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Patent Law

Chapter 8 - Validity: Latent Defects

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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. 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). In court proceedings, latent defects are most often addressed after consideration of anticipation and obviousness.

8.2. Disclosure Requirement

The *Patent Act* requires that the applicant file a "specification" comprised of a description ("the disclosure") and claims.[1] The Supreme Court recently held, "[a]dequate disclosure in the specification is a precondition for the granting of a patent".[2] Failure to make adequate disclosure as required under the *Patent Act* is a latent defect that can render the patent invalid.[3]

Subsection 27(3) of the *Patent Act* sets out the requirements for disclosure.[4] 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

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[1] *Patent Act,* R.S.C. 1985, c. P4, as amended. See also *Consolboard Inc. v. MacMillan Bloedel (Saskatchewan) Ltd.,* [1981] 1 S.C.R. 504 at 520.

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

[3] *Teva Canada Ltd. v. Pfizer Canada Inc. ("Sildenafil"),* 2012 SCC 60 at paras. 82-87, [2012] 3 S.C.R. 625, 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 at para. 27 (a patent must define the nature of the invention and how to put it into operation, failing which the patent is invalid for 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 PM(NOC) proceeding. 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.

[4] 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 166-67, "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 at 518-19; *Teva Canada Ltd. v. Pfizer Canada Inc.,* 2012 SCC 60 at para. 50, [2012] 3 S.C.R. 625; and the *Patent Rules,* SOR/96-423, s. 80(1).

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 of Canada 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."[5]

Courts have repeatedly endorsed the proposition that the 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.[6]

The applicant must disclose everything that is essential for the invention to function properly. It has been said that, to be complete, disclosure must meet two conditions: 1) describe the invention and 2) define the way it is produced or built.[7] Recently, however, the Supreme Court 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.[8]

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[5] *Consolboard Inc. v. MacMillan Bloedel (Saskatchewan) Ltd.,* [1981] 1 S.C.R. 504 at 517, referring to then s. 36(1) of the *Patent Act.* See also *Teva Canada Ltd. v. Pfizer Canada Inc.,* 2012 SCC 60 at para. 31, [2012] 3 S.C.R. 625; *Whirlpool Corp. v. Camco Inc.,* 2000 SCC 67, [2000] S.C.J. No. 68 at para. 42.

[6] *Pioneer Hi-Bred Ltd. v. Canada (Commissioner of Patents),* [1989] 1 S.C.R. 1623, [1989] S.C.J. No. 72 at para. 23, citing with approval Harold G. Fox, *Canadian Patent Law and Practice,* 4th ed. (Toronto: Carswell, 1969) at 163. The Court also 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 requires human activity for its development See also *Teva Canada Ltd. v. Pfizer Canada Inc.,* 2012 SCC 60 at para. 70, [2012] 3 S.C.R. 625 (the specification "must define the 'precise and exact extent' of the privilege being claimed").

[7] *Pioneer Hi-Bred Ltd. v. Canada (Commissioner of Patents),* [1989] 1 S.C.R. 1623 at 1638, [1989] S.C.J. No. 72 at para. 27.

[8] *Teva Canada Ltd. v. Pfizer Canada Inc.,* 2012 SCC 60 at paras. 70-71, [2012] 3 S.C.R. 625, citing with approval *Consolboard Inc. v. MacMillan Bloedel (Saskatchewan) Ltd.,* [1981] 1 S.C.R. 504 at 520, *Minerals Separation North American Corp. v. Noranda Mines Ltd*. (1947), 12 C.P.R. 99 at 102 (Can. Ex. Ct.), and *Pioneer Hi-Bred Ltd. v. Canada (Commissioner of Patents),* [1989] 1 S.C.R. 1623 at 1638.

Following the Supreme Court's recent 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?[9]

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.[10]

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.[11] 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.[12]

Although the relevant date has been debated in the case law, the date on which sufficiency is to be assessed now seems to be established as the date on which the patent issued for applications prior to October 1, 1989 under the old *Patent Act*, and the date of filing for applications under the new *Patent Act*.[13]

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.[14]

8.2.1. *Accuracy 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

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[9] 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 at para. 70, [2012] 3 S.C.R. 625.

[10] *Consolboard Inc. v. MacMillan Bloedel (Saskatchewan) Ltd.,* [1981] 1 S.C.R. 504 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.

[11] *VISX Inc. v. Nidek Co.*, [1999] F.C.J. No. 1971 (F.C.T.D.) at para. 144.

[12] *Consolboard Inc. v. MacMillan Bloedel (Saskatchewan) Ltd.,* [1981] 1 S.C.R. 504 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.

[13] *Teva Canada Ltd. v. Pfizer Canada Inc.,* 2012 SCC 60 at para. 90, [2012] 3 S.C.R. 625. See also *Teledyne Industries, Inc. v. Lido Industrial Products Ltd*., [1981] F.C.J. No. 703 (F.C.A.) at paras. 45-47; *TRW Inc. v. Walbar of Canada Inc.* (1991), 39 C.P.R. (3rd) 176 at 195 (F.C.A.); *Whirlpool Corp. v. Camco Inc.,* 2000 SCC 67, [2000] S.C.J. No. 68 note 4 at paras. 55-56; *Free World Trust v. Electro Sante Inc.*, 2000 SCC 66 at paras. 52-54, [2000] 2 S.C.R. 1024; *Hughes & Woodley on Patents*, 2 ed., looseleaf (Canada: Butterworth, 2005) at para. 31; *Aventis Pharma Inc. v. Apotex Inc.*, 2005 FC 1283 at para. 262, aff'd 2006 FCA 64, leave to appeal to SCC refused (2006), 55 C.P.R. (4th) vi.

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

public, having only the specification, to make the same successful use of the invention.[15]

What is the invention is a question of law.[16] 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*. recently 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.[17]

The Court rejected the broad conclusion that separate claims disclose separate inventions, but recognized that, in the event that each claim in a patent does disclose a separate invention, the court will consider the issue on a case-by-case having regard first to the specification as a whole.[18]

Taken as a whole, the sufficiency of the disclosure is a question of mixed fact and law, as the Judge is required to assess the evidence before him against a legal standard – sufficiency.[19] Whether or not a specification is sufficient depends on what a skilled person would consider sufficient to put the invention into practice.[20] The skilled person may have to conduct certain experiments to arrive at a successful result based on a patent specification, short of requiring any inventive faculty in arriving at the result."[21] However, if a skilled reader is required to undertake a "minor research project" to determine the true invention, a court may find disclosure to be inadequate.[22]

8.2.2. *Sufficiency of Disclosure and Utility*

For purposes of sufficiency, there is no requirement for a patentee to demonstrate utility in the patent disclosure as long as the court finds utility to have been proven upon a legal challenge. 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

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[15] *Teva Canada Ltd. v. Pfizer Canada Inc.,* 2012 SCC 60 at para. 70, [2012] 3 S.C.R. 625.

[16] *Apotex Inc v Pfizer Canada Inc*, 2011 FCA 236 at para. 17; *Apotex v. Pfizer Ireland Pharmaceuticals*, 2012 FC 1339 at para. 31.

[17] *Teva Canada Ltd. v. Pfizer Canada Inc.,* 2012 SCC 60 at para. 55, [2012] 3 S.C.R. 625.

[18] *Teva Canada Ltd. v. Pfizer Canada Inc.,* 2012 SCC 60 at para. 64, [2012] 3 S.C.R. 625.

[19] *Pfizer Canada Inc. v. Novopharm Ltd.* (2010), 88 C.P.R. (4th) 405 (FCA) at para 75, rev'd on other grounds, *Teva Canada Ltd. v. Pfizer Canada Inc.,* 2012 SCC 60.

[20] *Teva Canada Ltd. v. Pfizer Canada Inc.,* 2012 SCC 60 at paras. 75, 79, [2012] 3 S.C.R. 625.

[22] See *Teva Canada Ltd. v. Pfizer Canada Inc.,* 2012 SCC 60 at paras. 74-74, [2012] 3 S.C.R. 625 (where the Court found Pfizer's disclosure inadequate, because a skilled reader would have had to undertake a minor research project to determine what the true invention was).

[22] See *Teva Canada Ltd. v. Pfizer Canada Inc.,* 2012 SCC 60 at paras. 74-74, [2012] 3 S.C.R. 625 (where the Court found Pfizer's disclosure inadequate, because a skilled reader would have had to undertake a minor research project to determine what the true invention was).

> 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.[23]

There is a tendency to confuse the utility requirement under section 2 (an invention must be new and useful) and the disclosure requirement under subsection 27(3). In *Consolboard,* the Supreme Court had to decide whether a patentee was required to disclose the use to which the inventor intended to put the invention (i.e., the commercial application). 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".[24]

The Supreme Court of Canada in *Sildenafil* recently confirmed that there is no obligation on the patentee to demonstrate or prove utility in the patent disclosure. As far as the disclosure requirements are concerned under subsection 27(3), the patentee must provide enough 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. [25]

> 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 will depend on whether or not the specification makes a promise of a specific result.

> [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

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[23] *Pfizer Canada Inc. v. Canada (Minister of Health)*, 2008 FCA 108 at paras. 56-57, 67 C.P.R. (4th) 23.

[24] *Consolboard Inc. v. MacMillan Bloedel (Sask.) Ltd.*, [1981] S.C.T. 504 at 525-26.

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

> 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.[26]

For a thorough discussion on the concept of the “promise” of the patent, see Justice Hughes’ decision in *Pfizer Canada Inc. v. Mylan Pharmaceuticals ULC,* which was recently affirmed by the Federal Court of Appeal.[27]

The leading cases from the Supreme Court of Canada regarding adequacy of disclosure are *Consolboard*, *Pioneer Hi-Bred,* and *Sildenafil*. The latest decision, *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.[28]

These three cases set out the relevant considerations for a court when faced with an allegation that the patent is invalid for inadequate disclosure.[29]

In *Consolboard*, the Supreme Court of Canada found 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 is whether the specification adequately describes the invention "for a person skilled in the art."[30] The Supreme Court found that the Federal Court of Appeal had erred in holding that section 36(1) requires the distinct indication of the real utility of the invention. The Supreme Court further held that section 36(1) does 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.[31]

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

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[26] *Eli Lilly Canada Inc. v. Novopharm Ltd.,* 2010 FCA 197, 85 C.P.R. (4th) 413 at para 76, leave to appeal to SCC refused, 33870 (Feb. 10, 2011).

[27] *Pfizer Canada Inc. v. Mylan Pharmaceuticals ULC* (2011) 93 C.P.R. (4th) 81 at pp. 134-139, para 212-217.

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

[29] See also subsection 53(1) of the *Patent Act,* R.S.C. 1985, c. P4, as amended, note 1, 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.”

[30] *Consolboard Inc. v. MacMillan Bloedel (Saskatchewan) Ltd.,* [1981] 1 S.C.R. 504 at 521-23. 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.

[31] *Consolboard Inc. v. MacMillan Bloedel (Saskatchewan) Ltd*., [1981] 1 S.C.R. 504 at 525-27.

deposited seeds with U.S. and Canadian governmental agencies.

The Supreme Court decided the *Pioneer Hi-Bred* case solely on whether the applicant had made sufficient disclosure of its invention in the description and whether depositing samples of seeds constituted disclosure under the *Patent Act.*[32] After setting out the overall 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.[33]

In *Sildenafil*, the Supreme Court addressed sufficiency of disclosure in the context of a PM(NOC) proceeding for the patent for Viagra, 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 only active compound in Viagra. The claims ended with two individually claimed compounds, making it impossible for a skilled person in the art 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. In response to this tactic, the Court stated, "[a]s a matter of policy and sound statutory interpretation, patentees cannot be allowed to "game" the system in this way.[34]

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.[35]

8.2.3. *The "Best Mode" Requirement*

Paragraph 27(3) (c) of the Act requires the specification "in the case of a machine, [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

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[32] *Pioneer Hi-Bred Ltd. v. Canada (Commn'r. of Patents)*, [1989] 1 S.C.P. 1623 at para. 22. See now subsection 38.1(1) of the *Patent Act* regarding the deposit of biological material.

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

[34] *Teva Canada Ltd. v. Pfizer Canada Inc.,* 2012 SCC 60 at para. 80, [2012] 3 S.C.R. 625.

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

for carrying out the invention in terms of examples, where appropriate, and with reference to the drawings, if any."[36]

There is no statutory duty to disclose the "best mode" *per se* of applying the invention, 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.[37] Arguably, the obligation may be implied by subsection 27(3) (a) to "correctly and fully describe the invention".[38]

A statement of the principles 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. ...
>
> 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."[39]

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.[40]

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

[37] See *Teledyne Industries Inc. v. Lido Industrial Products Ltd.* (1981), 57 C.P.R. (2d) 29*,* [1981] F.C.J. No. 703 at para. 43 (FCA); *Hughes & Woodley on Patents,* 2d ed., loose-leaf (Canada: Butterworth's, 2005) at para. 31.

[38] *Bauer Nike Hockey Inc. v. Regan,* [2001] F.C.J. No. 1839 (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.

[39] *Teledyne Industries Inc. v. Lido Industrial Products Ltd.* (1981) 57 C.P.R. (2d) 29*,* [1981] F.C.J. No. 703 (F.C.A.) at para. 43, citing Harold G. Fox, Canadian Patent Law and Practice, 4th ed. (Toronto: Carswell, 1969) at 180.

[40] *Teledyne Industries Inc. v. Lido Industrial Products Ltd.* (1981) 57 C.P.R. (2d) 29*,* [1981] F.C.J. No. 703 (F.C.A.) at

8.2.4. *Ambiguity*

A related but distinct validity attack is the allegation of ambiguity. 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.

"Insufficiency" is a separate ground of invalidity from "ambiguity". "Insufficiency" is directed to the issue of whether the description is sufficient to enable those person's 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. As previously stated, sufficiency is a question of law. Ambiguity is a question of law as it depends on a legal construction of the claims.

Dismissing a motion for summary judgment on grounds that the patent was invalid for ambiguity, 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.).[41]

There is a dearth of cases in the Federal Court in which a patent has been held invalid for ambiguity.[42] As repeatedly noted by the Court, "ambiguity is truly a last resort, rarely, if ever, to be used."[43]

8.2.5. *"Selection Patents"*

The sufficiency of disclosure arises often 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.[44] In *Apotex v. Sanofi-Synthelabo Canada Inc.,* the Supreme Court of Canada upheld the permissibility of selection patents in principle.[45] For a selection patent to be valid, it should disclose a "substantial advantage to be secured or disadvantage

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para. 50. See *TRW Inc. v. Walbar of Canada Inc.*, [1991] F.C.J. No. 1075 (FCA), 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*.

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

[42] *Pfizer Canada Inc. v. Canada (Minister of Health),* 2005 FC 1725, [2005] F.C.J. No. 2155 at para. 51 (F.C.).

[43] *Pfizer Canada Inc. v. Canada (Minister of Health),* 2005 FC 1725, [2005] F.C.J. No. 2155 at paras. 49-53.

[44] *Apotex Inc. v. Sanofi-Synthelabo Canada Inc.,* 2008 SCC 61, 69 C.P.R. (4th) 251 at paras. 10, 32.

[45] *Apotex Inc. v. Sanofi-Synthelabo Canada Inc.,* 2008 SCC 61, 69 C.P.R. (4th) 251 at para. 19.

to be avoided by the use of the selected members" that was not disclosed in the prior genus patent.[46] "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."[47]

The Federal Court recently considered the sufficiency of disclosure with respect to selection patents.[48] The price to be paid by a patentee who has already enjoyed a monopoly from a prior patent is clear and explicit disclosure of what the invention in the selection patent is. 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."[49] In refusing to hear the appeal from this decision on grounds of mootness, a majority of the Federal Court of Appeal held 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[50]

In determining whether a patent is a selection patent, 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 where its claims are limited to the discovery of an inventive 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.[51]

8.3. Misrepresentation in the Patent Application

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.
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> (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

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[46] *Apotex Inc. v. Sanofi-Synthelabo Canada Inc.,* 2008 SCC 61, 69 C.P.R. (4th) 251 at paras. 10, 32.

[47] *Pfizer Canada Inc. v. Canada (Minister of Health),* 2008 FCA 108 at para. 41, [2009] 1 F.C.R. 253.

[48] *Eli Lilly Canada v. Novopharm Ltd.,* 2007 FC 596, [2007] F.C.J. No. 800 at paras. 128-165, appeal dismissed for mootness, 2007 FCA 359, [2007] F.C.J. No. 809, leave to appeal to S.C.C. refused, [2007] S.C.C.A. No. 9. See also Harold G. Fox, *Canadian Patent Law and Practice,* 4th ed. (Toronto: Carswell, 1969) at 193.

[49] *Eli Lilly Canada v. Novopharm Ltd.,* 2007 FC 596, [2007] F.C.J. No. 800 at para. 139, appeal dismissed for mootness, 2007 FCA 359, [2007] F.C.J. No. 809, leave to appeal to S.C.C. refused, [2007] S.C.C.A. No. 9.

[50] *Eli Lilly Canada v. Novopharm Ltd.*, 2007 FC 596, [2007] F.C.J. No. 800 at para. 30, appeal dismissed for mootness, 2007 FCA 359, [2007] F.C.J. No. 809, leave to appeal to S.C.C. refused, [2007] S.C.C.A. No. 9.

[51] *Novopharm Ltd. v. Eli Lilly and Co.* (2010), 87 C.P.R. (4th) 301 (FC) at 337-338, para 88-89, aff'd. without comment (2011), 94 C.P.R. (4th) 95 (FCA), leave to appeal to SCC refused, [2011] S.C.C.A. No. 362.

> 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 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.[52] 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 intention.[53] It is the addressee of the patent, the person skilled in the art, that must be misled by the alleged misrepresentation.[54] The relevant date for interpreting 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 included.[55]

The party making the allegation of invalidity under section 53 must prove the allegation, notwithstanding that knowledge may particularly lie with the patentee. It must lead evidence or take steps to obtain evidence from the patentee by request or appropriate Court Order.[56] There is no obligation on the patentee to lead evidence.[57]

Section 53 gives rise to the spectre of fraud. 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.[58]

It was 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.[59] 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'."[60]

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[52] *Eli Lilly Canada Inc. v. Apotex Inc.*, 2007 FC 455 at para. 245 (F.C.T.D.), aff'd 2009 FCA 44.

[53] *Eli Lilly Canada Inc. v. Apotex Inc.*, 2007 FC 455 at para. 381 (F.C.T.D.), aff'd 2009 FCA 44.

[54] *Corning Glass Works v. Canada Wire & Cable Ltd.* (1984), 81 C.P.R. (2d) 39 at 74-76.

[55] *Weatherford Canada Ltd. v. Corlac Inc.*, 2011 FCA 228 at para 119, 95 C.P.R. (4th)101, leave to appeal to SCC refused, 2012 CarswellNat 846, referring to *Jules Gilbert Ltd. V. Sandoz Ltd.* (1970), 64 C.P.R. 14 (Ex. Ct.) rev'd. on other grounds [1974] S.C.R. 1336.

[56] *Eli Lilly Canada Inc. v. Novopharm Ltd.* (2007), 58 C.P.R. (4th) 214 at para. 169.

[57] *Eli Lilly Canada Inc. v. Novopharm Ltd.* (2007), 58 C.P.R. (4th) 214 at para. 172.

[58] *Eli Lilly Canada Inc. v. Apotex Inc.*, 2009 FCA 97 at paras. 62-63. See however *Johnson & Johnson v. Boston Scientific Ltd.*, 2008 FC 817 (F.C. per Layden-Stevenson J.) at para. 9.

[59] 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)."

[60] 2003 FCA 241, [2003] 4 F.C. 713, 27 C.P.R. (4th) 385, recently applied in *Weatherford Canada Ltd. v. Corlac Inc.,* 2011 FCA 228 at para 116, 95 C.P.R. (4th) 101 at 140, leave to appeal to SCC refused, 34459 (March, 29, 2012).

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.[61]

Whether a misrepresentation is material under subsection 53(1) is a mixed question of fact and law.[62]

Relying on *Jules R. Gilbert Ltd. v. Sandoz Patents Ltd*.[63] , 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".[64] Allegations concerning subject-matter other than the claims of the patent are immaterial.[65] For example, the 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.[66] 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.[67] The Federal Court in *Q'Max* characterized the remedy in subsection 53(1) as being "draconian" and it seems clear that Courts are reluctant to invoke it absent compelling evidence of wrong-doing.[68] That said, the Court of Appeal recently advised that whether the failure to name the proper inventor is material depends on a fact specific analysis and that the materiality of inventorship will depend on the circumstances of any particular case.[69]

Courts have held that an improper claim to a priority date[70] and an applicant's failure to disclose all prior applications are not material allegations.[71] 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.[72]

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[61] *Patent Act*, R.S.C. 1985, c. P-4, as amended, s. 53(2).

[62] *Weatherford Canada Ltd. V. Corlac Inc.*, 2011 FCA 228 at para. 115, 95 C.P.R. (4th) 101, leave to appeal to SCC refused, 2012 CarswellNat 846.

[63] *Jules R. Gilbert v. Sandoz Patents Ltd.* (1970), 64 C.P.R. 14 (Ex. Ct.); see also *Rothmans, Benson & Hedges Inc. v. Imperial Tobacco Ltd.*, [1991] 35 C.P.R. (3d) 417 at para. 28 (F.C.T.D.).

[64] *Apotex Inc. v. Wellcome Foundation Ltd.* (1998), 79 C.P.R. (3d) 193.

[65] *Jules R. Gilbert v. Sandoz Patents Ltd.* (1970), 64 C.P.R. 14 (Ex. Ct.).

[66] *Eli Lilly and Co. v. Apotex Inc.* (1998), 80 C.P.R. (3d) 80 at para. 27.

[67] *671905 Alberta Inc. v. Q'Max Solutions Inc.* (2001), 27 C.P.R. (4th) 385 at para. 23-32 (FCA), leave to appeal denied [2003] S.C.C.A. No. 381

[68] *Weatherford Canada Ltd. v. Corlac Inc.,* 2011 FCA 228 at para. 123, 95 C.P.R. (4th) 101, leave to appeal to SCC refused, 2012 CarswellNat 846, referencing *671905 Alberta Inc. v. Q'Max Solutions Inc.* (2001), 27 C.P.R. (4th) 385 (FCA) at para 32.

[69] *Weatherford Canada Ltd. v. Corlac Inc.,* 2011 FCA 228 at para. 128, 95 C.P.R. (4th) 101, leave to appeal to SCC refused, 2012 CarswellNat 846,and see discussion of cases at paras. 126-127 at pp. 143-144.

[70] *Canadian Marconi Co. v. Vera Prinzen Enterprises Ltd.* (1964), 46 C.P.R. 97 (Ec. Ct.).

[71] *Bayer AG v. Apotex Inc.* (1998), 84 C.P.R. (3d) 23 at paras. 19-23 (F.C.T.D.)

[72] *Bourgault Industries Ltd. v. Flexi-Coil Ltd.* (1998), 80 C.P.R. (3d) 1 at 87-92 (F.C.T.D.), Ord (1999), 86 C.P.R. (3d) 221 (F.C.A.); see also *Eli Lilly and* Co. *v. Apotex Inc.* (1998), 80 C.P.R. (3d) 80 at paras. 27-29 (F.C.T.D.), aff'd 259 N.R. 225

Alleged missteps in the application for or prosecution of 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 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."[73] 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.[74]

The same 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 not be followed.[75]

(F.C.A.).

[73] *Weatherford Canada Ltd. v. Corlac Inc.,* 2011 FCA 228 at para. 139, [2011] 95 C.P.R. (4th) 101 at 147, leave to appeal to SCC refused, 2012 CarswellNat 846.

[74] *Weatherford Canada Ltd. v. Corlac Inc.* 2011 FCA 228 at para. 150, 95 C.P.R., leave to appeal to SCC refused, 2012 CarswellNat 846.

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

8.4. Over-claiming or "Claims Broader"

The proper scope of claims drafting is a frequent issue in patent litigation. 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.[76]

The challenge was well expressed by Thorson P. in *Minerals Separation North American Corp. v. Noranda Mines Ltd.*[77]

> 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. In a recent decision of the Patent Appeal Board, it was 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.[78]

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.[79] For example, a claim will be invalid as overly broad where it fails to include an essential element of the invention as disclosed in the specification.[80] 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.[81]

Over-claiming may render a claim invalid on the basis that the scope of the claims granted to

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[76] *Patent Rules*, SOR/96-423, s. 84.

[77] [1947] Ex. C.R. 306 (Can. Ex. Ct.) at 352

[78] Re Geron Corp. Patent Application No. 2,285,672 (2011), 93 C.P.R. (4th) 384 at para 52

[79] *Pfizer Canada Inc. v. Canada (Minister of Health)*, 2007 FCA 209 at para. 39.

[80] *Amfac Foods Inc. v. living Pulp & Paper Ltd.* (1986), 12 C.P.R. (3d) 193 (F.C.A.); *VISX Inc. v. Nidek* Co., [1999] F.C.J. No. 1971 at para. 145 (F.C.T.D.).

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

the inventor is broader than the invention made and disclosed in the patent. Valid claims must not be broader than either: 1) the new and useful invention as invented by the inventor; and 2) the invention as described in the specification of the patent.[82] Simply stated, "a patent claim must not exceed either the invention made or the invention disclosed."[83]

The Federal Court of Appeal in *Pfizer Canada Inc. v. Canada (Minister of Health)* recently confirmed: "It is now settled law that a patent which claims more than what was invented or disclosed can be found invalid for being overly broad."[84] The test is that "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."[85] The Federal Court of Appeal decision in *Amfac Foods Inc. v. Irving Pulp & Paper Ltd.* summarized the earlier case law.[86]

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.[87] 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 demonstrating that the invention would work as the patent promised, or if not, the utility could be soundly predicted. Thus, in a case where the patent contained claims to the use of a known compound for the effective treatment of ADHD, the Federal Court of Appeal upheld the lower court's determination that a single pilot study conducted with animals was insufficient to establish the utility promised and claimed by the patent as being an effective treatment in humans.[88]

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.[89] This is sometimes referred to as "covetous claiming".

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[82] *Leithiser et al. v. Pengo Hydra-Pull of Canada Ltd.*, [1974] 2 F.C. 954, 17 C.P.R. (2d) 110 at 118 (F.C.A.).

[83] *Farbwerke Hoechst A.G. Vormals Meister Lucius & Bruning v. Canada (Commissioner of Patents)* (1965), [1966] Ex. C.R. 91 (Can. Ex. Ct.), aff'd [1966] S.C.R. 604; *Pfizer Canada Inc. v. Canada (Minister of Health)*, 2007 FCA 209 at para. 115; *Eli Lilly Canada Inc. v. Apotex Inc.*, 2008 FC 142, 63 C.P.R. (4th) 406 at para. 180, aff'd 2009 FCA 97.

[84] *Pfizer Canada Inc. v. Canada (Minister of Health)*, 2007 FCA 209, 60 C.P.R. (4th) 81 at para. 115, leave to appeal to S.C.C. refused, [2007] S.C.C.A. No. 377.

[85] *Pfizer Canada Inc. v. Canada (Minister of Health)*, 2007 FCA 209, 60 C.P.R. (4th) 81 at para. 115, leave to appeal to S.C.C. refused, [2007] S.C.C.A. No. 377at para. 116.

[86] *Amfac Foods Inc. v. Irving Pulp & Paper Ltd.* (1986), 12 C.P.R. (3d) 193 (F.C.A.).

[87] *Pfizer Canada Inc. v. Canada (Minister of Health),* 2008 FC 11 at para. 46.

[88] *Novopharm Ltd. v. Eli Lilly and Co.* (2011), 94 C.P.R. (4th) 95 (FCA) at pp. 105-106, para 37-43, leave to appeal to SCC refused, 2011 CarswellNat 5075.

[89] *Unilever PLC v. Procter & Gamble Co.* (1995), 61 C.P.R. (3d) 499 (F.C.A.).

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.[90]

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 there really is only one invention involved.[91] The prohibition against double patenting relates to the "ever greening" problem described by the Supreme Court of Canada in *Whirlpool Corp. v. Camco Inc*., [92] that the issuance of another patent for the same invention would result in an improper extension of the patent monopoly; a patentee must not be allowed to prolong its monopoly beyond what the public has agreed to through successive obvious patents.[93] The *Patent Act* provides that an inventor is only entitled to one patent for each invention.[94]

There are two branches of double patenting: "same invention" (identical or coterminous claims) and "obviousness" double patenting (claims not patentably distinct).[95] For old patents, those 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.[96]

The prohibition on double patenting does not require identical language in the two patents'

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[90] *Radio Corp. of America v. Raytheon Manufacturing Co*. (1957), 27 C.P.R. 1 at 12 (Ex. Ct.), as cited in *Leithiser et al. v. Pengo Hydra-Pull of Canada Ltd.*, [1974] 2 F.C. 954, 17 C.P.R. (2d) 110 (F.C.A.) at 112.

[91] *Merck & Co. Inc. v. Apotex Inc.*, 2006 FC 524 at para. 207 (F.C.T.D.).

[92] *Whirlpool Corp. v. Camco Inc.,* 2000 SCC 67, [2000] S.C.J. No. 68.

[93] See also *Aventis Pharma Inc. v. Mayne Pharma (Canada) Inc.*, (2005), 42 C.P.R. (4th) 481 at para. 73 (F.C.T.D.).

[94] *Patent Act,* R.S.C. 1985, c. P-4, as amended, s. 36(1).

[95] *Whirlpool Corp. v. Camco Inc.*, 2000 SCC 67, [2000] S.C.J. No. 68 at note 4 at paras. 65-66.

[96] *Aventis Pharma Inc. v. Pharmascience Inc.*, (2005), 38 C.P.R. (4th) 441 at para. 85 (F.C.T.D.).

claims. The claims may claim the same invention regardless of the words used.[97] 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.[98] More recently, 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.[99] In that same decision, the Court noted that *Mayne* should not be regarded as authority for the proposition that "obviousness" double patenting excludes claims for a compound that has also been the subject of an earlier process-dependent patent.[100]

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.[101] Historically, double patenting was not limited to patents issued to the same inventors or patentees.[102] However, in a recent decision Justice Hughes held that double patenting "only applies when dealing with the same person getting two or more patents." [103]

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.[104] 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 *Patented Medicines (Notice of Compliance) Regulations*.[105] 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.[106]

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.[107] A selection patent that claims a compound that is patentably distinct from the prior genus patent will not be invalid for obviousness double patenting.[108]

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[97] *Apotex Inc. v. Sanofi-Synthelabo Canada Inc.*, 2008 SCC 61 at para. 109.

[98] *Commr. of Patents v. Farbwerke Hoechst A/G.,* [1964] S.C.R. 49 at para. 5; *Consolboard Inc. v. MacMillan Bloedel (Saskatchewan) Ltd.*, [1981] 1 S.C.R. 504 at 536.

[99] *Bayer Schering Pharma Aktiengesellschaft v. A.G. (Canada)*, 2010 FCA 275 at para. 49; 90 C.P.R. (4th) 313 at 325.

[100] *Aventis Pharma Inc. v. Mayne Pharma (Canada) Inc.* (2005), 42 C.P.R. (4th) 481 at paras. 72-76 (F.C.T.D.).

[101] *Whirlpool Corp. v. Camco Inc.,* 2000 SCC 67, [2000] S.C.J. No. 68 at para. 63.

[102] *Aventis Pharma Inc. v. Pharmascience Inc.* (2005), 38 C.P.R. (4th) 441 at para. 59 (F.C.T.D.).

[103] *Bristol-Myers Squibb Canada Co. et al v. Apotex Inc. et al*, 2009 FC 137 at para. 174.

[104] *Glaxo SmithKline Inc. v. Apotex Inc.* (2003), 27 C.P.R. (4th) 114 at paras. 85-91 (F.C.T.D.).

[105] *Glaxo SmithKline Inc. v. Apotex Inc.* (2003), 27 C.P.R. (4th) 114 at paras. 90-91 (F.C.T.D.).

[106] *Xerox of Canada Ltd. v. IBM Canada Ltd.* (1977), 33 C.P.R. (2d) 24 at 57 (F.C.T.D.)

[107] *Pfizer Canada Inc. v. Canada (Minister of Health)* (2008), 67 C.P.R. (4th) 23 at para. 77 (F.C.A.).

[108] *Apotex Inc. v. Sanofi-Synthelabo Canada Inc.,* 2008 SCC 61, 60 C.P.R. (4th) 251 at para. 113.

8.6. Sound Prediction

As previously stated, there is no requirement for a patentee to prove utility in the patent disclosure so long as the court finds utility to have been proven at the date of filing upon a legal challenge such as in a challenge to the patent's validity. Alternatively, if the inventor has not established the utility of the invention at the time of filing, he 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.[109]

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.[110]

(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; [111]

(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.'[112]

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.[113] 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

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[109] *Aventis Pharma Inc. v. Apotex Inc.*, 2006 FCA 64 at para. 24 (F.C.A.).

[110] *Apotex Inc. v. Wellcome Foundation Ltd.*, [2002] 4 S.C.R. 153 at para. 70.

[111] *Eli Lilly Canada Inc. v. Apotex Inc.* (2008), 63 C.P.R. (4th) 406 at para. 164 (F.C.), aff'd 2009 FCA 97 at para 15.

[112] *Eli Lilly Canada Inc. v. Apotex Inc.,* 2009 FCA 97 at para 18, leave to appeal to SCC refused [2009] S.C.C.A. No. 219.

[113] *Apotex Inc. v. Wellcome Foundation Ltd.,* [2002] 4 S.C.R. 153 at para. 76*; Goldfarb v. WI Gore & Associates Inc.*, 2001 FCT 45 at para. 114, referring to *Monsanto Co. v. Commissioner of Patents* (1979), 42 C.P.R. (2d) 161.

invention.[114]

> 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.[115]

The doctrine of sound prediction is applicable to patents claiming new uses for old compounds as well as patents claiming new compounds.[116] An inventor is not required to disclose test results in support of every claim in a patent to prove utility if the inventor had sufficient information and expertise that would enable him to soundly predict the utility of the claims. Conversely, where 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."[117] The Commissioner of Patents must reject a patent application if the inventor is unable to establish utility, either on the basis of actual results or sound prediction, at the relevant date.[118] 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.[119] While the prediction must be sound, it need not be certain.[120] "[T]esting is not an absolute requirement for a patent based on sound prediction."[121]

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.[122] 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.[123] As a legal commentator recently 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

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[114] *Apotex Inc. v. Wellcome Foundation Ltd.,* [2002] 4 S.C.R. 153 at para. 84.

[115] *Apotex Inc. v. Wellcome Foundation Ltd.*, [2002] 4 S.C.R. 153 at para. 66.

[116] *Pfizer Canada Inc. v. Apotex Inc.,* [2007] F.C. 26 at para 36 (F.C.T.D.) aff'd, 2007 FCA 195 at para 3.

[117] *Aventis Pharma Inc. v. Apotex Inc.,* 2006 FCA 64 at para. 25-26 (F.C.A.).

[118] *Apotex Inc. v. Wellcome Foundation Ltd.,* [2002] 4 S.C.R. 153 at para. 46; *Patent Act*, R.S.C. 1985, c. P-4, as amended, s. 40.

[119] *Aventis Pharma Inc. v. Apotex Inc.*, 2005 FC 1283 at paras. 92-93 (F.C.T.D.).

[120] *Aventis Pharma Inc. v. Apotex Inc.,* 2005 FC 1283 at para. 87 (F.C.T.D.).

[121] *Apotex Inc. v. Wellcome Foundation Ltd., supra* note 89 at paras. 70-72 (citations omitted).

[122] *Eli Lilly v. Apotex,* [2009] F.C.J. No. 404

[123] *Novopharm Ltd. v. Eli Lilly and Co.,* (2011), 94 C.P.R. (4th) 95 (FCA) at p. 107 para 47.

> 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.[124]

Recently, the Supreme Court of Canada was asked to consider the disclosure requirement for applications relying on sound prediction. However, as the issue was not relevant to the case at hand, the Court declined to address whether there is in fact a heightened disclosure requirement for patents relying upon sound prediction.[125]

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 the patent application and patent in good standing.[126] 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.[127] Where a deadline was missed by inadvertence, a letter requesting that a regular payment be accepted is not a "request" for reinstatement.[128] Annual maintenance fees are designed to "discourage the proliferation of deadwood patents and patent applications."[129] The fees may only come from persons authorized under subsection 6(1) of the *Patent Act* to correspond with CIPO.[130] 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.[131]

The patent maintenance fees are divided into standard fees, i.e., "large entity" fees, and lower "small entity" fees.[132] The small entity fees are half the amount of the large entity fees.[133] For example, a small entity must pay $50.00 each year until the sixth anniversary of the patent application filing date, while the large entity fee is $100.00 per year. This regime of different maintenance fees provides "modest monetary relief to inventors who are

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[124] Jonathan Stainsby, “Appeal Court Clarifies Utility Tests for Patents”, The Lawyers Weekly, 8 May 2009, pp. 9-10.

[125] Teva Canada Inc. v. Pfizer Canada Inc., 2012 SCC 60 at para. 43.

[126] *Patent Act*, R.S.C. 1985, c. P-4, s. 27.1(1), as amended S.C. 1993, c. 15; *Patent Rules*, SOR/96-423, ss. 99(1) or 154(1); *Patent Rules*, SOR/96-423, item 30, Schedule II.

[127] *Patent Act*, R.S.C. 1985, c. P-4, s. 73(1) (c), as amended S.C. 1993, c. 15.

[128] *Actelion Pharmaceuticals Ltd. v. Canada (Attorney General)* (2008), 64 C.P.R. (4th) 381 at para. 9.

[129] *Barton No-Till Disk Inc. v. Dutch Industries Ltd.*, [2003] F.C.J. No. 396, [2003] 4 F.C. 67 at para. 30 (F.C.A.), leave to appeal to S.C.C. refused, [2003] S.C.C.A. No. 204. See also *Actelion Pharmaceuticals Ltd. v. Canada (Attorney General)*, *ibid*. at para. 13.

[130] *Rendina v. Canada (Attorney General)* (2008), 60 C.P.R. (4th) 436 at para. 20 (F.C.).

[131] *Sarnoff Corp. v. Canada (Attorney General)* (2008), 66 C.P.R. (4th) 167 at para. 27 (F.C.).

[132] *Patent Rules*, SOR/2007-90, s. 3(7).

[133] *Patent Rules*, SOR/96-423, item 30, Schedule II.

presumed to be of limited means."[134]

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.[135]

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.[136]

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 fee and the large entity fee if the applicant/patentee had incorrectly paid the small entity fee in the past.[137] 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 addressed in the *Patent Act* or *Rules*.[138]

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 incorrectly paid the small entity fee and the Commissioner was not entitled to accept the corrective top-up payments made by Barton.[139] In response, Barton asserted that the Commissioner had the jurisdiction to accept the top-up payments.[140] Barton argued that

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[134] *Barton No-Till Disk Inc. v. Dutch Industries Ltd.,* [2003] F.C.J. No. 396, [2003] 4 F.C. 67 at para. 30 (F.C.A.), leave to appeal to S.C.C. dismissed [2003] S.C.C.A. No. 204.

[135] *Patent Rules*, SOR/2007-90, s. 3.01(3).

[136] *Patent Rules*, SOR/2007-90, s. 3.01(1).

[137] *Barton No-Till Disk Inc. v. Dutch Industries Ltd.*, [2003] F.C.J. No. 396, [2003] 4 F.C. 67 at para. 2 (F.C.A.), leave to appeal to S.C.C. dismissed [2003] S.C.C.A. No. 204; *Johnson & Johnson Inc. v. Boston Scientific Ltd.*, [2004] F.C.J. No. 2040, 2004 FC 1672 at para. 10 (F.C.T.D.), rev'd on other grounds [2006] F.C.J. No. 785 (F.C.A.).

[138] *Barton No-Till Disk Inc. v. Dutch Industries Ltd.*, [2003] F.C.J. No. 396, [2003] 4 F.C. 67 at para. 25 (F.C.A.), leave to appeal to S.C.C. dismissed [2003] S.C.C.A. No. 204.

[139] *Barton No-Till Disk Inc. v. Dutch Industries Ltd.*, [2003] F.C.J. No. 396, [2003] 4 F.C. 67 at paras. 12-20 (F.C.A.), leave to appeal to S.C.C. dismissed [2003] S.C.C.A. No. 204.

[140] *Barton No-Till Disk Inc. v. Dutch Industries Ltd.*, [2002] 1 F.C. 325, 14 C.P.R. (4th) 499 at para. 39 (F.C.T.D.), rev'd on other grounds [2003] F.C.J. No. 396 (F.C.A.), leave to appeal to S.C.C. dismissed [2003]

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.[141]

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.[142] The Federal Court of Appeal affirmed the Commissioner's lack of discretion to accept top-up payments.[143] However, Madam Justice Sharlow 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.[144] 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, but 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.[145]

The applicable date for determining the status of the entity is the actual filing date of the Canadian patent application and not a priority filing date based on an overseas filing.[146]

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.[147] 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.[148]

The Federal Court of Appeal has since interpreted the remedial effects of section 78.6(1)

S.C.C.A. No. 204.

[141] *Barton No-Till Disk Inc. v. Dutch Industries Ltd.,* [2003] F.C.J. No. 396, [2003] 4 F.C. 67 at para. 48 (F.C.A.), leave to appeal to S.C.C. dismissed [2003] S.C.C.A. No. 204.

[142] *Barton No-Till Disk Inc. v. Dutch Industries Ltd.*, [2002] 1 F.C. 325, 14 C.P.R. (4th) 499 at paras. 42-47 (F.C.T.D.), rev'd on other grounds [2003] F.C.J. No. 396 (F.C.A.), leave to appeal to S.C.C. dismissed [2003] S.C.C.A. No. 204.

[143] *Barton No-Till Disk Inc. v. Dutch Industries Ltd.*, [2003] F.C.J. No. 396, [2003] 4 F.C. 67 at para. 48 (F.C.A.), leave to appeal to S.C.C. dismissed [2003] S.C.C.A. No. 204.

[144] *Barton No-Till Disk Inc. v. Dutch Industries Ltd.,* [2003] F.C.J. No. 396, [2003] 4 F.C. 67 at para. 46 (F.C.A.), leave to appeal to S.C.C. dismissed [2003] S.C.C.A. No. 204.

[145] *Barton No-Till Disk Inc. v. Dutch Industries Ltd.,* [2003] F.C.J. No. 396, [2003] 4 F.C. 67 at paras. 46-48 (F.C.A.), leave to appeal to S.C.C. dismissed [2003] S.C.C.A. No. 204.

[146] *Johnson & Johnson Inc. v. Boston Scientific Ltd.*, 2004 FC 1672 at paras. 78, 83 (F.C.T.D.), reversed on other grounds [2006] F.C.J. No. 785.

[147] *Johnson & Johnson Inc. v. Boston Scientific Ltd.*, [2006] F.C.J. No. 785, 53 C.P.R. (4th) 182 at para. 6 (F.C.A.); "The Clock is Ticking: Coming into Force of Section 78.6 of the *Patent Act* (Bill C-29)", CIPO News Updates, February 1, 2006, available at http://strategis.ic.gc.ca/sc_mrksv/cipo/new/ciponews/news_feb06-e.html.

[148] *Patent Act*, 2005, c. 18, s. 78.6.

broadly by holding that it retroactively affirmed the validity of all top-up payments made in the past.[149] In particular, Sharlow J.A. held that the legislation must have a retroactive effect to achieve the desired result of alleviating the harshness of *Dutch Industries*.

Section 78.6(1) does not, however, apply where the patentee had simply stopped making maintenance fee payments as it "does not address ... patent applications that were abandoned for non-payment of fees."[150]

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 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. [151]

8.7.4. *Failure to Pay Maintenance Fees*

Two recent Federal Court decisions dealt 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. A.G. (Canada),*[152] 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 particular 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 <u>in limited cases of clerical errors in any instrument of record</u> to be corrected under the authority of the Commissioner taking into account <u>all</u> 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

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[149] *Johnson & Johnson Inc. v. Boston Scientific Ltd.,* [2006] F.C.J. No. 785, 53 C.P.R. (4th) 182 at para. 5 (F.C.A.).

[150] *Wicks v. Canada (Commissioner of Patents)*, 2007 CarswellNat 468, 2007 FC 222 at para. 33 (F.C.T.D.)

[151] *Barton No-Till Disk Inc. v. Dutch Industries Ltd.*, [2003] F.C.J. No. 396, [2003] 4 F.C. 67 at paras. 31-32 (F.C.A.), leave to appeal to S.C.C. dismissed [2003] S.C.C.A. No. 204.

[152] (2010), 90 C.P.R. (4th) 409 (FC)

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.[153]

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.[154] 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 recent decision, *Excelsior Medical Corp v. Attorney General (Canada)*, 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.[155] The Patent Office initially accepted the fees and sent a notice indicating the application had been reinstated. A few days later, the Patent Office sent a further letter seeking to retract its earlier letter and offered to refund the fees. Several months later the firm tendering the fees requested a refund and the fees were refunded. Two years later the same firm submitted an appointment of 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 representative.[156]

The difficulty in this case was that prior to the time expiring for reinstatement, the Patent Office gave notification it had accepted the maintenance fees. Only after the time had expired for reinstatement did the Patent Office notify the applicant that it would not accept the maintenance 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

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[153] (2010), 90 C.P.R. (4th) 409 (FC) at 426-27.

[154] *Repligen Corp. v. Canada (Attorney General)*, 2012 FC 931.

[155] (2011), 92 C.P.R. (4th) 220 (FC), aff'd 2011 FCA 303.

[156] (2011), 92 C.P.R. (4TH) 220 (FC) at p. 234-5, para 34, aff'd 2011 FCA 303.

the Court was unable to revive it under law or equity.[157]

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.[158]

8.8. Disclaimer

8.8.1. *Definition*

Disclaimer is a statutory mechanism by which a patentee may amend a patent to claim less than what was claimed in the original patent.[159] Paraphrasing subsection 48(1), 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.[160]

The patentee can disclaim all or part of a patent claim, or part of the patent specification, as long as the disclaimer does not extend the monopoly of the patent.[161]

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.[162] Disclaimers cannot widen the scope of an invention or change the character of the invention.[163]

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[157] (2011), 92 C.P.R. (4TH) 220 (FC) at p. 238-240, para 44 and 50, aff'd 2011 FCA 303. See also *Unicrop Ltd. v. Canada (Attorney General)* (2011), 91 C.P.R. (4th) 289 (FCA), 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).

[158] *Excelsior Medical Corp v. Attorney General (Canada),* 2011 FCA 303 at para. 5.

[159] *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 CarswellNat 36, 2007 FC 11 at para. 1 (F.C.T.D.), aff'd 2008 FCA 4.

[160] *Patent Act* R.S.C. 1985, c. P-4, as amended, s. 48(1).

[161] *Monsanto Co. v. Commr. of Patents,* [1975] F.C. 197 at para. 24 (F.C.T.D.), rev'd on other grounds, [1976] 2 F.C. 476 (F.C.A.).

[162] *AMP Inc. v. Hellerman Ltd.,* [1961] R.P.C. 160 at 178, [1962] R.P.C. 55 at 71.

[163] *Chain Bar Mill Co. Ltd.'s Application* (1941), 58 R.P.C. 200 at 205; *White's Patent*, [1958] R.P.C. 287.

The patent that remains after the disclaimer retains the prima facie presumption of validity that existed before the disclaimer.[164] The patentee can maintain an action based on the remaining patent claims.[165] If the disclaimer is entered during the course of litigation, only the validity of the patent in its disclaimed form is considered.[166]

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.[167] The mistake, accident or inadvertence — and the absence of the intent to defraud must occur when the patentee made the specification.[168] The onus of showing mistake, accident or inadvertence, and the lack of intent to defraud, is on the patentee if the disclaimer is challenged.[169] 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.[170] The validity of the disclaimer depends solely upon the state of mind of the patentee at the time he made his specification.[171] The Commissioner's acceptance of the disclaimer is not determinative of whether the disclaimed language was included by mistake, accident or inadvertence.[172] A disclaimer may be permissible even if it is made in response to the decision of a Court on a related patent.[173]

In a recent 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 a appellate standard of “palpable and overriding error”.[174]

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

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[164] *Patent Act*, R.S.C. 1985, c. P-4, s. 48(6); *Richards Packaging Inc. v. Canada (Attorney General)*, 2007 CarswellNat 36, 2007 FC 11 at para. 9 (F.C.T.D.), aff'd, (2008), 66 C.P.R. (4th) 1 (F.C.A.); *Cooper & Beatty v. Alpha Graphics Ltd.* (1980), 49 C.P.R. (2d) 145 at para. 58 (F.C.T.D.); *Canadian Celanese Ltd. v. B.V.D. Co.,* [1939] 1 All E.R. 410, 2 D.L.R. 289 at para. 12 (Canada P.C.).

[165] *Richards Packaging Inc. v. Canada (Attorney General),* 2007 CarswellNat 36, 2007 FC 11 (F.C.T.D.), aff'd, (2008), 66 C.P.R. (4th) 1 (F.C.A.).

[166] *Canadian Celanese Ltd. v. B.V.D. Co.*, *supra* note 155; *Cooper & Beatty v. Alpha Graphics Ltd.*, *supra* note 155 at paras. 52-55.

[167] *Patent Act,* R.S.C. 1985, c. P-4, as amended, s. 48(1).

[168] *Trubenizing Process Corp. v. John Forsyth Ltd.* (1941), 2 Fox Pat. C. 11, 1941 CarswellOnt 44 at para. 39 (Ont. S.C.), rev’d on other grounds, [1943] S.C.R. 422.

[169] *Trubenizing Process Corp. v. John Forsyth Ltd*. (1941), 2 Fox Pat. C. 11, 1941 CarswellOnt 44 at para. 46 (Ont. S.C.), rev'd on other grounds, [1943] S.C.R. 422.

[170] *Pfizer Canada Inc. v. Apotex Inc.* (2007), 61 C.P.R. (4th) 305 at para. 38 (F.C.), aff'd 2009 FCA 8.

[171] *Pfizer Canada Inc. v. Apotex Inc.* (2007), 61 C.P.R. (4th) 305 at para. 38 (F.C.), aff'd 2009 FCA 8..

[172] *ICN Pharmaceuticals, Inc. v. Canada (Patented Medicine Prices Review Board),* (1996) 68 C.P.R. (3d) 417 at para. 70 (F.C.A.).

[173] *Pfizer Canada Inc. v. Apotex Inc.* (2007), 61 C.P.R. (4th) 305 at paras. 39-43 (F.C.), aff'd 2009 FCA 8..

[174] *Hershkovitz v. Tyco Safety Products Canada Ltd.* (2010), 89 C.P.R. (4th) 101 (FCA) at 112-13, paras. 39-42.

the required fee requesting that parts of the patent be disclaimed.[175]

As long as the required formalities for filing a disclaimer are satisfied, the Patent Office does not have any discretion whether or not to reject a disclaimer.[176] The propriety or validity of a disclaimer can only be reviewed by the courts.[177] 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:[178] 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.[179]

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 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.[180] The court held that the patentee does not have free reign to avoid jurisdiction in an ongoing proceeding through disclaimers or by dedicating its patent to the public.[181]

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."[182] 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."[183] The same court had difficulty in construing the

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[175] *Patent Act,* R.S.C. 1985, c. P-4, as amended, s. 48(2)-(3).

[176] *Richards Packaging Inc. v. Canada (Attorney General)*, 2007 CarswellNat 36, 2007 FC 11 at paras. 10, 25-25, 28, 30-31 (F.C.T.D.), aff'd 2008 FCA 4.; *Monsanto Co. v. Canada (Commr. of Patents)*, [1976] 2 F.C. 476, 28 C.P.R. (2d) 118 at para. 3 (F.C.A.).

[177] *Richards Packaging Inc. v. Canada (Attorney General),* 2007 CarswellNat 36, 2007 FC 11 at paras. 10, 28 (F.C.T.D.), aff'd 2008 FCA 4.

[178] *[152] Richards Packaging Inc. v. Canada (Attorney General),* 2007 CarswellNat 36, 2007 FC 11 at paras. 21, 30-31 (F.C.T.D.), aff'd 2008 FCA 4.

[179] *Richards Packaging Inc. v. Canada (Attorney General),* 2007 CarswellNat 36, 2007 FC 11 at para. 28 (F.C.T.D.), aff'd 2008 FCA 4.

[180] *Richards Packaging Inc. v. Canada (Attorney General*), 2007 CarswellNat 36, 2007 FC 11 at paras. 71-73 (F.C.T.D.), aff'd 2008 FCA 4.

[181] *Richards Packaging inc. v. Canada (Attorney General),* 2007 CarswellNat 36, 2007 FC 11 at para. 72 (F.C.T.D.), aff'd 2008 FCA 4.

[182] *Patent Act, R.S.C. 1985, c. P-4, as amended, s. 48(1).*

[183] *Canadian Celanese Ltd. v. B.V.D. Co.,* [1939] 1 All E.R. 410, 2 D.L.R. 289.

clause "unless there is unreasonable neglect or delay" in subsection 48(4).[184]

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*.[185]

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.[186] 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 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.[187]

Being a creature of the common law, dedications are not circumscribed by statutory requirement or conditions, but the Court must ensure that the use of a dedication is not inconsistent with the *Patent Act*.[188] 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.[189] 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.

In a recent decision in a PM(NOC) proceeding, 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, as to do otherwise would allow the

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[184] *Canadian Celanese Ltd. v. B.V.D. Co.,* [1939] 1 All E.R. 410, 2 D.L.R. 289.

[185] *Parke-Davis Division v. Canada (Minister of Health)* (2002), 22 C.P.R. (4th) 417 at para. 81 (F.C.A.).

[186] *Merck & Co. v. Apotex Inc.*, (2006) 53 C.P.R. (4th) 1 at para. 164 (F.C.T.D.) rev'd on other grounds, 55 C.P.R. (4th) 81 (F.C.A.).

[187] Paraphrasing Justice O'Reilly in *Merck & Co., Inc. v. Minister of Health* (2010), 88 C.P.R. (4th) 81 (FC) at 86, paras.16-17.

[188] *Merck & Co., Inc. v. Minister of Health* (2010), 88 C.P.R. (4th) 81 (FC) at p. 87 para 19

[189] *Merck & Co. v. Apotex Inc., (2006) 53 C.P.R. (4th) 1 at para. 164 (F.C.T.D.), rev'd on other grounds, 55 C.P.R. (4th) 81 (F.C.A.).*

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.[190]

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 to enforce the remaining undedicated patent claims.[191] 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.[192] 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.[193] 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.[194]

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.[195]

8.9.3. *Revocability*

Dedication to the public is analogous to a gift; it is irrevocable unless the patentee can show that it lacked the requisite intent to do so when the patent was dedicated.[196] In *Parke-Davis Division 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

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[190] *Merck & Co., Inc. v. Canada (Minister of Health)* (2010), 88 C.P.R. (4th) 81 (FC) p. 89 at para 31.

[191] *G.D. Searle &* Co. v. *Merck & Co.* (2002), 20 C.P.R. (4th) 103 *at* paras. 85-86, 95-96 (F.C.T.D.).

[192] *G.D. Searle &* Co. v. *Merck &* Co. (2002), 20 C.P.R. (4th) 103 *at* para. 26 (F.C.T.D.).

[193] *G.D. Searle & Co. v. Merck & Co.* (2002), 20 C.P.R. (4th) 103 at paras. 54-60 (F.C.T.D.).

[194] *G.D. Searle &* Co. v. *Merck &* Co. (2002), 20 C.P.R. (4th) 103 at para. 85 (F.C.T.D.).

[195] *Merck &* Co. v. *Apotex Inc.,* (2006) 53 C.P.R. (4th) 1 at para. 166 (F.C.T.D.), rev'd on other grounds, 55 C.P.R. (4th) 81 (F.C.A.).

[196] *Parke-Davis Division v. Canada (Minister of Health)* (2002), 22 C.P.R. (4th) 417 *at* paras. 85-86

'768 patent).[197]

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.[198] 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.[199]

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.[200] 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.[201]

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.[202] 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 to the public after the proceeding had already commenced.[203] 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.[204] 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.[205]

8.10. Reissue of Patents

Section 47 allows, after the grant of a patent, a patentee to request that a patent be reissued by the Commissioner.[206] This remedy is available where the "patent is deemed defective or

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[197] *Parke-Davis Division v. Canada (Minister of Health)* (2002), 22 C.P.R. (4th) 417 at para. 11.

[198] *Parke-Davis Division v. Canada (Minister of Health)* (2002), 22 C.P.R. (4th) 417 at para. 22.

[199] *Parke-Davis Division v. Canada (Minister of Health)* (2002), 22 C.P.R. (4th) 417 at para. 89.

[200] *Parke-Davis Division v. Canada (Minister of Health)* (2002), 22 C.P.R. (4th) 417 at para. 103.

[201] *Parke-Davis Division v. Canada (Minister of Health)* (2002), 22 C.P.R. (4th) 417 at paras. 94-97.

[202] *Genentech Canada Inc., Re* (1992), 44 C.P.R. (3d) 316 (Can. Pat. Medicine Prices Rev. Bd.); *Novopharm Ltd. v. Merck & Co.* (1992), 44 C.P.R. (3d) 13 (Can. Pat. Commr.).

[203] *Genentech Canada Inc., Re* (1992), 44 C.P.R. (3d) 316 (Can. Pat. Medicine Prices Rev. Bd.) at para 35.

[204] *Genentech Canada Inc., Re* (1992), 44 C.P.R. (3d) 316 (Can. Pat. Medicine Prices Rev. Bd.) at para 39.

[205] *Novopharm Ltd. V. Merck & Co., Inc.* (1992), 44 C.P.R. (3rd) 13 at para 4 (Can. Pat. Commr.).

[206] *Patent Act,* R.S.C. 1985, c. P-4, as amended, s. 47.

inoperative by reason of insufficient description and specification, or by reason of the patentee's claiming more or less than he had a right to claim as new."[207] The patentee must persuade the Commissioner that the error arose through "inadvertence, accident or mistake, without any fraudulent or deceptive intention."[208] The "patentee" includes assignees of the patent.[209]

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.[210] 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.[211] The patentee must complete Form I of Schedule I to the Patent Rules to apply for a reissued patent.[212]

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."[213]

A patent cannot be reissued merely to broaden the scope of the claims in order to catch subsequent infringers.[214] 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 the patent to reissue.[215]

For a trial commenced after the patent has re-issued, the amended description and specification are treated as if they had been originally filed in their corrected form.[216] 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.[217]

In construing the term "identical", the Federal Court of Appeal has favourably reviewed American jurisprudence in part due to the similarities in the wording of the respective statutory sections dealing with the reissue of patents.[218] The term "identical" does not mean

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[207] *Patent Act,* R.S.C. 1985, c. P-4, as amended, s. 47(1).

[208] *Paul Moore Co. v. Canada (Patent Commissioner)* (1979), 35 N.R. 203 at para. 10 (F.C.A.).

[209] *Curl-Master Manufacturing Co. v. Atlas Brush Ltd.*, [1967] S.C.R. 514 at para. 43.

[210] *Patent Act,* R.S.C. 1985, c. P-4, as amended, s. 47(1).

[211] *Curl-Master Manufacturing Co. v. Atlas Brush Ltd.,* [1967] S.C.R. 514 at para. 46.

[212] *Patent Rules*, S.O.R./96-423, s. 43.

[213] *Northern Electric Co. v. Photo Sound Corp.*, [1936] S.C.R. 649 at para. 5.

[214] *Halbrite Well Services Co. Patent Application No. 616,196, Re* (1993), 3 C.P.R. (4th) 94 at para. 25 (Canada Patent Appeal Board & Patent Commissioner).

[215] *Halbrite Well Services Co. Patent Application No. 616,196, Re* (1993), 3 C.P.R. (4th) 94 at para. 19 (Canada Patent Appeal Board & Patents Commissioner); see also *Hydril Co. Patent Application No. 616,666, Re* (1997), 85 C.P.R. (3d) 503 (Patent Appeal Board & Patent Commissioner).

[216] *Patent Act,* R.S.C. 1985, c. P-4, as amended, s. 47(2).

[217] *Patent Act*, R.S.C. 1985, c. P-4, as amended.

[218] *Stamicarbon B.V. v. Urea Casale S.A.* (2002), 17 C.P.R. (4th) 377 at paras. 17-20 (F.C.A.).

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 construction of the claims.[219]

The reissued patent must describe and claim the same invention.[220] 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.[221] The question is whether the patentee is seeking to reissue the patent to reflect his or her original intention.[222] 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 not sufficient to warrant the reissue of a patent:[223]

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.[224] If the patentee properly understood the scope and effect of the patent there may be no error to correct with a reissued patent.[225] That is, the patent was never defective despite the patentee's subsequent desire to change it and have it reissued.[226]

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.[227] Only a valid patent may be reissued.[228]

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*.[229] This is so even if the cause of action was pending before the Court.[230]

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[219] *Stamicarbon B.V. v. Urea Casale S.A.* (2002), 17 C.P.R. (4th) 377 (F.C.A.) at para 22.

[220] *Northern Electric Co. v. Photo Sound Corp.*, [1936] S.C.R. 649 at para. 2.

[221] *Curl-Master Manufacturing Co. v. Atlas Brush Ltd.,* [1967] S.C.R. 514 at para. 21.

[222] *Curl-Master Manufacturing Co. v. Atlas Brush Ltd., [*1967] S.C.R. 514 at para. 32; *Farbwerke Hoechst AG v. Canada (Commissioner of Patents)*, [1966] S.C.R. 604 at para. 33; *Northern Electric Co. v. Photo Sound Corp.*, [1936] S.C.R. 649 at paras. 33-34

[223] *Farbwerke Hoechst Aktiengesellschaft Vormals Meister Lucius & Bruning v. Commissioner of Patents,* [1966] S.C.R. 604 at para. 39.

[224] *Mobil Oil Corp. v. Hercules Canada Inc.* (1995), 63 C.P.R. (3d) 473 at p. 480 (F.C.A.).

[225] *Northern Electric Co. v. Photo Sound Corp.,* [1936] S.C.R. 649 at para 2.

[226] *Curl-Master Manufacturing Co. v. Atlas Brush Ltd.,* [1967] S.C.R. 514 at para. 24.

[227] *Burton Parsons Chemicals Inc. v. Hewlett-Packard (Canada) Ltd.*, [1976] 1 S.C.R. 555 at para. 21

[228] *Farbwerke Hoechst Aktiengesellschaft Vormals Meister Lucius & Bruning v. Commissioner of Patents*, [1966] S.C.R. 604 (but see *Burton Parsons Chemicals Inc. v. Hewlett-Packard (Canada) Ltd.,* [1976] 1 S.C.R. 555 at para. 19; and *Curl-Master Manufacturing Co. v. Atlas Brush Ltd.,* [1967] S.C.R. 514 at para. 19).

[229] *Stamicarbon B.V. v. Urea Casale S.A.* (2002), 17 C.P.R. (4th) 377 at para. 32 (F.C.A.).

[230] *Stamicarbon B.V. v. Urea Casale S.A.* (2002), 17 C. P. R. (4th) 377 (F.C.A.). See also *Northern Electric Co. v. Photo Sound Corp*., [1936] S.C.R. 649 at para. 8.

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.[231] 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.[232]

A patentee may not be able to reissue claims that have been previously disclaimed.[233]

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 involves 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. Only the re-examination board and the patentee are parties at this stage. 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).[234]

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.[235]

If the requester qualifies as a small entity, the requisite fee is $1,000.00.[236] For a large entity,

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[231] *Stamicarbon B.V. v. Urea Casale S.A. (*2002), 17 C.P.R. (4th) 377 at para. 34 (F.C.A.).

[232] *Procter & Gamble Pharmaceuticals Canada Inc. v. Canada (Minister of Health)* (2003), 26 C.P.R. (4th) 180 at paras. 38-40 (F.C.).

[233] *Parke-Davis Division, Warner-Lambert Canada Inc. v. Canada (Minister of Health)* (2001), 14 C.P.R. (4th) 335 at para. 91 (F.C.).

[234] *Genencor International Inc. v. Canada (Commissioner of Patents)* (2007), 55 C.P.R. (4th) 378 at paras. 7-8 (F.C.A.).

[235] *Patent Act,* R.S.C. 1985, c. P-4, as amended, s. 48.1(1).

[236] *Patent Rules*, S.O.R./96-423, Sched. II, Pt. III, Item 14(a).

this fee is $2,000.00.[237]

The requester must set forth the "pertinency" of the prior art to the request[238] - 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).[239]

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.[240] 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.[241] 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.[242] 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.[243]

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.[244] 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*

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.[245]

Once re-examination has commenced, the patentee may propose any amendment to the

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[237] *Patent Rules*, S.O.R./96-423, Sched. II, Pt. III, Item 14(b).

[238] *Patent Act,* R.S.C. 1985, c. P-4, as amended, note 1, s. 48.1(2).

[239] *Patent Act,* R.S.C. 1985, c. P-4, as amended, s. 48.1(3).

[240] *Patent Act,* R.S.C. 1985, c. P-4, as amended, s. 48.2(1).

[241] *Patent Act,* R.S.C. 1985, c. P-4, as amended, s. 48.2(2).

[242] *Patent Act,* R.S.C. 1985, c. P-4, as amended, s. 48.2(3).

[243] *Patent Act,* R.S.C. 1985, c. P-4, as amended, s. 48.2(4).

[244] *Patent Act,* R.S.C. 1985, c. P-4, as amended, s. 48.2(5).

[245] *Patent Act,* R.S.C. 1985, c. P-4, as amended, s. 48.3(1).

patent or any new claims so long as the claims do not enlarge the scope of the patent.[246] 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. [247]

8.10.5. *Certificate of Board*

Once the re-examination board has reached its conclusion, it must issue a certificate:[248] 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.[249] 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).[250] 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.[251]

8.10.6. *Appeal*

Only the patentee may appeal a decision of the re-examination board.[252] 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.[253] However, a party may be granted leave to intervene if it can demonstrate that the facts warrant such an Order.[254] An appeal must be taken within three months from the date of the certificate.[255]

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[246] *Patent Act,* R.S.C. 1985, c. P-4, as amended, s. 48.3(2).

[247] *Patent Act,* R.S.C. 1985, c. P-4, as amended, s. 48.3(3).

[248] *Patent Act,* R.S.C. 1985, c. P-4, as amended, s. 48.4(1).

[249] *Patent Act,* R.S.C. 1985, c. P-4, as amended, s. 48.4(3) (a).

[250] *Patent Act,* R.S.C. 1985, c. P-4, as amended, s. 48.4(3) (b).

[251] *Patent Act,* R.S.C. 1985, c. P-4, as amended, s. 48.4(3) (c).

[252] *Patent Act,* R.S.C. 1985, c. P-4, as amended, 48.5(1).

[253] *Genencor International Inc. v. Commissioner of Patents*, 2006 FC 1021 (per Justice Pinard), aff'd 2007 FCA 129.

[254] *Genencor International Inc. v. Canada (Commissioner of Patents),* 2006 FC 1021 at para. 8.

[255] *Patent Act,* R.S.C. 1985, c. P-4, as amended, s. 48.5(2).

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.[256] For further reading, see Chapter 23.02 of the Manual of Patent Office Practice.[257]

[256] *Patent Rules*, S.O.R./96-423, s. 45.

[257] Available online at http://www.cipo.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/h_wr00720.html.