

**SUPREME COURT OF CANADA**

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| **Citation:** AstraZeneca Canada Inc. *v.* Apotex Inc., 2017 SCC 36, [2017] 1 S.C.R. 943 | **Appeal Heard:** November 8, 2016**Judgment Rendered:** June 30, 2017**Docket:** 36654 |

Between:

AstraZeneca Canada Inc., AstraZeneca Aktiebolag and AstraZeneca UK Limited

Appellants

and

Apotex Inc. and Apotex Pharmachem Inc.

Respondents

- and -

Innovative Medicines Canada, BIOTECanada, Centre for Intellectual Property Policy, Canadian Generic Pharmaceutical Association, Fédération internationale des conseils en propriété intellectuelle, Intellectual Property Owners Association and Intellectual Property Institute of Canada

Interveners

**Coram:** McLachlin C.J. and Abella, Moldaver, Karakatsanis, Wagner, Gascon, Côté, Brown and Rowe JJ.

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| **Reasons for Judgment:**(paras. 1 to 64) | Rowe J. (McLachlin C.J. and Abella, Moldaver, Karakatsanis, Wagner, Gascon, Côté and Brown JJ. concurring) |

Astrazeneca Canada Inc. *v.* Apotex Inc., 2017 SCC 36, [2017] 1 S.C.R. 943

AstraZeneca Canada Inc.,

AstraZeneca Aktiebolag and

AstraZeneca UK Limited Appellants

v.

Apotex Inc. and

Apotex Pharmachem Inc. Respondents

and

Innovative Medicines Canada, BIOTECanada,

Centre for Intellectual Property Policy,

Canadian Generic Pharmaceutical Association,

Fédération internationale des conseils en propriété intellectuelle,

Intellectual Property Owners Association and

Intellectual Property Institute of Canada Interveners

**Indexed as:** AstraZeneca Canada Inc. ***v.*** Apotex Inc.

2017 SCC 36

File No.: 36654.

2016: November 8; 2017: June 30.

Present: McLachlin C.J. and Abella, Moldaver, Karakatsanis, Wagner, Gascon, Côté, Brown and Rowe JJ.

on appeal from the federal court of appeal

 *Intellectual property — Patents — Medicines — Validity — Pharmaceutical patent invalidated for want of utility on basis of promise of patent doctrine — Whether doctrine is correct approach to determine whether invention has sufficient utility under s. 2 of Patent Act — Whether drug for which pharmaceutical patent was granted is “useful” within meaning of s. 2 of Patent Act at filing date — Patent Act, R.S.C. 1985, c. P‑4, s. 2 “invention”.*

 AstraZeneca applied for the 2,139,653 patent (“‘653 patent”) which claimed the optically pure salts of esomeprazole, a proton pump inhibitor used in the reduction of gastric acid and in the treatment of reflux esophagitis and related maladies. Apotex applied to the federal Minister of Health for a Notice of Compliance, allowing it to sell its generic version of the drug. AstraZeneca’s application to prohibit the Minister from issuing a Notice of Compliance to Apotex was dismissed, allowing Apotex to bring its generic drug to the market. AstraZeneca brought an action against Apotex for patent infringement, and Apotex counter‑claimed to have the ‘653 patent impeached. The Federal Court held that the ‘653 patent was invalid for lack of utility because, applying the promise of the patent doctrine (“Promise Doctrine”), it promised more than it could provide. The Federal Court of Appeal upheld this decision. AstraZeneca appeals, arguing its patent was improperly invalidated on the basis of the Promise Doctrine.

 Held: The appeal should be allowed.

 The Promise Doctrine is not the correct method of determining whether the utility requirement under s. 2 of the *Patent Act* is met. This doctrine holds that if a patentee’s patent application promises a specific utility, only if that promise is fulfilled, can the invention have the requisite utility, but where no specific utility is promised, a mere scintilla of utility will suffice. Generally, an analysis regarding issues of validity will focus on the claims alone, and only consider the disclosure where there is ambiguity in the claims.This is in accordance with the Court’s direction that claims construction precedes all considerations of validity. The Promise Doctrine, by contrast, directs courts to make determinations regarding utility by reading both the claims and the disclosure to identify potential promises, even in an absence of ambiguity in the claims. The Promise Doctrine then provides that if any one of the promises is not fulfilled, the utility requirement in s. 2 is not met and the patent, in its entirety, is invalid.

 The Promise Doctrine is incongruent with both the words and the scheme of the *Patent Act*. First, it conflates ss. 2 and 27(3), by requiring that to satisfy the utility requirement in s. 2, any use disclosed in accordance with s. 27(3) must be demonstrated or soundly predicted at the time of filing. If that is not done successfully, the entire patent is invalid, as the pre‑condition for patentability — an invention under the s. 2 of the Act — has not been fulfilled. Second, to require all multiple uses be met for the patent’s validity to be upheld, runs counter to the words of the Act and has the potential for unfair consequences. The Promise Doctrine risks, as was the case here, for an otherwise useful invention to be deprived of patent protection because not every promised use was sufficiently demonstrated or soundly predicted by the filing date. Such a consequence is antagonistic to the bargain on which patent law is based wherein we ask inventors to give fulsome disclosure in exchange for a limited monopoly.

 The words in s. 2 of the Act ground the type of utility that is pertinent by requiring that it is the subject‑matter of an invention or improvement thereof that must be useful. To determine whether a patent discloses an invention with sufficient utility under s. 2, courts must first identify the subject‑matter of the invention. Second, courts must then ask whether that subject‑matter is useful, that is, whether it is capable of a practical purpose. The Actdoes not prescribe the degree of usefulness required, or that every potential use be realized. Therefore, a single use related to the nature of the subject‑matter is sufficient, and that utility must be established by either demonstration or sound prediction as of the filing date. Even though utility of the subject‑matter is a requirement of patent validity, a patentee is not required to disclose the utility of the invention to fulfill the requirements of s. 2.

 In the present case, the subject-matter of the ‘653 patent that must be useful for the purposes of s. 2 is the optically pure salts of the enantiomer of omeprazole. It was soundly predicted by the relevant date that the drug for which the ‘653 patent was granted would be useful as a proton pump inhibitor to reduce production of gastric acid. Such use is appropriately related to the subject‑matter of the ‘653 patent and makes it useful within the meaning of s. 2. The ‘653 patent is therefore not invalid for want of utility.

**Cases Cited**

 **Applied:** *Consolboard Inc. v. MacMillan Bloedel (Sask.) Ltd.*, [1981] 1 S.C.R. 504; **referred to:** *Apotex Inc. v. Sanofi‑Synthelabo Canada Inc.*, 2008 SCC 61, [2008] 3 S.C.R. 265; *Eli Lilly and Co. v. Canada*, I.C.S.I.D. Case No. UNCT/14/2, March 16, 2017; *Apotex Inc. v. Wellcome Foundation Ltd.*, 2002 SCC 77, [2002] 4 S.C.R. 153; *Teva Canada Ltd. v. Pfizer Canada Inc.*, 2012 SCC 60, [2012] 3 S.C.R. 625; *Pfizer Canada Inc. v. Mylan Pharmaceuticals ULC*, 2011 FC 547, 394 F.T.R. 1; *Eli Lilly Canada Inc. v. Novopharm Ltd.*, 2010 FCA 197, [2012] 1 F.C.R. 349; *Free World Trust v. Électro Santé Inc.*, 2000 SCC 66, [2000] 2 S.C.R. 1024; *Whirlpool Corp. v. Camco Inc.*, 2000 SCC 67, [2000] 2 S.C.R. 1067; *Bristol‑Myers Squibb Co. v. Apotex Inc.*, 2005 FC 1348, 45 C.P.R. (4th) 423; *Laboratoires Servier v. Apotex Inc.*, 2009 FCA 222, 392 N.R. 96; *Sanofi‑Aventis Canada Inc. v. Apotex Inc.*, 2009 FC 676, 350 F.T.R. 165; *AstraZeneca Canada Inc. v. Mylan Pharmaceuticals ULC*, 2012 FCA 109, 432 N.R. 292; *Hatmaker v. Joseph Nathan & Co.* (1919), 36 R.P.C. 231; *Alsop’s Patent (Re)* (1907), 24 R.P.C. 733; *Bloxam v. Elsee* (1827), 6 B. & C. 169, 108 E.R. 415; *Pioneer Hi‑Bred Ltd. v. Canada (Commissioner of Patents)*, [1989] 1 S.C.R. 1623; *British United Shoe Machinery Co. v. A. Fussell & Sons Ltd.* (1908), 25 R.P.C. 631; *Re Application of Abitibi Co.* (1982), 62 C.P.R. (2d) 81.

**Statutes and Regulations Cited**

*Patent Act*, R.S.C. 1985, c. P‑4, ss. 2 “invention”, 27(1), (2), (3), (4), (5), 53, 58.

*Patented Medicines (Notice of Compliance) Regulations*, SOR/93‑133.

**Authors Cited**

Fox, Harold G. *The Canadian Law and Practice Relating to Letters Patent for Inventions*, 4th ed. Toronto: Carswell, 1969.

Siebrasse, Norman. “The False Doctrine of False Promise” (2013), 29 *C.I.P.R.* 3.

Vaver, David. *Intellectual Property Law: Copyright, Patents, Trade‑marks*, 2nd ed. Toronto: Irwin Law, 2011.

 APPEAL from a judgment of the Federal Court of Appeal (Dawson, Ryer and Webb JJ.A.), 2015 FCA 158, 474 N.R. 296, 138 C.P.R. (4th) 1, [2015] F.C.J. No. 802 (QL), 2015 CarswellNat 2431 (WL Can.), affirming a decision of Rennie J., 2014 FC 638, 457 F.T.R. 227, 129 C.P.R. (4th) 1, [2014] F.C.J. No. 671 (QL), 2014 CarswellNat 2268 (WL Can.). Appeal allowed.

 Gunars A. Gaikis, Yoon Kang and Y. Lynn Ing, for the appellants.

 Harry B. Radomski, Andrew R. Brodkin, Richard Naiberg and Sandon Shogilev, for the respondents.

 Patrick E. Kierans and Kristin Wall, for the interveners Innovative Medicines Canada and BIOTECanada.

 Jeremy de Beer and E. Richard Gold, for the intervener the Centre for Intellectual Property Policy.

 Jonathan Stainsby and Scott A. Beeser, for the intervener the Canadian Generic Pharmaceutical Association.

 Julie Desrosiers, Kang Lee and Alain M. Leclerc, for the intervener Fédération internationale des conseils en propriété intellectuelle.

 Andrew Bernstein and Yael S. Bienenstock, for the intervener the Intellectual Property Owners Association.

 Jason Markwell, for the intervener the Intellectual Property Institute of Canada.

 The judgment of the Court was delivered by

 Rowe J. —

1. Introduction
2. In the context of infringement/impeachment proceedings in the lower courts, this appeal involves a challenge to the validity of the appellants’ (“AstraZeneca”) 2,139,653 patent (“‘653 patent”) for want of utility.
3. The main issue in this appeal is whether AstraZeneca’s patent is invalid for want of utility under s. 2 of the *Patent Act*, R.S.C. 1985, c. P-4, on the basis of the “promise of the patent” doctrine (“Promise Doctrine”). Unquestionably, a patent is invalid if it lacks utility. However, for the reasons that follow, I conclude the application of the Promise Doctrine is not the correct approach to determine whether a patent has sufficient utility. Had the trial judge not applied this doctrine, he would have been compelled to find that the ‘653 patent had sufficient utility, and upheld its validity. Accordingly, I would set aside the decisions of the Federal Court and the Federal Court of Appeal which held that the ‘653 patent was invalid for want of utility.
4. Facts
5. In 1994, AstraZeneca applied for the ‘653 patent which claimed the optically pure salts of the (-) enantiomer of omeprazole, esomeprazole (“drug”). Esomeprazole is a proton pump inhibitor (“PPI”) used in the reduction of gastric acid and in the treatment of reflux esophagitis and related maladies. This means that it is a compound that acts by blocking acid producing pumps within cells to reduce the amount of acid in the stomach. Commercialized under the name NEXIUM, it has been a very successful drug for AstraZeneca.
6. The respondents (“Apotex”), seeking to sell a generic version of the drug, applied to the Minister of Health for a Notice of Compliance allowing it to do so. AstraZeneca, in response, brought an application for prohibition under the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133, to prohibit the Minister from issuing a Notice of Complianceto Apotex. On June 30, 2010, Justice Hughes dismissed the application for prohibition (2010 FC 714, 88 C.P.R. (4th) 28).
7. Apotex subsequently began to sell its generic version of the drug. AstraZeneca brought an action against Apotex for patent infringement, and Apotex counter-claimed to have the ‘653 patent impeached (i.e. declared invalid).
8. The Federal Court judge found that although the ‘653 patent was novel and non-obvious, it was invalid because it lacked utility. In so doing, he accepted that it was useful for certain purposes, but declared the patent invalid because, applying the Promise Doctrine, it “promised more than it could provide”. On appeal, AstraZeneca argued the Federal Court erred by relying on the Promise Doctrine to invalidate the patent. The Federal Court of Appeal dismissed the appeal. AstraZeneca then appealed to this Court arguing that the Promise Doctrine is unsound.
9. Judicial History
	1. Federal Court, 2014 FC 638, 129 C.P.R. (4th) 1 (Rennie J.)
10. Justice Rennie dismissed AstraZeneca’s action for infringement and granted Apotex’s counter-claim for a declaration of invalidity. He held that: “The ‘653 patent, though it was novel and non-obvious, is invalid because it lacks utility” (para. 367).
11. Justice Rennie’s utility analysis was premised on two propositions. First, “an alleged patent satisfies the requirement of utility if, from the perspective of the skilled person as of the filing date (May 27, 1994), its utility is *demonstrated*, or in the alternative, if its utility is *soundly predicted*” (para. 83 (emphasis in original)). Second, central to his utility analysis was the doctrine of the “promise of the patent”, which Rennie J. termed “the yardstick against which utility is measured” (para. 86).
12. Applying this doctrine, Justice Rennie ultimately identified two promises of utility in the ‘653 patent: (1) use as a PPI; and (2) improved pharmacokinetic and metabolic properties which would give an improved therapeutic profile such as a lower degree of interindividual variation. In other words, the drug would (1) reduce the amount of acid in the stomach; and (2) work more effectively for a wider range of persons, having less variation in patient response. The fulfilment of the first promise was not in dispute; it was soundly predicted that the drug did act as a PPI to reduce acid in the stomach. However, he found that the second promise was neither demonstrated nor soundly predicted at the filing date.
13. Applying the Promise Doctrine, he declared the entire patent to be invalid on the basis that the utility requirement for an “invention” under s. 2 of the *Patent Act* was not met, notwithstanding that on his findings the patent fulfilled one of the two promises of utility that he had identified.
14. Justice Rennie’s reasons also dealt with other requirements of validity. He applied the tests for anticipation and obviousness as set out by this Court in *Apotex Inc. v. Sanofi-Synthelabo Canada Inc.*,2008 SCC 61, [2008] 3 S.C.R. 265, and found that the ‘653 patent was both novel and not obvious. Neither novelty nor non-obviousness, however, is in issue before this Court. Rather, the only issue in this appeal relates to the utility requirement in the definition of an invention under s. 2 of the Act.
	1. Federal Court of Appeal, 2015 FCA 158, 138 C.P.R. (4th) 1 (Dawson, Ryer and Webb JJ.A.)
15. Dawson J.A., writing for the Federal Court of Appeal, dismissed AstraZeneca’s appeal. Essentially, she adopted Justice Rennie’s analysis, which affirmed both the status and application of the Promise Doctrine.
16. Dawson J.A. found that the Federal Court did not err in the following ways.
17. First, the Federal Court did not err in applying the Promise Doctrine by construing the promises across the patent. She wrote: “It is also now settled law that some promises can be construed to impose utility requirements across each of a patent’s claims, while other promises may touch only a subset of the claims” (para. 5).
18. Second, the Federal Court did not err in construing the utility of the claims. Dawson J.A. wrote: “The Court’s reasons show that the Federal Court directed itself to the correct legal tests applicable to claims construction, inventive concept and utility” (para. 11).
19. Third, the Federal Court did not err in its approach to construing a promise in the patent: “The Federal Court’s construction of the promise was reached reading the patent as a whole through the eyes of the skilled reader. . . . [T]he Federal Court did not err in law by applying too low a threshold in order to establish a promise” (para. 13).
20. Dawson J.A., thus, upheld the Federal Court’s decision based on the Promise Doctrine. She further stated “it is unnecessary to consider the assertions advanced by Apotex that the Federal Court erred in failing to find the patent to be both obvious and anticipated” (para. 15).
21. Positions of the Parties
22. AstraZeneca appeals to this Court arguing its patent was improperly invalidated on the basis of the Promise Doctrine. It argues the “law of patents is wholly statutory” (A.F., at para. 2), and that the Promise Doctrine is an extra-statutory requirement of utility with no basis in law. It maintains that the Promise Doctrine has no foundation in either the *Patent Act* or the patent jurisprudence of this Court.
23. Apotex bases its argument on the correctness of the Promise Doctrine and its application in this case. Apotex says that the law of utility under the *Patent Act* requires that a patentee’s invention do what the patent says it will do. The Promise Doctrine merely requires a patentee to be held to what is disclosed in the patent. Applying the Promise Doctrine, AstraZeneca’s patent specification contained one promise that was neither demonstrated nor soundly predicted at the time it was filed and, therefore, the ‘653 patent, in its entirety, was properly declared to be invalid.
24. This Court also heard from several interveners regarding the Promise Doctrine.
25. Five interveners argued against the Promise Doctrine. Fédération internationale des conseils en propriété intellectuelle highlighted that the Promise Doctrine puts Canada’s patent law out of step with international standards; the utility standard should reflect a low threshold that would be in accordance with Canada’s international obligations under NAFTA (North American Free Trade Agreement) and TRIPS (Trade-Related Aspects of Intellectual Property Rights) agreement.[[1]](#footnote-1) Innovative Medicines Canada and BIOTECanada likewise stressed that the Promise Doctrine was a departure from Canada’s international obligations. The Intellectual Property Owners Association argued that the Promise Doctrine encourages inventors to disclose less, which is inconsistent with the objectives of the *Patent Act*. The Intellectual Property Institute of Canada emphasised that the Promise Doctrine does not appear in the Act and its application leads to inconsistent results that could be avoided if utility were assessed having regard to the subject-matter of a claim.
26. Two interveners argued in support of the Promise Doctrine. The Canadian Generic Pharmaceutical Association argued that the Promise Doctrine is not a new trend, but simply requires a patent to do what it says it will do. As well, changes to patent law to harmonize Canadian law with that of other major jurisdictions should be left to Parliament. The Centre for Intellectual Property Policy said that it is the specification as a whole and not just the claims that are important to determine the utility of an invention as the uses disclosed to fulfill the requirements under s. 27(3) of the *Patent Act* are related to the utility requirement under s. 2 (further discussed below).
27. Issues
28. There are two issues. First, is the Promise Doctrine the correct approach for the requirement in s. 2 of the Actthat an “invention” be “useful”? Second, was the drug for which the ‘653 patent was granted “useful” within the meaning of s. 2 of the Actat the filing date?
29. I conclude that the Promise Doctrine is not the correct method of determining whether the utility requirement under s. 2 of the *Patent Act* is met. Given the correct approach, as set out below, the drug for which the ‘653 patent was granted is useful as a PPI; thus, it is an “invention” under s. 2 of the Act. The ‘653 patent is therefore not invalid for want of utility.
30. Relevant Legislation Provisions
31. The following statutory provisions of the *Patent Act* are relevant in this appeal:

**2** In this Act, except as otherwise provided,

. . .

***invention***means any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement in any art, process, machine, manufacture or composition of matter;

**Commissioner may grant patents**

27 (1) The Commissioner shall grant a patent for an invention to the inventor or the inventor’s legal representative if an application for the patent in Canada is filed in accordance with this Act and all other requirements for the issuance of a patent under this Act are met.

**Application requirements**

(2) The prescribed application fee must be paid and the application must be filed in accordance with the regulations by the inventor or the inventor’s legal representative and the application must contain a petition and a specification of the invention.

**Specification**

(3) The specification of an invention must

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

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

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

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

**Claims**

(4) 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.

**Alternative definition of subject-matter**

(5) For greater certainty, where a claim defines the subject-matter of an invention in the alternative, each alternative is a separate claim for the purposes of sections 2, 28.1 to 28.3 and 78.3.

**Void in certain cases, or valid only for parts**

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.

**Invalid claims not to affect valid claims**

**58** When, in any action or proceeding respecting a patent that contains two or more claims, one or more of those claims is or are held to be valid but another or others is or are held to be invalid or void, effect shall be given to the patent as if it contained only the valid claim or claims.

1. Analysis
	1. Issue #1: Is the Promise Doctrine the Correct Standard of Utility Under the Patent Act?
2. Section 2 of the *Patent Act* is the source of the utility requirement; it defines an invention as a “new and useful art, process, machine, manufacture or composition of matter” or a “new and useful improvement” thereof. The utility requirement is a necessary pre-condition to patentability (*Consolboard Inc. v. MacMillan Bloedel (Sask.) Ltd.*,[1981] 1 S.C.R. 504*,* at p. 527). “If it is not useful, it is not an invention within the meaning of the Act” (*Apotex Inc. v. Wellcome Foundation Ltd.*, 2002 SCC 77, [2002] 4 S.C.R. 153 (“*AZT*”), at para. 51). In order for a patent to be valid, the invention it purports to protect must be useful (*Teva Canada Ltd. v. Pfizer Canada Inc.*, 2012 SCC 60, [2012] 3 S.C.R. 625, at para. 37).
3. It is the utility requirement that is at the core of this appeal.
	* 1. The Promise Doctrine
4. Requiring that a patent have utility begs the question “useful for what?” (trial judgment, at para. 86). The Federal Courts have answered that question with the “promise of the patent” (*Pfizer Canada Inc. v. Mylan Pharmaceuticals ULC*, 2011 FC 547, 394 F.T.R. 1). The Promise Doctrine, as developed by the Federal Courts’ jurisprudence, holds that if a patentee’s patent application promises a specific utility, *only if* that promise is fulfilled, can the invention have the requisite utility — “the promise of the patent is the yardstick against which utility is measured” (trial judgment, at para. 86).
5. The Promise Doctrine has been articulated by the Federal Court of Appeal as follows:

 Where the specification does not promise a specific result, no particular level of utility is required; a “mere scintilla” of utility will suffice. However, where the specification sets out an explicit “promise”, utility will be measured against that promise: *Consolboard*; *Pfizer Canada Inc. v. Canada (Minister of Health)*, 2008 FCA 108, [2009] 1 F.C.R. 253 (*Ranbaxy*). The question is whether the invention does what the patent promises it will do. [Emphasis added.]

(*Eli Lilly Canada Inc. v. Novopharm Ltd.,* 2010 FCA 197, [2012] 1 F.C.R. 349, at para. 76)

1. Applying the promise of the patent doctrine, as the name suggests, involves identifying “promises” by considering the “patent as a whole”:

 The promise of the patent must be ascertained. Like claims construction, the promise of the patent is a question of law. Generally, it is an exercise that requires the assistance of expert evidence: *Bristol-Meyers Squibb Co. v. Apotex Inc*., 2007 FCA 379, at paragraph 27. This is because the promise should be properly defined, within the context of the patent as a whole, through the eyes of the POSITA [person of ordinary skill in the art], in relation to the science and information available at the time of filing.

(*Eli Lilly*, at para. 80)

1. That is, the Promise Doctrine requires the identification of promises based on a review of the entire specification, i.e.both the claims and the disclosure. Generally, an analysis regarding issues of validity, such as novelty or non-obviousness, focuses on the claims alone, and only considers the disclosure where there is ambiguity in the claims (*Sanofi-Synthelabo*).This is in accordance with this Court’s direction that claims construction precedes all considerations of validity: *Free World Trust v. Électro Santé Inc.*, 2000 SCC 66, [2000] 2 S.C.R. 1024, at paras. 33-50; *Whirlpool Corp. v. Camco Inc.*, 2000 SCC 67, [2000] 2 S.C.R. 1067, at paras. 42-43. The Promise Doctrine, by contrast, directs courts to read both the claims and the disclosure to identify potential promises, rather than the claims alone, even in an absence of ambiguity in the claims. After a process of identifying promises, the doctrine equates the fulfillment of these promises (by demonstration or sound prediction) with the requirement in s. 2 that an invention be useful. The doctrine then goes on to provide that if any one of the promises is not fulfilled, then the utility requirement in s. 2 is not met and the patent, in its entirety, is invalid.
2. In recent years, the Federal Courts have applied this doctrine to determine whether a patent has sufficient utility in several cases: see *Bristol-Myers Squibb Co. v. Apotex Inc.*, 2005 FC 1348, 45 C.P.R. (4th) 423; *Laboratoires Servier v. Apotex Inc.*, 2009 FCA 222, 392 N.R. 96; *Sanofi-Aventis Canada Inc. v. Apotex Inc.,* 2009 FC 676, 350 F.T.R. 165; *Eli Lilly*; *AstraZeneca Canada Inc. v.* *Mylan Pharmaceuticals ULC*, 2012 FCA 109, 432 N.R. 292.
3. While the Promise Doctrine, in its current formulation, has been said to be “uniquely Canadian”, it has its roots in English law (N. Siebrasse,“The False Doctrine of False Promise” (2013), 29 *C.I.P.R.* 3, at pp. 5-6).
4. The doctrine can be traced back to the early 20th century in the United Kingdom, specifically in *Hatmaker v. Joseph Nathan & Co.* (1919), 36 R.P.C. 231 (H.L.), and *Alsop’s Patent (Re)* (1907), 24 R.P.C. 733 (Ch.). The doctrine in England was referred to as the “False Promise Doctrine”. It was premised on the nature of patents at that time — a grant from the Crown as an exercise of the Royal prerogative. It was argued that where the Crown had been deceived in the grant, an objection could be made. As explained by Norman Siebrasse:

 . . . the false promise doctrine is based on the view that the grant of a patent is a discretionary decision and the consideration for the grant is the entirety of the representations made by the applicant in its petition to the Crown. Consequently, it is not for the courts to second-guess the Crown and presume to decide that the Crown would have granted the patent on the basis of some lesser consideration, simply because the court would have upheld the same patent on that lesser basis. [p. 17]

1. Thus, the origin and justification of the Promise Doctrine in English law was the “unwillingness of the courts to second-guess the Crown in the exercise of its discretion” (Siebrasse, at p. 17; *Bloxam v. Elsee* (1827), 6 B. & C. 169, 108 E.R. 415 (K.B.)). While the False Promise Doctrine is now extinct in the English law, it has found a new home in the Federal Courts’ jurisprudence as the “promise of the patent” doctrine.
2. This doctrine, however, is unsound. It is an interpretation of the utility requirement that is incongruent with both the words and the scheme of the *Patent Act*.
3. The Promise Doctrine is excessively onerous in two ways: (1) it determines the standard of utility that is required of a patent by reference to the promises expressed in the patent; and (2) where there are multiple expressed promises of utility, it requires that all be fulfilled for a patent to be valid.
	* + 1. Expressed Promises
4. First, the Promise Doctrine runs counter to the scheme of the Actby conflating ss. 2 and 27(3) — the very confusion this Court sought to clarify in *Consolboard*, as described below.
5. The Actsets out a scheme to ensure that an “inventor is granted exclusive rights in a new and useful invention for a limited period in exchange for disclosure of the invention so that society can benefit from this knowledge” (*Teva*, at para. 32). Thus, the patent regime has a dual purpose — to incentivise the creation of inventions and to encourage inventors to publicly disclose the knowledge regarding these inventions for society’s benefit.
6. The Actdefines whatmay receive the protection of a patent. For a creation to be an *invention* under the Act, s. 2 mandates that the art, process, machine, manufacture or composition of matter (i.e. the subject-matter) be useful. The subject-matter of an invention is defined by the claims, in accordance with s. 27(4). The claims set out the scope of the monopoly granted under the patent and allow others “to ascertain with some measure of exactness the boundaries of the exclusive privilege upon which they may not trespass during the exercise of the grant” (*Pioneer Hi-Bred Ltd. v. Canada (Commissioner of Patents)*,[1989] 1 S.C.R. 1623, at p. 1636, quoting H. G. Fox, *Canadian Patent Law and Practice* (4th ed. 1969), at p.163).
7. Once an inventor seeks to patent something that qualifies as an invention under s. 2, this invention must be properly disclosed in accordance with the Act.
8. Section 27(3) of the Actprovides that in the specification, a “patentee must describe 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’” (*Whirlpool*,atpara. 42, quoting *Consolboard*,at p. 517).
9. There is a difference between the requirement in s. 2 that an invention be “useful” and the requirement to disclose an invention’s “operation or use” as per s. 27(3). As explained by Dickson J. (as he then was) in *Consolboard*, the former is a “condition precedent to an invention” and the latter a “disclosure requirement, independent of the first”:

 . . . the Federal Court of Appeal erred also in holding that s. 36(1) [now s. 27(3) and (4)] requires distinct indication of the real utility of the invention in question. There is a helpful discussion in *Halsbury’s Laws of England* (3rd ed.), vol. 29, at p. 59, on the meaning of “not useful” in patent law. It means “that the invention will not work, either in the sense that it will not operate at all or, more broadly, that it will not do what the specification promises that it will do”. There is no suggestion here that the invention will not give the result promised. . . .

. . .

 . . . the Federal Court of Appeal has confused the requirement of s. 2 of the *Patent Act* defining an invention as new and “useful”, with the requirement of s. 36(1) [now s. 27(3)] of the *Patent Act* that the specification disclose the “use” to which the inventor conceived the invention could be put. The first is a condition precedent to an invention, and the second is a disclosure requirement, independent of the first. [Emphasis added.]

(*Consolboard*, at pp. 525 and 527)

While the above passage uses the word “promise”, it does not refer to, nor does it embody, the Promise Doctrine.

1. The Promise Doctrine effectively imports s. 27(3) into s. 2 inappropriately, by requiring that to satisfy the utility requirement in s. 2, any disclosed use (by virtue of s. 27(3)) be demonstrated or soundly predicted at the time of filing. If that is not done successfully, the entire patent is invalid, as the pre-condition for patentability — an invention under s. 2 of the Act — has not been fulfilled.
2. Supporters of the doctrine assert that the consequences of the Promise Doctrine play a key role in ensuring patentees do not “overpromise” in their patent applications. That is, a patentee will be dissuaded from stating the invention can be used for things that are not sufficiently established at the time of filing if doing so would risk invalidating the entire patent. The utility requirement should not be interpreted, however, as the Federal Courts have done, to address such concerns. Nonetheless, overpromising is a mischief.
3. The scheme of the Acttreats the mischief of overpromising in multiple ways. There are consequences for failing to properly disclose an invention by claiming, for instance, that you have invented more than you have. A disclosure which is not correct and full, or states an unsubstantiated use or operation of the invention, may be found to fail to fulfill the requirements of s. 27(3). An overly broad claim may be declared invalid; however, under the operation of s. 58 of the *Patent Act*, remaining valid claims can be given effect. As well, this mischief may result in a patent being void under s. 53 of the Act, where overpromising in a specification amounts to an omission or addition that is “wilfully made for the purpose of misleading”.
	* + 1. Multiple Uses
4. Second, the Promise Doctrine runs counter to the words of the Actby requiring that where multiple promised uses are expressed, they all must be satisfied for the patent to meet the utility requirement in s. 2.
5. Section 2 of the Actrequires a “useful” subject-matter; a single use makes a subject-matter useful.
6. The subject-matter of an invention can be multi-faceted, such that a single subject-matter can be described in many ways. As explained by David Vaver:

 For simplicity’s sake, the rule is “one invention, one application, one patent.” But inventions are like a many-faceted prism: multiple claims (sometimes running into the hundreds) covering all facets are allowed in the same patent if a “single general inventive concept” links them.

(D. Vaver, *Intellectual Property Law* (2nd ed. 2011), at p. 275)

Yet, ultimately, every invention pertains to a single subject-matter, and any single use of that subject-matter that is demonstrated or soundly predicted by the filing date is sufficient to make an invention useful for the purposes of s. 2.

1. To require all multiple uses be met for the patent’s validity to be upheld, has the potential for unfair consequences. The Promise Doctrine risks, as was the case here, for an otherwise useful invention to be deprived of patent protection because not every promised use was sufficiently demonstrated or soundly predicted by the filing date.
2. The effect of the Promise Doctrine to deprive such an invention of patent protection if even one “promised” use is not soundly predicted or demonstrated is punitive and has no basis in the Act. Furthermore, such a consequence is antagonistic to the bargain on which patent law is based wherein we ask inventors to give fulsome disclosure in exchange for a limited monopoly (*British United Shoe Machinery Co.* *v. A. Fussell & Sons Ltd.* (1908), 25 R.P.C. 631 (C.A.), at p. 650). To invalidate a patent solely on the basis of an unintentional overstatement of even a single use will discourage a patentee from disclosing fully, whereas such disclosure is to the advantage of the public. The Promise Doctrine in its operation is inconsistent with the purpose of s. 27(3) of the Actwhich calls on an inventor to “fully describe the invention and its operation or use”. Thus, the Promise Doctrine undermines a key part of the scheme of the Act; it is not good law.
	* 1. The Correct Approach to Utility
3. The words in s. 2 of the Act ground the type of utility that is pertinent by requiring that it is the *subject-matter* of an invention or improvement thereof that must be useful. For the subject-matter to function as an inventive solution to a practical problem, the invention must be capable of an actual relevant use and not be devoid of utility. As stated by Justice Binnie in *AZT*, a patent“is a method by which inventive solutions to practical problems are coaxed into the public domain by the promise of a limited monopoly for a limited time” (para. 37 (emphasis added)).
4. Utility will differ based on the subject-matter of the invention as identified by claims construction. Thus, the scope of potentially acceptable uses to meet the s. 2 requirement is limited — not *any* use will do. By requiring the usefulness of the proposed invention to be related to the nature of the subject-matter, a proposed invention cannot be saved by an entirely unrelated use. It is not sufficient for an inventor seeking a patent for a machine to assert it is useful as a paperweight.
5. To determine whether a patent discloses an invention with sufficient utility under s. 2, courts should undertake the following analysis. First, courts must identify the subject-matter of the invention as claimed in the patent. Second, courts must ask whether that subject-matter is useful — is it capable of a practical purpose (i.e. an actual result)?
6. The Actdoes not prescribe the degree or quantum of usefulness required, or that every potential use be realized — a scintilla of utility will do. A single use related to the nature of the subject-matter is sufficient, and the utility must be established by either demonstration or sound prediction as of the filing date (*AZT*, at para. 56).
7. The utility requirement serves a clear purpose. To avoid granting patents prematurely, and thereby limiting potentially useful research and development by others, the case law has imposed a requirement that an invention’s usefulness be demonstrated or soundly predicted at the time of application, rather than at some later point. This ensures patents are not granted where the use of the invention is speculative. What matters is that an invention “be useful, in the sense that it carries out some useful known objective”and is not merely a “laboratory curiosity whose only possible claim to utility is as a starting material for further research”(*Re Application of Abitibi Co.* (1982), 62 C.P.R. (2d) 81 (Patent Appeal Board and Commissioner of Patents), at p. 91).
8. The application of the utility requirement in s. 2, therefore, is to be interpreted in line with its purpose — to prevent the patenting of fanciful, speculative or inoperable inventions.
9. Even though utility of the subject-matter is a requirement of patent validity, a patentee is not required to disclose the utility of the invention to fulfill the requirements of s. 2. As was stated by Dickson J. in *Consolboard*:

 . . . I do not read the concluding words of s. 36(1) [now s. 27(4)] as obligating the inventor in his disclosure or claims to describe in what respect the invention is new or in what way it is useful. He must say what it is he claims to have invented. [p. 526]

See also *Teva*, atpara. 40.

* 1. Issue #2: Was the Drug for Which Patent ‘653 Was Granted “Useful” Within the Meaning of Section 2 of the Act?
1. The second issue in this appeal is whether AstraZeneca’s ‘653 patent is valid, or whether it is invalid for want of utility as found by Justice Rennie, applying the Promise Doctrine. As the Promise Doctrine is unsound, Justice Rennie’s analysis must be re-visited.
2. Justice Rennie identified the subject-matter of the ‘653 patent:

. . . the *subject matter* of the ‘653 patent was optically pure salts of the enantiomers of omeprazole, described as novel compounds, having improved pharmacokinetic and metabolic properties and high stability to racemization in neutral and basic pH, a method to make them, and therapeutic uses. [Emphasis in original; para. 93.]

1. The subject-matter of the patent that must be useful for the purposes of s. 2 is the “optically pure salts of the enantiomers of omeprazole”.
2. Justice Rennie accepted that it was soundly predicted by the relevant date that the optically pure salts of the enantiomer of omeprazole would be useful as a PPI to reduce production of gastric acid. Use as a PPI is appropriately related to the subject-matter of the ‘653 patent and makes it useful within the meaning of s. 2.
3. Justice Rennie found that the ‘653 patent failed for lack of utility because it promised more than it could provide. Yet, promises are not the yardstick against which utility is to be measured. Justice Rennie found that the subject-matter described by AstraZeneca’s patent was soundly predicted to be useful as a PPI. This is sufficient utility to satisfy the requirement in s. 2.
4. Relief
5. The appeal is allowed. The ‘653 patent is not invalid for want of utility. AstraZeneca will have its costs in this Court and the courts below.

 *Appeal allowed with costs throughout.*

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 Solicitors for the respondents: Goodmans, Toronto.

 Solicitors for the interveners Innovative Medicines Canada and BIOTECanada: Norton Rose Fulbright Canada, Toronto.

 Solicitor for the intervener the Centre for Intellectual Property Policy: McGill University, Montréal.

 Solicitors for the intervener the Canadian Generic Pharmaceutical Association: Aitken Klee, Toronto.

 Solicitors for the intervener Fédération internationale des conseils en propriété intellectuelle: Fasken Martineau, Montréal; Goudreau Gage Dubuc, Montréal.

 Solicitors for the intervener the Intellectual Property Owners Association: Torys, Toronto.

 Solicitors for the intervener the Intellectual Property Institute of Canada: Belmore Neidrauer, Toronto.

1. This argument was advanced prior to the final arbitration award in *Eli Lilly and Co. v. Canada* rendered by the International Centre for Settlement of Investment Disputes under NAFTA (I.C.S.I.D. Case No. UNCT/14/2, March 16, 2017). [↑](#footnote-ref-1)