICN Pharmaceuticals Inc. v. Canada (Patented Medicine Prices Review Board,)*[1996] F.C.J. No. 1065, 138 D.L.R. (4th) 71 at paras 71–73.

dedicating its patent to the public.[191]

Subsection 48(4) provides that "no disclaimer affects any action pending at the time when it is made, unless there is unreasonable neglect or delay in making it."[192] This provision has been interpreted to mean "that the rights and liabilities of the parties to a pending action are to be ascertained and declared on the footing that the person who disclaims obtains no advantage in the action from his action."[193] The same court had difficulty in construing the clause "unless there is unreasonable neglect or delay" in subsection 48(4).[194]

8.9 DEDICATION TO THE PUBLIC

8.9.1 Definition

There are no statutory provisions that address dedicating part or all of a patent to the public. Despite the lack of statutory authority, courts have consistently recognized the ability to terminate patent rights through dedication to the public as it does not contradict anything in the *Patent Act*.[195]

Dedication to the public operates in the same manner as a disclaimer in that the patentee is surrendering part or all of the invention. Once a patent claim is dedicated to the public, the patentee can no longer enforce that claim.

One key difference from disclaimers is that dedication to the public does not require the patentee to show that the surrendered language was included in the original patent by mistake, accident, or inadvertence.[196] Another difference from disclaimers is that it is unclear whether the patentee can dedicate only part of a claim or the patent specification to the public.

The *Patent Act* contains two mechanisms for correcting a faulty patent – reissue (s. 47) and disclaimer (s. 48). Unlike reissue or disclaimer, dedications are a creature of the common law; a patentee may publicly declare through a declaration that it will not enforce certain claims of its patent.[197] Although dedications are not circumscribed by statutory requirements or conditions, the Court must still ensure that the use of a dedication is not inconsistent with the *Patent Act.* [198]

In a recent decision under the *Patented Medicines (Notice of Compliance) Regulations* regime, the Court refused to give affect to the patentee's dedication of certain claims of one patent so as to avoid an allegation of double patenting in respect of certain claims of a second patent. It was held that to do otherwise would allow the patentee to secure an advantage.

> In my view, the Court should not permit a dedication to have the effect that [the patentee] suggests. Here, the advantage obtained is a mere 28 days of extra monopoly. While it is not a lengthy extension, neither is it *de minimus*… If [the patentee] made a good faith mistake when it acquired the '211 patent as a divisional, it had available to it remedies provided in the *Patent Act* – reissuance or disclaimer. The legal effect of those remedies would have been clear. The overlapping claims of the '211 patent would have been severed off. [The patentee] would not have derived any advantage in proceeding that way.[199]

8.9.2 Enforceability of Undedicated Claims

If the patentee dedicates to the public some but not all of the claims of a patent, it does not affect the patentee's right

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[191] *ICN Pharmaceuticals Inc. v. Canada (Patented Medicine Prices Review Board,)*[1996] F.C.J. No. 1065, 138 D.L.R. (4th) 71 at para 72.
[192] *Patent Act*, s. 41, as amended, s. 48(4).
[193] *Canadian Celanese Ltd. v. B.V.D. Co.*, [1939] 2 D.L.R. 289, [1939] 1 All E.R. 410 (Canada P.C.).
[194] *Canadian Celanese Ltd. v. B.V.D. Co.*, [1939] 2 D.L.R. 289, [1939] 1 All E.R. 410 (Canada P.C.).
[195] *Parke-Davis Division, Warner-Lambert Canada Inc. v. Canada (Minister of Health)* (2002), 22 C.P.R. (4th) 417 (Fed. C.A.) at para. 81, leave to appeal refused 2003 CarswellNat 1369 (S.C.C.).
[196] *Merck & Co. v. Apotex Inc.* (2006), 53 C.P.R. (4th) 1 (F.C.) at para 164, additional reasons 2006 CarswellNat 1407 (F.C.), reversed in part on other grounds (2006), 55 C.P.R. (4th) 81 (F.C.A.), reversed in part 2006 CarswellNat 3206 (F.C.A.), leave to appeal refused 2007 CarswellNat 1097 (S.C.C.).
[197] Paraphrasing Justice O'Reilly in *Merck & Co. v. Canada (Minister of Health)* (2010), 88 C.P.R. (4th) 81 (F.C.) at 86, paras 16–17.
[198] *Merck & Co. v. Canada (Minister of Health)*, 2010 FC 1043, 88 C.P.R. (4th) 81 (F.C.) at para 19.
[199] *Merck & Co. v. Canada (Minister of Health)*, 2010 FC 1043, 88 C.P.R. (4th) 81 (F.C.) at para 31.

to enforce the remaining undedicated claims.[200] In *G.D. Searle & Co. v. Merck & Co.*, the patentee (Searle) dedicated 136 of 200 claims of a patent pertaining to an anti-inflammatory medication.[201] The defendants (Merck) sought summary judgment primarily on the ground that because the subject matter of the asserted claims in the litigation was encompassed by the dedicated claims, Searle was estopped from alleging infringement of the asserted claims.[202] The Court dismissed Merck's argument on the basis of "the legal proposition that each claim in a patent is separate and distinct [cite omitted]. Since each claim is separate, it follows that an act affecting certain distinct claims does not necessarily affect the remaining claims."[203]

It is possible to dedicate patent claims to the public without inadvertently surrendering other claims when the patentee uses clear and precise language to indicate that the dedication was without prejudice to the undedicated claims.[204]

8.9.3 Revocability

Dedication to the public is analogous to a gift; it is irrevocable unless the patentee can show it lacked the requisite intent to do so when the patent was dedicated.[205] In *Parke-Davis Division, Warner-Lambert Canada Inc. v. Canada (Minister of Health)*, the patentee (Parke-Davis) dedicated approximately 600 patents to the public by providing a list of patents to the Patent Office. The Patent Office published the list of dedicated patents in the Canadian Patent Office Record. Parke-Davis, however, continued to pay maintenance fees for one of the dedicated patents included (the '768 patent).[206]

Subsequently, Apotex delivered a Notice of Allegation under the *Patented Medicines (Notice of Compliance) Regulations* in which it asserted that the '768 patent was invalid because Parke-Davis had dedicated it to the public.[207] The Trial Court dismissed Parke-Davis' application to prevent the issuance of the Notice of Compliance to Apotex as Parke-Davis had failed to show that the '768 patent was dedicated to the public by accident.[208]

The Federal Court of Appeal reversed the Trial Court on the grounds that Parke-Davis had satisfied its burden of establishing on a balance of probabilities that it accidentally included the '768 patent in the list of dedicated patents.[209] In particular, the evidence established that the '768 patent was on "keep" and "active" patent lists when the list of dedicated patents was submitted to the Patent Office, Parke-Davis informed the Patent Office as soon as it became aware of the error, the '768 patent did not match the profile of the other dedicated patents, and Parke-Davis never stopped paying the annual maintenance fees for the '768 patent.[210]

8.9.4 Jurisdiction in Pending Actions

As with disclaimers, the patentee cannot rely on dedicating patent claims to the public to thwart jurisdiction in an ongoing proceeding.[211] For example, in *Genentech Canada Inc., Re*, the Patented Medicine Prices Review Board retained jurisdiction over a matter where the patentee had dedicated the patent encompassing the medication at issue

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[200] *G.D. Searle & Co. v. Merck & Co.* (2002), 20 C.P.R. (4th) 103 (Fed. T.D.) at paras 85–86, 95–96.
[201] *G.D. Searle & Co. v. Merck & Co.* (2002), 20 C.P.R. (4th) 103 (Fed. T.D.) at para 26.
[202] *G.D. Searle & Co. v. Merck & Co.* (2002), 20 C.P.R. (4th) 103 (Fed. T.D.) at paras 54–60.
[203] *G.D. Searle & Co. v. Merck & Co.* (2002), 20 C.P.R. (4th) 103 (Fed. T.D.) at para 85.
[204] *Merck & Co. v. Apotex Inc.* (2006), 53 C.P.R. (4th) 1 (F.C.) at para 164, additional reasons 2006 CarswellNat 1407 (F.C.), reversed in part on other grounds (2006), 55 C.P.R. (4th) 81 (F.C.A.), reversed in part 2006 CarswellNat 3206 (F.C.A.), leave to appeal refused 2007 CarswellNat 1097 (S.C.C.).
[205] *Parke-Davis Division, Warner-Lambert Canada Inc. v. Canada (Minister of Health)* (2002), 22 C.P.R. (4th) 417 (Fed. C.A.) at paras 85–86, leave to appeal refused 2003 CarswellNat 1369 (S.C.C.).
[206] *Parke-Davis Division, Warner-Lambert Canada Inc. v. Canada (Minister of Health)* (2002), 22 C.P.R. (4th) 417 (Fed. C.A.) at para 11, leave to appeal refused 2003 CarswellNat 1369 (S.C.C.).
[207] *Parke-Davis Division, Warner-Lambert Canada Inc. v. Canada (Minister of Health)* (2002), 22 C.P.R. (4th) 417 (Fed. C.A.) at para 22, leave to appeal refused 2003 CarswellNat 1369 (S.C.C.).
[208] *Parke-Davis Division, Warner-Lambert Canada Inc. v. Canada (Minister of Health)* (2002), 22 C.P.R. (4th) 417 (Fed. C.A.) at para 89, leave to appeal refused 2003 CarswellNat 1369 (S.C.C.).
[209] *Parke-Davis Division, Warner-Lambert Canada Inc. v. Canada (Minister of Health)* (2002), 22 C.P.R. (4th) 417 (Fed. C.A.) at para 103, leave to appeal refused 2003 CarswellNat 1369 (S.C.C.).
[210] *Parke-Davis Division, Warner-Lambert Canada Inc. v. Canada (Minister of Health)* (2002), 22 C.P.R. (4th) 417 (Fed. C.A.) at paras 94–97, leave to appeal refused 2003 CarswellNat 1369 (S.C.C.).
[211] *Genentech Canada Inc., Re* (1992), 44 C.P.R. (3d) 316 (Can. Pat. Medicine Prices Rev. Bd.); *Application for compulsory licence by Novopharm Ltd., Re* (1992), 44 C.P.R. (3d) 13 (Can. Pat. Commr.).

to the public after the proceeding had commenced.[212] In terms of timing, the Board determined that if the medicine which is the subject of the proceeding is a patented invention on the date of the Notice of Hearing, the Board's jurisdiction is not affected by any subsequent acts that may alter intellectual property rights for the relevant patents.[213] Similarly, in another context, the Commissioner of Patents found that dedicating the relevant patent to the public after compulsory licensing proceedings were commenced, did not preclude the Commissioner from granting a compulsory license.[214]

8.10 REISSUE OF PATENTS

Following the grant of a patent, section 47 allows a patentee to request that a patent be reissued by the Commissioner.[215] This remedy is available where the "patent is deemed defective or inoperative by reason of insufficient description and specification, or by reason of the patentee's claiming more or less than he or she had a right to claim as new."[216] The patentee must persuade the Commissioner that the error arose through "inadvertence, accident or mistake, without any fraudulent or deceptive intention."[217] The "patentee" includes assignees of the patent.[218]

This remedy is available until the fourth anniversary of the issuance of the patent, and results in the surrender of the original patent at the same time as the reissued patent is brought into force.[219] This four-year anniversary refers to the date at which the patentee must have taken the step of applying for a reissued patent — it does not require that the patent be reissued by the Commissioner prior to the four-year anniversary.[220] The patentee must complete Form I of Schedule I to the Patent Rules to apply for a reissued patent.[221]

The "inadvertence, accident or mistake must be inadvertence, accident or mistake affecting the sufficiency of the description or specification in the original patent, and it is only in respect of such inadvertence, accident or mistake that the statute contemplates relief."[222]

A patent cannot be reissued merely to broaden the scope of the claims in order to catch subsequent infringers.[223] Where decisions have been deliberately made during examination in order to have the original patent validly issued, such decisions may not provide the requisite "mistake" to permit reissue.[224]

For a trial commenced after the patent has been re-issued, the amended description and specification are treated as if they had been originally filed in their corrected form.[225] For a trial commenced prior to the reissue, the surrender does not affect any pending action to the extent its claims are identical with the original patent.[226]

In construing the term "identical", the Federal Court of Appeal has favourably reviewed American jurisprudence, in part due to the similar wording of the respective statutory sections dealing with the reissue of patents.[227] The term "identical" does not mean that the claims must be literally, word for word, the same. Instead, drawing on U.S. jurisprudence, there cannot be a "substantive change" in the scope of the reissued claim. This requires the

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[212] *Genentech Canada Inc., Re* (1992), 44 C.P.R. (3d) 316 (Can. Pat. Medicine Prices Rev. Bd.) at para 35.
[213] *Genentech Canada Inc., Re* (1992), 44 C.P.R. (3d) 316 (Can. Pat. Medicine Prices Rev. Bd.) at para 39.
[214] *Application for compulsory licence by Novopharm Ltd., Re* (1992), 44 C.P.R. (3d) 13 (Can. Pat. Commr.) at para 4.
[215] *Patent Act*, s. 47, as amended.
[216] *Patent Act*, s. 47(1), as amended.
[217] *Paul Moore Co. v. Canada (Patent Commissioner)* (1979), 35 N.R. 203 (Fed. C.A.) at para 10, leave to appeal refused 1980 CarswellNat 889 (S.C.C.).
[218] *Curl-Master Manufacturing Co. v. Atlas Brush Ltd.*, [1967] S.C.R. 514 (S.C.C.) at para 43.
[219] *Patent Act*, s. 47(1), as amended.
[220] *Curl-Master Manufacturing Co. v. Atlas Brush Ltd.*, [1967] S.C.R. 514 (S.C.C.) at para 46.
[221] *Patent Rules*, s. 43.
[222] *Northern Electric Co. v. Photo Sound Corp.*, [1936] S.C.R. 649 (S.C.C.) at para 5.
[223] *Halbrite Well Services Co. Patent Application No. 616,196, Re* (1993), 3 C.P.R. (4th) 94 (Can. Pat. App. Bd. & Pat. Commr.) at para 25.
[224] *Halbrite Well Services Co. Patent Application No. 616,196, Re* (1993), 3 C.P.R. (4th) 94 (Can. Pat. App. Bd. & Pat. Commr.) at para 19; see also *Hydril Co. Patent Application No. 616,666, Re* (1997), 85 C.P.R. (3d) 503 (Can. Pat. App. Bd. & Pat. Commr.).
[225] *Patent Act*, s. 47(2).
[226] *Patent Act*, s. 47(2).
[227] *Stamicarbon B.V. v. Urea Casale S.A.* (2002), 17 C.P.R. (4th) 377 (Fed. C.A.) at paras 17–20, leave to appeal refused 2002 CarswellNat 2820 (S.C.C.).

construction of the claims.[228]

The reissued patent must describe and claim the same invention.[229] The reissued patent persists for the unexpired term of the original patent. If a patent fails to disclose an invention it is invalid and may not be reissued; however, if the invention is imperfectly described, the patent may be reissued.[230] The question is whether the patentee is seeking to reissue the patent to reflect his or her original intention.[231] A mistake of law made by the patentee's attorney that nonetheless reflected the patentee's true intention with regard to the scope of the original patent was insufficient to warrant the reissue of a patent.[232]

Did the original patent reflect the complete invention that the inventors intended to disclose and cover? The mistake need not be that of the inventor's making.[233] If the patentee properly understood the scope and effect of the patent there may be no error to correct with a reissued patent.[234] That is, the patent was never defective despite the patentee's subsequent desire to change it and have it reissued.[235]

Whether the "error" — i.e., the inadvertence — was on the part of the patentee or their attorney is not relevant since a party should not suffer a deprivation of his or her rights due to the error or neglect of his or her attorney.[236] Only a valid patent may be reissued.[237]

There is no cause of action in respect of the claims of the original patent upon the surrender of that patent unless the claims relied upon in the reissued patent are "identical" as required pursuant to subsection 47(2) of the *Patent Act*.[238] This is so even if the cause of action was pending before the Court.[239]

In *obiter dicta*, Justice Stone for the Federal Court of Appeal suggested that, upon the surrender of the patent, the patentee is not entitled to reasonable compensation pursuant to subsection 55(2) in respect of the time that the original patent application was published but prior to the issuance of the original patent.[240] It is unclear whether this is so even if the claims of the surrendered and reissued patents are subsequently held to be identical.

The reissue of a patent did not exempt the patentee from the mandatory timelines set out in subsection 4(4) of the *PM(NOC) Regulations* as they read prior to the October 2007 amendments.[241]

A patentee may not be able to reissue claims that have been previously disclaimed.[242]

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[228] *Stamicarbon B.V. v. Urea Casale S.A.* (2002), 17 C.P.R. (4th) 377 (Fed. C.A.) at para 22, leave to appeal refused 2002 CarswellNat 2820 (S.C.C.).
[229] *Northern Electric Co. v. Photo Sound Corp.*, [1936] S.C.R. 649 (S.C.C.) at para 2.
[230] *Curl-Master Manufacturing Co. v. Atlas Brush Ltd.*, [1967] S.C.R. 514 (S.C.C.) at para 21.
[231] *Curl-Master Manufacturing Co. v. Atlas Brush Ltd.*, [1967] S.C.R. 514 (S.C.C.) at para 32; *Farbwerke Hoechst A.G. vormals Meister Lucius & Bruning v. Canada (Commissioner of Patents)*, [1966] S.C.R. 604 (S.C.C.) at para 33; *Northern Electric Co. v. Photo Sound Corp.*, [1936] S.C.R. 649 (S.C.C.) at paras 33–34.
[232] *Farbwerke Hoechst A.G. vormals Meister Lucius & Bruning v. Canada (Commissioner of Patents)*, [1966] S.C.R. 604 (S.C.C.) at para 39.
[233] *Mobil Oil Corp. v. Hercules Canada Inc.* (1995), 63 C.P.R. (3d) 473 (Fed. C.A.) at 480, leave to appeal refused 1996 CarswellNat 3159.
[234] *Northern Electric Co. v. Photo Sound Corp.*, [1936] S.C.R. 649 (S.C.C.) at para 2.
[235] *Curl-Master Manufacturing Co. v. Atlas Brush Ltd.*, [1967] S.C.R. 514 (S.C.C.) at para 24.
[236] *Burton Parsons Chemicals Inc. v. Hewlett-Packard (Canada) Ltd.* (1974), [1976] 1 S.C.R. 555 (S.C.C.) at para 21.
[237] *Farbwerke Hoechst A.G. vormals Meister Lucius & Bruning v. Canada (Commissioner of Patents)*, [1966] S.C.R. 604 (S.C.C.) (but see *Burton Parsons Chemicals Inc. v. Hewlett-Packard (Canada) Ltd.* (1974), [1976] 1 S.C.R. 555 (S.C.C.) at para 19; and *Curl-Master Manufacturing Co. v. Atlas Brush Ltd.*, [1967] S.C.R. 514 (S.C.C.) at para 19).
[238] *Stamicarbon B.V. v. Urea Casale S.A.* (2002), 17 C.P.R. (4th) 377 (Fed. C.A.) at para 32, leave to appeal refused 2002 CarswellNat 2820 (S.C.C.).
[239] *Stamicarbon B.V. v. Urea Casale S.A.* (2002), 17 C.P.R. (4th) 377 (Fed. C.A.), leave to appeal refused 2002 CarswellNat 2820 (S.C.C.). See also *Northern Electric Co. v. Photo Sound Corp.*, [1936] S.C.R. 649 (S.C.C.) at para 8.
[240] *Stamicarbon B.V. v. Urea Casale S.A.* (2002), 17 C.P.R. (4th) 377 (Fed. C.A.) at para 34, leave to appeal refused 2002 CarswellNat 2820 (S.C.C.).
[241] *Procter & Gamble Pharmaceuticals Canada Inc. v. Canada (Minister of Health)* (2003), 26 C.P.R. (4th) 180 (Fed. T.D.) at paras 38–40, affirmed 2003 CarswellNat 3843 (F.C.A.); The *PM(NOC) Regulations* were most recently amended on September 21, 2017, the details of which are beyond the scope of this chapter. For further reading see the Office of Patented Medicines and Liasion's Guidance Document, available online: <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/patented-medicines/notice-compliance-regulations.html#wb-cont>
[242] *Parke-Davis Division, Warner-Lambert Canada Inc. v. Canada (Minister of Health)* (2001), 14 C.P.R. (4th) 335 (Fed. T.D.) at para 91, reversed 2002 CarswellNat 3282 (Fed. C.A.), leave to appeal refused 2003 CarswellNat 1369 (S.C.C.).

8.10.1 Re-Examination

Section 48.1 of the *Patent Act* allows any person to request that patent claims be re-examined. The "person" need not be the patentee. In basic terms, re-examination allows a person to test the validity of any or all claims of a patent.

Re-examination of a patent involves two stages. Stage one requires the filing of a request by a requester (section 48.1), the establishment of a re-examination board by the Commissioner in response to this request (section 48.2(1)); and the preliminary decision by the re-examination board as to whether the request raises a substantial new question of patentability (section 48.2(2) to (4)). Stage two follows the re-examination board's determination that a substantial new question of patentability is raised (section 48.2(4)). The requester is not a party to this second phase of the process; at this stage the parties are limited to the re-examination board and the patentee. Only the patentee is given notice of the determination (section 48.2(4)) and is entitled to make submissions (section 48.2(5)), to propose amendments to the patent, (section 48.3(2)) and to receive a copy of the certificate (section 48.4(2)). Only the patentee is given a right of appeal (section 48.5).[243]

8.10.2 Request for Re-Examination

To request re-examination, the requester must file with the Commissioner the prior art (patents and printed publications) relevant to the request along with the appropriate fee.[244]

If the requester qualifies as a small entity, the requisite fee is $1,000.00.[245] For a large entity, this fee is $2,000.00.[246]

The requester must set forth the "pertinency" of the prior art to the request[247] — which amounts to a written argument in favour of the position taken by the requester.

If the requester is not the patentee, the Commissioner is directed to, forthwith, provide notice to the patentee of the request under subsection 48.1(1).[248]

8.10.3 Establishment of Re-Examination Board

Upon receiving the request under subsection 48.1(1), the Commissioner must establish a re-examination board of at least three individuals.[249] This board, once constituted, must determine whether "a substantial new question of patentability affecting any claim of the patent concerned is raised by the request for re-examination" within three months.[250] This preliminary step determines whether a full re-examination is required.

Where the board determines that the request does not raise a substantial new question affecting the patentability of a claim of the patent, it must notify the person (not the patentee) of this decision.[251] No appeal route is provided in respect of this decision.

Where the board determines that the request does raise a substantial new question affecting the patentability of claims of the patent, it must notify the patentee and provide reasons.[252]

After receiving notice from the board of the substantial new question affecting the patentability of claims in the patent, the patentee has three months from the date of the notice to submit reply submissions.[253] If the request under subsection 48.1(1) had been made by another party, this will be the first time that the patentee will be able to present its case to the board.

8.10.4 Re-Examination Proceeding

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[243] *Genencor International Inc. v. Canada (Commissioner of Patents)* (2007), 55 C.P.R. (4th) 378 (F.C.A.) at paras 7–8, leave to appeal refused 2007 CarswellNat 3566 (S.C.C.).
[244] *Patent Act*, s. 48.1(1).
[245] *Patent Rules*, Sched. II, Pt. III, Item 14(a).
[246] *Patent Rules*, Sched. II, Pt. III, Item 14(b).
[247] *Patent Act*, note 1, s. 48.1(2).
[248] *Patent Act*, s. 48.1(3).
[249] *Patent Act*, s. 48.2(1).
[250] *Patent Act*, s. 48.2(2).
[251] *Patent Act*, s. 48.2(3).
[252] *Patent Act*, s. 48.2(4).
[253] *Patent Act*, s. 48.2(5).

If the patentee submits reply submissions to the board (or if the time to submit has expired), the board must then cause a re-examination to be made of the claims set out in the initial request.[254]

Once re-examination has commenced, the patentee may propose any amendment to the patent or any new claims so long as the claims do not enlarge the scope of the patent.[255] It is for this reason that re-examination proceedings are not chosen by parties wishing to attack the validity of a patent. Even if claims are found invalid, the patentee has the opportunity to amend — saving the validity of the patent and their rights to the invention. By way of contrast, in an action to impeach the validity of claims, the claims will be held valid or invalid based on their text — there is no opportunity for amendments at that time.

The re-examination proceeding must be completed within 12 months of the commencement of the re-examination.[256]

8.10.5 Certificate of Board

Once the re-examination board has reached its conclusion, it must issue a certificate:[257] cancelling any claim of the patent determined to be unpatentable; confirming any claim of the patent determined to be patentable; or incorporating in the patent any proposed amended or new claim determined to be patentable.

Any claims that are cancelled are deemed to have never been a part of the issued patent.[258] If all of the claims of the patent are cancelled, the patent is deemed never to have been issued (though note that the application may still have been published and publicly available).[259] If the patentee amends any claims or incorporates new claims these amendments are effective from the date of certification for the unexpired term of the patent.[260]

8.10.6 Appeal

Only the patentee may appeal a decision of the re-examination board.[261] If the patentee appeals the decision of the re-examination board, the other party (if there is another party) is not entitled to be added as a respondent in the appeal.[262] However, a party may be granted leave to intervene if it can demonstrate that the facts warrant such an Order.[263] An appeal must be taken within three months from the date of the certificate.[264]

8.10.7 Patent Rules

Rule 45 of the Patent Rules requires that a request pursuant to subsection 48.1 of the *Patent Act*, along with the prior art, be filed in duplicate.[265] For further reading, see Chapter 23.02 of the Manual of Patent Office Practice.[266]

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[254] *Patent Act*, s. 48.3(1).
[255] *Patent Act*, s. 48.3(2).
[256] *Patent Act*, s. 48.3(3).
[257] *Patent Act*, s. 48.4(1).
[258] *Patent Act*, s. 48.4(3)(a).
[259] *Patent Act*, s. 48.4(3)(b).
[260] *Patent Act*, s. 48.4(3)(c).
[261] *Patent Act*, s. 48.5(1).
[262] *Genencor International Inc. v. Canada (Commissioner of Patents)*, 2006 FC 1021 (per Justice Pinard), affirmed 2007 FCA 129, leave to appeal refused 2007 CarswellNat 3566 (S.C.C.).
[263] *Genencor International Inc. v. Canada (Commissioner of Patents)*, 2006 FC 1021 at para. 8, affirmed 2007 FCA 129, leave to appeal refused 2007 CarswellNat 3566 (S.C.C.).
[264] *Patent Act*, s. 48.5(2).
[265] *Patent Rules*, s. 45.
[266] Available online at <http://www.cipo.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/h_wr00720.html>.