



**SUPREME COURT OF CANADA**

**CITATION:** Teva Canada Ltd. v. Pfizer Canada Inc., 2012 SCC 60      **DATE:** 20121108  
**DOCKET:** 33951

**BETWEEN:**

**Teva Canada Limited**  
Appellant  
and  
**Pfizer Canada Inc., Pfizer Inc., Pfizer Ireland Pharmaceuticals,  
Pfizer Research and Development Company N.V./S.A. and  
Minister of Health**  
Respondents  
- and -  
**Canadian Generic Pharmaceutical Association and  
Canada's Research-Based Pharmaceutical Companies**  
Interveners

**CORAM:** McLachlin C.J. and LeBel, Deschamps, Abella, Rothstein, Cromwell and Moldaver JJ.

**REASONS FOR JUDGMENT:** LeBel J. (McLachlin C.J. and Deschamps, Abella, Rothstein, Cromwell and Moldaver JJ. concurring)  
(paras. 1 to 91)

**NOTE:** This document is subject to editorial revision before its reproduction in final form in the *Canada Supreme Court Reports*.

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TEVA CANADA LTD. v. PFIZER CANADA INC.

**Teva Canada Limited**

*Appellant*

v.

**Pfizer Canada Inc., Pfizer Inc., Pfizer Ireland Pharmaceuticals,  
Pfizer Research and Development Company N.V./S.A. and  
Minister of Health**

*Respondents*

and

**Canadian Generic Pharmaceutical Association and  
Canada's Research-Based Pharmaceutical Companies**

*Interveners*

**Indexed as: Teva Canada Ltd. v. Pfizer Canada Inc.**

**2012 SCC 60**

File No.: 33951.

2012: April 18; 2012: November 8.

Present: McLachlin C.J. and LeBel, Deschamps, Abella, Rothstein, Cromwell and  
Moldaver JJ.

ON APPEAL FROM THE FEDERAL COURT OF APPEAL

*Intellectual property — Patents — Disclosure requirements — Patent for use of compound to treat erectile dysfunction — Patent application containing cascading claims ending with two individual compounds — Claims not specifying active compound — Whether patent application meeting disclosure requirements of Patent Act — Whether patent based on sound prediction — Patent Act, R.S.C. 1985, c. P-4, s. 27(3).*

P holds Patent 2,163,446 for the use of a “compound of formula (I)” or a “salt thereof” as a medicament for the treatment of erectile dysfunction (“ED”). The patent’s specification ends with seven cascading claims for successively smaller ranges of compounds, with Claims 6 and 7 relating to a single compound each. Only sildenafil, the subject of Claim 7 and the active compound in Viagra, had been shown to be effective in treating ED at the time of the patent application. Although the patent includes the statement that “one of the especially preferred compounds induces penile erection in impotent males”, the patent application does not disclose that the compound that works is sildenafil, that it is found in Claim 7, or that the remaining compounds had not been found to be effective in treating ED.

T applied for a notice of compliance in order to produce a generic version of Viagra. The Federal Court prohibited the Minister from issuing the requested notice of compliance. The Federal Court of Appeal dismissed the appeal.

*Held:* The appeal should be allowed. Patent 2,163,446 is void.

The patent application did not satisfy the disclosure requirements set out in the *Patent Act*, R.S.C. 1985, c. P-4 (“Act”). The patent system is based on a “bargain”: the 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. Sufficiency of disclosure lies at the very heart of the patent system, so adequate disclosure in the specification is a precondition for the granting of a patent.

Although s. 58 of the Act allows courts to consider valid claims separately from those that are not valid, and although valid claims survive in the face of one or more invalid claims, s. 58 is engaged only *after* the validity analysis is carried out. It does not allow a court to consider the validity of a single claim independently of the rest of the specification, even if the claim in question is the only one that may be valid. The lower courts held that each claim in the patent is a separate invention. As a result, they considered the disclosure requirements with respect to each individual claim, not to the specification as a whole. This confused the principle that the claims define the scope of the exclusive right being sought with the principle that the content of the specification determines whether the disclosure requirements have been met. The Act requires that the court consider the specification as a whole, which includes the claims and the disclosure, from the perspective of a person skilled in the art to determine whether the patent meets the disclosure requirements. Only where the specification as a whole shows that each

claim in a patent application concerns a separate invention will the consideration of the disclosure requirements be limited to a single claim.

In this case, the disclosure in the specification would not have enabled the public “to make the same successful use of the invention as the inventor could at the time of his application” because it does not indicate that sildenafil is the effective compound. Considering the specification as a whole, the use of sildenafil and the other compounds for the treatment of ED comprise one inventive concept. Even though a skilled reader will know that, when a patent contains cascading claims, the useful claim will usually be at the end concerning an individual compound, the claims in the patent ended with two individually claimed compounds. There was no basis for a skilled person to determine which of Claim 6 and Claim 7 contained the useful compound, further testing would have been required to determine which of those two compounds was actually effective in treating ED.

Although s. 27 does not specify a remedy for insufficient disclosure, the *quid pro quo* underpinning the Act leads to the conclusion that deeming the patent invalid is the logical consequence of a failure to properly disclose the invention and how it works. If there is no *quid* — proper disclosure — then there can be no *quo* — exclusive monopoly rights. Even if s. 53 was not raised and its requirements were not met, this does not mean that the disclosure was adequate for the purposes of s. 27(3). These provisions can be independent of each other.

There is no question that sildenafil's utility had been demonstrated as of the time of filing of the patent application. This takes the invention out of the realm of sound prediction. As to the delay of 13 years between the filing of the patent and the challenge, the relevant question is whether the disclosure was sufficient as of the date of filing, so the delay is inconsequential.

### Cases Cited

**Disapproved in part:** *Merck & Co. v. Apotex Inc.*, 2006 FC 524, 53 C.P.R. (4th) 1, aff'd 2006 FCA 323, [2007] 3 F.C.R. 588; **distinguished:** *Eli Lilly Canada Inc. v. Apotex Inc.*, 2008 FC 142, 63 C.P.R. (4th) 406, aff'd 2009 FCA 97, 78 C.P.R. (4th) 388; **referred to:** *C. H. Boehringer Sohn v. Bell-Craig Ltd.*, [1962] Ex. C.R. 201, aff'd [1963] S.C.R. 410; *Pfizer Canada Inc. v. Canada (Minister of Health)*, 2008 FCA 108, [2009] 1 F.C.R. 253; *Consolboard Inc. v. MacMillan Bloedel (Sask.) Ltd.*, [1981] 1 S.C.R. 504; *Minerals Separation North American Corp. v. Noranda Mines, Ltd.*, [1947] Ex. C.R. 306; *Apotex Inc. v. Wellcome Foundation Ltd.*, 2002 SCC 77, [2002] 4 S.C.R. 153; *Tubes, Ld. v. Perfecta Seamless Steel Tube Company, Ld.* (1902), 20 R.P.C. 77; *Monsanto Canada Inc. v. Schmeiser*, 2004 SCC 34, [2004] 1 S.C.R. 902; *Whirlpool Corp. v. Camco Inc.*, 2000 SCC 67, [2000] 2 S.C.R. 1067; *Pioneer Hi-Bred Ltd. v. Canada (Commissioner of Patents)*, [1989] 1 S.C.R. 1623; *Hoechst Pharmaceuticals of Canada Ltd. v. Gilbert & Co.*, [1965] 1 Ex. C.R. 710, aff'd [1966] S.C.R. 189.

## Statutes and Regulations Cited

*Intellectual Property Law Improvement Act*, S.C. 1993, c. 15, s. 29(1).

*Patent Act*, R.S.C. 1985, c. P-4, ss. 2, “invention”, 27, 36, 53, 58.

## International Treaties

*Patent Cooperation Treaty*, Can. T.S. 1990 No. 22.

## Authors Cited

Hughes, Roger T., and Dino P. Clarizio. *Hughes & Woodley on Patents*, vol. 1, 2nd ed. Markham, Ont.: LexisNexis, 2005 (loose-leaf updated April 2012, release 30).

Perry, Stephen J., and T. Andrew Currier, with contributions by Damian Kraemer. *Canadian Patent Law*. Markham, Ont.: LexisNexis, 2012.

APPEAL from a judgment of the Federal Court of Appeal (Blais C.J. and Nadon and Trudel J.J.A.), 2010 FCA 242, [2012] 2 F.C.R. 69, 408 N.R. 166, 88 C.P.R. (4th) 405, [2010] F.C.J. No. 1200 (QL), 2010 CarswellNat 3445, affirming a decision of Kelen J., 2009 FC 638, 76 C.P.R. (4th) 83, 352 F.T.R. 35, [2009] F.C.J. No. 688 (QL), 2009 CarswellNat 1766. Appeal allowed.

*David W. Aitken, Marcus Klee and Ildiko Mehes, for the appellant.*

*Andrew Shaughnessy, Andrew Bernstein and Yael Bienenstock*, for the respondents Pfizer Canada Inc., Pfizer Inc., Pfizer Ireland Pharmaceuticals and Pfizer Research and Development Company N.V./S.A.

*Jonathan Stainsby and Andrew Skodyn*, for the intervener the Canadian Generic Pharmaceutical Association.

*Patrick S. Smith and Jane E. Clark*, for the intervener Canada's Research-Based Pharmaceutical Companies.

No one appeared for the respondent the Minister of Health.

The judgment of the Court was delivered by

LEBEL J. —

## I. Introduction

[1] This appeal involves a challenge to the validity of the patent of the Pfizer respondents ("Pfizer") for Viagra, a drug currently on the market for treating erectile dysfunction ("ED"). The appellant, Teva Canada Limited ("Teva"), claims that Pfizer's patent application did not meet the disclosure requirements set out in the

*Patent Act*, R.S.C. 1985, c. P-4 (the “Act”). Pfizer, on the other hand, submits that it complied fully with those requirements.

[2] The main issue in this appeal is whether Pfizer failed to properly disclose its invention when it obtained the patent for Viagra. For the reasons that follow, I conclude that Pfizer’s patent application did not satisfy the disclosure requirements provided for in s. 27(3) of the Act. I would accordingly allow the appeal.

## II. Facts

[3] In 1994, Pfizer applied for a patent for a range of compounds it claimed to be effective for the treatment of ED by oral administration. Pfizer received Patent 2,163,446 (“Patent ’446”) on July 7, 1998. This patent expires in 2014.

[4] The specification for Patent ’446 explains that the invention concerns the use of a “compound of formula (I)” or a “salt thereof” as a medicament for the treatment of ED. The specification ends with a number of claims. Claim 1 sets out formula (I), which produces 260 quintillion possible compounds. Claims 2 to 5 are for successively smaller ranges of compounds of formula (I), with Claim 5 being narrowed down to a range of nine compounds. Claims 6 and 7 relate to a single compound each. Claim 7 relates to sildenafil, the active compound in Viagra.

[5] At the time of Pfizer’s patent application, Pfizer had conducted tests that demonstrated that sildenafil was effective in treating ED. None of the other

compounds in Patent '446 had been shown to be effective in doing so. Although Patent '446 includes the statement that “one of the especially preferred compounds induces penile erection in impotent males” (A.R. vol. X, at p. 173), neither the disclosure — the descriptive portion of the patent application — nor the claims specify that sildenafil is the compound that works. Nowhere in the patent application is it disclosed that the compound that works is found in Claim 7 or that the remaining compounds in the patent had not been found to be effective in treating ED.

[6] Novopharm Limited, now Teva Pharmaceutical Industries, applied for a notice of compliance in order to produce a generic version of Viagra, alleging that Pfizer’s patent was invalid for obviousness, lack of utility and insufficient disclosure. A Federal Court judge found that the invention was not obvious, that it was useful and that the patent did not fail to adequately disclose it. He prohibited the Minister from issuing the requested notice of compliance (2009 FC 638, 76 C.P.R. (4th) 83). On appeal, Teva dropped its argument regarding obviousness. The Federal Court of Appeal dismissed the appeal (2010 FCA 242, [2012] 2 F.C.R. 69). Teva now appeals to this Court.

### III. Judicial History

#### A. *Federal Court (Kelen J.)*

[7] Kelen J. began his analysis by reviewing the jurisprudence on the construction of patents. In his view, the jurisprudence establishes that if a patent contains many claims, the court will consider the claim that is relevant to the issues.

He considered it important for the disposition of the case that the Exchequer Court of Canada had found in *C. H. Boehringer Sohn v. Bell-Craig Ltd.*, [1962] Ex. C.R. 201 (“*Boehringer*”), aff’d [1963] S.C.R. 410, that an individually claimed substance is a separate invention. Because sildenafil is specifically claimed and described in Claim 7 of Patent ’446, Kelen J. concluded that it should be considered separately.

[8] Kelen J. found that the use of sildenafil as a treatment for ED was not obvious. He dismissed Novopharm’s argument on this issue and also held that, as required, the utility of sildenafil had been demonstrated by the Canadian filing date.

[9] As to Novopharm’s argument that the disclosure contained inoperative compounds, Kelen J. noted that under s. 58 of the Act, invalid claims do not affect valid claims. Therefore, the invalidity of Claims 1 to 6 — because they contain inoperative compounds — did not affect the validity of Claim 7, nor did it alter Kelen J.’s conclusion regarding the utility of sildenafil for treating ED.

[10] The final question — and the one most relevant to the appeal — was whether the disclosure in Patent ’446 was adequate and met the requirements of s. 27(3) of the Act. Kelen J. endorsed the view that sufficiency of disclosure lies at the heart of the entire patent system. At para. 105 of his reasons, he quoted Nadon J.A. in *Pfizer Canada Inc. v. Canada (Minister of Health)*, 2008 FCA 108, [2009] 1 F.C.R. 253, who had written that a patent applicant had to “disclose everything that is essential for the invention to function properly”: the applicant must both “describe the invention and define the way it is produced or built”. However, he

also pointed out that Nadon J.A., who was relying on *Consolboard Inc. v. MacMillan Bloedel (Sask.) Ltd.*, [1981] 1 S.C.R. 504 (“*Consolboard*”), had held that the patent need answer only two questions to meet the sufficiency requirement for the purposes of s. 27(3): “What is the invention?” and “How does it work?” Kelen J. noted that Nadon J.A. had stated at para. 59 of his reasons that “[i]f the patent specification (disclosure and claims) answers these questions, the inventor has held his part of the bargain” (para. 103).

[11] The trial judge considered Viagra to be a meritorious invention. Relying on *Hughes & Woodley on Patents* (2nd ed. (loose-leaf), vol. 1, at p. 333 (now p. 347)), he concluded that, “while an allegation of insufficiency normally does not operate to defeat a patent for a meritorious invention, an insufficiency attack will succeed where a person skilled in the art could not put the invention into practice” (para. 106). He went on to observe that the language in the patent “cannot obfuscate, obscure or bewilder the skilled reader of the patent”, and must be “free from avoidable obscurity or ambiguity and be as simple and distinct as the difficulty of the description permits” (para. 107; see also *Noranda Mines v. Minerals Separation North America Corp.*, [1947] Ex. C.R. 306, at p. 102). He continued:

The description must not be misleading or calculated to deceive or render it difficult for the skilled reader, without trial and experimentation, to comprehend what the invention is. The description must give all the information necessary for the successful use of the invention without leaving such result to the chance of successful experiment. The inventor must provide all of the information in good faith. [para. 107]

[12] Kelen J. stated that a specification must be construed through the eyes of a person skilled in the art with a view to determining whether it is sufficient to enable such a person to understand and make the invention as of the date the patent was laid open to the public. Each claim must be considered separately in relation to the disclosure.

[13] Turning to the facts of the case before him, Kelen J. found that Patent '446 did not disclose that sildenafil (Claim 7) was the only claimed compound that Pfizer had found in the patient studies to induce penile erection in impotent males. Nor did it disclose that sildenafil was the only active compound in the invention sold commercially under the trade name Viagra. He characterized the other six claims as “red herrings”, since they concerned compounds that had been found not to work for treating ED (para. 118). However, Kelen J. observed that Patent '446 did claim the use of sildenafil in Claim 7.

[14] According to Kelen J., the evidence from the experts of both Novopharm and Pfizer indicated that a person reading the disclosure would not know that sildenafil was the tested compound, nor would the person know how the “especially preferred” compounds were selected or how to choose between the extremely large number of compounds in Claim 1. In light of the expert evidence, Kelen J. noted that one of the experts was concerned that the “concealment of the identity of the compound tested is nothing short of astounding”, and that such an action prevents effective peer review and is poorly viewed in the scientific community” (para. 126).

[15] In construing the specification, Kelen J. mentioned that Novopharm had submitted that Patent '446 did not sufficiently describe the invention because a skilled reader would not be able to determine which of the compounds embodied the invention. However, he also observed that each of the claims represented a separate monopoly and that each claim had to be viewed separately in relation to the disclosure. He acknowledged that he was unaware of any authority in which a court had considered the issue of sufficiency with respect to a patent that contained many claims but did not disclose the claim that actually described the invention found to be the commercial product.

[16] But, in Kelen J.'s view, the timing of the objection to Patent '446 was a relevant consideration. He made the following observation, at para. 133:

The importance and value of this patent should not be invalidated by such an objection 13 years after the patent was laid open for public inspection because it was allegedly not clear to the notional skilled reader that sildenafil was the active compound which made the invention work. The credibility of this allegation is undermined since it has only been raised in 2007, 13 years after the patent was laid open for public inspection.

[17] In *obiter*, however, he expressed discomfort with the existing jurisprudence, which condones a patent description by way of cascading claims for groups of compounds that requires the skilled reader to undertake a minor research project in order to determine which of the claims describes the true invention. He felt that a disclosure such as this “plays games with the reader”:

Why did the disclosure not simply state that [the] compound in Claim 7 was sildenafil? The patent plays “hide and seek” with the reader. The reader is expected to look for the “needle in the haystack”, or “the tree in the forest”. Remember, Claim 1 is for a range of compounds which includes 260 quintillion compounds. [para. 135]

[18] Having raised these concerns, he went on to say that there was “comfort” in the fact that the disclosure stated that “one of the especially preferred compounds induces penile erection in impotent males” and then specified nine “especially preferred” compounds, only two of which were individually claimed — those in Claims 6 and 7. He was also comforted by the testimony of one of the expert witnesses to the effect that a skilled reader would know that the compound which worked must be one of those two compounds, and would test only them.

[19] Kelen J. held that Pfizer had established the validity of Patent '446, since it had shown on a balance of probabilities that the allegations of invalidity for obviousness, lack of utility and insufficiency of disclosure were unjustified. He prohibited the Minister of Health from issuing a notice of compliance to Novopharm until after the patent expired. However, he indicated that he would “welcome judicial correction on appeal” if he was wrong in reading or following the case law that indicated that Claim 7 was a separate monopoly (para. 148).

B. *Federal Court of Appeal (Blais C.J., and Nadon and Trudel J.J.A.)*

[20] Nadon J.A., writing for the Federal Court of Appeal, began its analysis by addressing the issue of the relevant invention. He found that Kelen J. had not erred in finding that the invention was contained in Claim 7 and that the disclosure requirements related to that claim.

[21] Nadon J.A. considered *Boehringer*, which had been followed, albeit reluctantly, in *Merck & Co. v. Apotex Inc.*, 2006 FC 524, 53 C.P.R. (4th) 1 (“*Apotex ACE*”), aff’d 2006 FCA 323, [2007] 3 F.C.R. 588. On the basis of *Apotex ACE*, he affirmed the applications judge’s conclusion that Claim 7 was correctly seen as describing a single compound — sildenafil — from the class of compounds of formula (I) for the treatment of ED. Utility and disclosure had to be determined on that basis.

[22] Nadon J.A. then turned to the other issues before him. Novopharm was arguing that the invention had not been disclosed sufficiently in the specification: the patent claimed 260 quintillion compounds, and although attention was drawn to two of the compounds, further testing would be required in order to determine which of these two compounds was the invention. Nadon J.A. held that a clear description is not necessarily the same as sufficient disclosure, but that these two requirements were identical in this case: Claim 7 described the invention, and as it clearly stated the formula for sildenafil, it met both requirements. The judge was required to find, not that Patent ’446 as a whole was clear, but that it clearly revealed the invention

disclosed by Claim 7. Nadon J.A. found that Kelen J. had not erred in finding that it did so.

[23] Nadon J.A. also considered whether there was sufficient disclosure of the invention contained in Claim 7. He concluded that the judge was correct in finding that the disclosure was sufficient. He reiterated that the invention was the compound disclosed in Claim 7, not the patent as a whole. He agreed with Kelen J. that, even if Patent '446 was taken as a whole, a skilled reader would be able to narrow the range of compounds down to the two “especially preferred compounds” listed separately in Claims 6 and 7. A skilled reader would then conduct tests on those two compounds and determine which of them worked. Claim 7 disclosed the effective compound and described it sufficiently and clearly. According to Nadon J.A., the judge had turned his mind to the relevant expert evidence and had reached a conclusion open to him on that evidence.

[24] As to Kelen J.’s comments about the time that had elapsed before the patent was challenged, Nadon J.A. noted that the relevant question was whether the disclosure was sufficient as of the date of filing — “anything which occurred subsequent thereto is of no relevance” (para. 79). The comments on timing were made after the finding of sufficiency and, although “misguided”, did not form the basis of a reviewable error (para. 79).

[25] Nadon J.A. then turned to the second question raised by Teva: whether Pfizer was required to demonstrate utility in the patent disclosure. Nadon J.A. agreed

that there is no requirement that the utility of a patent be demonstrated in the patent disclosure so long as the trier of fact can find that its utility has been proven when the patent is challenged. He stated that an inventor must describe the invention so that it can be produced, but is not obliged to describe its effect, advantage or usefulness. In so holding, Nadon J.A. noted that this Court's most recent decision on utility did not mention a requirement to prove utility in the disclosure: *Apotex Inc. v. Wellcome Foundation Ltd.*, 2002 SCC 77, [2002] 4 S.C.R. 153 ("AZT").

[26] The final question was whether a study conducted by Pfizer known as Study 350 actually disclosed sildenafil's utility. Nadon J.A. noted that Kelen J. had found that this study revealed a "significant improvement" in treating ED. He had also correctly stated that the test for utility was whether the invention did what was promised. Nadon J.A. held that the level of proof need not reach the level required for regulatory approval. He therefore dismissed the appeal.

#### IV. Analysis

##### A. *Issues*

[27] The main issue in this appeal is whether Patent '446 meets the disclosure requirements of the Act. In addition, Teva argues that Claim 7 is invalid for insufficient disclosure of sound prediction. It claims on the basis of the information provided in the patent that the promise of sildenafil's utility was not demonstrated but predicted.

[28] For the reasons that follow, I conclude that Patent '446 does not meet the disclosure requirements set out in the Act. This is not a case about sound prediction, so Teva's arguments in that regard must fail. I would therefore allow the appeal on the basis of insufficient disclosure.

B. *Positions of the Parties*

[29] Teva's position is that the patent is invalid for concealment and avoidable obscurity. In its view, the patent's cryptic description of sildenafil as "one of the especially preferred compounds" is undeniably obscure. Teva also submits that Claim 7 is invalid for insufficient disclosure of sound prediction. On the basis of the information provided in Patent '446, it says, the promise of sildenafil's utility was not demonstrated but predicted. Teva's third argument is that, because Patent '446 does not disclose that sildenafil was the one compound found in Study 350 to have utility in treating ED, it fails to correctly and fully describe the invention as required by s. 27(3) of the Act. Teva further submits that the appeal court erred in limiting the inquiry into the sufficiency of the disclosure to the questions from *Consolboard*: "What is your invention?" and "How does it work?" Finally, Teva contends that the Court of Appeal erred in confining its analysis of the sufficiency of the disclosure to Claim 7.

[30] Pfizer responds, first, that there is no avoidable obscurity in Patent '446, since courts will only invalidate for avoidable obscurity if the claim is too ambiguous for a skilled person to know what the invention is or if the description does not enable

the skilled person to perform the invention across the entire breadth of the claim at issue. It says that neither of these conditions applies in the case at bar. Second, it argues that this is not a case about sound prediction. It submits that there was no need to predict the utility of sildenafil since its utility had been demonstrated. Third, Pfizer says that the disclosure was sufficient because the requirements of s. 27(3) were met. It contends that what must be disclosed is the invention and that, since the invention in this case is sildenafil, the disclosure must be assessed only in relation to that claimed invention. According to Pfizer, even if a skilled person were to consider Patent '446 as a whole, he or she would understand the invention to be a class of compounds useful to treat ED, where nine specific compounds (including sildenafil) are especially preferred and two specific compounds (including sildenafil) are individually claimed. Therefore, it argues, there is no “leaf in the forest” — the skilled person would be able to narrow the range of listed compounds down to the two “especially preferred compounds” listed separately in Claim 6 and Claim 7.

C. *The Patent Bargain*

[31] The issues in this appeal are best understood by reference to the fundamental principles underlying the patent system. As the courts below noted, sufficiency of disclosure lies at the very heart of this system. If the issues are viewed through this lens, the case becomes more straightforward, and the conclusion flows easily from this principle.

[32] The patent system is based on a “bargain”, or *quid pro quo*: the 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. This is the basic policy rationale underlying the Act. The patent bargain encourages innovation and advances science and technology. Binnie J. explained the *quid pro quo* as follows in *AZT*, at para. 37:

A patent, as has been said many times, is not intended as an accolade or civic award for ingenuity. It 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. Disclosure is the *quid pro quo* for valuable proprietary rights to exclusivity which are entirely the statutory creature of the *Patent Act*.

[33] The role of the patent specification in the *quid pro quo* was described as follows by Lord Halsbury in *Tubes, Ld. v. Perfecta Seamless Steel Tube Company, Ld.* (1902), 20 R.P.C. 77, at pp. 95-96:

. . . if one has to look at first principles and see what the meaning of a Specification is . . . why is a Specification necessary? It is a bargain between the State and the inventor: the State says, “If you will tell what your invention is and if you will publish that invention in such a form and in such a way as to enable the public to get the benefit of it, you shall have a monopoly of that invention for a period of fourteen years.” That is the bargain. The meaning which I think, in my view of the patent law, has always been placed on the object and purpose of a specification, is that it is to enable, not anybody, but a reasonably well informed artisan dealing with a subject-matter with which he is familiar, to make the thing, so as to make it available for the public at the end of the protected period. [Emphasis added.]

Lord Halsbury's view was cited with approval by Dickson J. (as he then was) in *Consolboard*, at p. 523.

[34] Therefore, adequate disclosure in the specification is a precondition for the granting of a patent. As Hughes J. stated in *Eli Lilly Canada Inc. v. Apotex Inc.*, 2008 FC 142, 63 C.P.R. (4th) 406, at para. 74:

Thus, one must both advance the state of the art and disclose that advance in order to gain the patent monopoly. Failing to do so, thus invalidating the monopoly, can be in the form of one or more of several matters such as, the "invention" was not new, or the so-called invention was "obvious" or the disclosure was "insufficient" or "what you disclosed doesn't support the monopoly that you claim".

[35] The issues in this case must be considered in light of the *quid pro quo*: Is the public getting what it ought to be getting in exchange for exclusive monopoly rights?

#### D. *Sound Prediction*

[36] Before turning to the main issue in this appeal, I wish to address Teva's argument that Claim 7 is invalid for insufficient disclosure of sound prediction. As I stated at the outset, I am of the view that this is not a case about sound prediction and that Teva's argument on this point must fail.

[37] For a patent to be valid, the invention it purports to protect must be useful. This requirement of utility comes from the definition of “invention” in s. 2 of the Act, which requires that the purported invention be “new and useful”. Sound prediction is a concept that becomes relevant only when an invention’s utility cannot actually be demonstrated by way of tests or experiments, but can nevertheless be successfully predicted: see, e.g., *AZT*. The lack of certainty that comes from predicting rather than demonstrating an invention’s utility has led some courts to conclude that there is a “heightened” or “enhanced” disclosure requirement in cases in which a claim of utility is based on sound prediction: see e.g. *Eli Lilly Canada Inc. v. Apotex Inc.*, 2009 FCA 97, 78 C.P.R. (4th) 388 (F.C.A.), at paras. 14-15. Teva submits that this heightened requirement was not met in the case at bar.

[38] As the courts below noted, all that is required to meet the utility requirement in s. 2 is that the invention described in the patent do what the patent says it will do, that is, that the promise of the invention be fulfilled: see also S. J. Perry and T. A. Currier, *Canadian Patent Law*, (2012), at §7.11. Patent ’446 states that the claimed compounds, including sildenafil, will be useful in treating ED. At the time the application was filed, sildenafil could assist in treating ED. This is all that is required. The fact that Pfizer did not disclose that the tested compound was sildenafil goes to the issue of disclosure of the *invention*, not to that of disclosure of the invention’s *utility*.

[39] That the invention must be useful as of the date of the claim or as of the time of filing is consistent with this Court's comments in *AZT*, at para. 56:

Where the new use is the *gravamen* of the invention, the utility required for patentability (s. 2) must, as of the priority date, either be demonstrated or be a sound prediction based on the information and expertise then available. If a patent sought to be supported on the basis of sound prediction is subsequently challenged, the challenge will succeed if . . . the prediction at the date of application was not sound, or, irrespective of the soundness of the prediction, “[t]here is evidence of lack of utility in respect of some of the area covered”. [Emphasis added.]

[40] 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”.

[41] In any event, Pfizer disclosed the utility of sildenafil by disclosing that tests had been conducted. Sildenafil was found to be useful before the priority date, which means that the requirement in *AZT* is met. Further, “[e]vidence as to utility may be found in the reception of the invention by the public. Enthusiastic reception by those to whom it is directed will tend to indicate that the invention is useful”: Perry and Currier, at §7.12.

[42] There is no question that sildenafil's utility had been demonstrated, in Study 350, as of the time of filing of the patent application. This takes the invention out of the realm of sound prediction. The claims that were determined not to be useful in the clinical study are in any event invalid — which is not contested — but this does not affect the validity of the claims that are useful: see s. 58 of the Act.

[43] Since sound prediction is not an issue, the question whether there is an “enhanced” or “heightened” disclosure requirement with respect to sound predictions does not arise in this case and need not be addressed. I will now turn to the issue at the heart of this appeal: whether Patent '446 meets the requirements of s. 27(3) of the Act.

E. *Disclosure under the Act*

(1) Relevant Provisions

[44] A patent can only be granted for an invention. “Invention” is defined in s. 2 of the Act as

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.

Thus, to constitute an “invention”, the subject of the patent must be “new and useful”, or a “new and useful improvement”.

[45] Since patents are a creature of statute, the “patent bargain” underlying the patent system is embodied in the Act. More specifically, ss. 27(1) to 27(3) of the Act reflect the patent “bargain theory” or *quid pro quo*. The disclosure requirements for the specification are found in s. 27(3):

(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.

[46] Section 27(4) says the following with respect to 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.

[47] If one or more claims in a patent are void for failure to meet the requirements of s. 27, s. 58 provides that any valid claims nevertheless survive:

**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.

[48] Finally, s. 53(1) is relevant to this appeal. It provides that a patent will be void if proper disclosure is wilfully withheld “for the purpose of misleading”:

**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.

(2) Jurisprudence

[49] In *Consolboard*, this Court reviewed the Act’s disclosure requirements, which at that time were found in s. 36. Although there are variations in wording between that section and the current s. 27(3), the substance of the disclosure requirements has remained the same.

[50] Dickson J. discussed what the specification must contain in order to meet the disclosure requirements. He stated clearly that the nature of the invention must be disclosed and that the entire specification, including the claims, must be considered in determining the nature of the invention and whether disclosure was sufficient:

In essence, what is called for in the specification (which includes both the “disclosure”, *i.e.* the descriptive portion of the patent application, and the “claims”) is a description of the invention and the method of producing or

constructing it, coupled with a claim or claims which state those novel features in which the applicant wants an exclusive right. The specifications must define the precise and exact extent of the exclusive property and privilege claimed.

Section 36(1) seeks an answer to the questions: “What is your invention? How does it work?” With respect to each question the description must be correct and full in order that, as Thorson P. said in *Minerals Separation North American Corporation v. Noranda Mines, Limited* [[1947] Ex. C.R. 306]:

. . . when the period of monopoly has expired the public will be able, having only the specification, to make the same successful use of the invention as the inventor could at the time of his application. [at p. 316]

We must look to the whole of the disclosure and the claims to ascertain the nature of the invention and methods of its performance, . . . being neither benevolent nor harsh, but rather seeking a construction which is reasonable and fair to both patentee and public. There is no occasion for being too astute or technical in the matter of objections to either title or specification for, as Duff C.J.C. said, giving the judgment of the Court in *Western Electric Company, Incorporated, and Northern Electric Company v. Baldwin International Radio of Canada* [[1934] S.C.R. 570], at p. 574, “where the language of the specification, upon a reasonable view of it, can be so read as to afford the inventor protection for that which he has actually in good faith invented, the court, as a rule, will endeavour to give effect to that construction”. Sir George Jessel spoke to like effect at a much earlier date in *Hinks & Son v. Safety Lighting Company* [(1876), 4 Ch. D. 607]. He said the patent should be approached “with a judicial anxiety to support a really useful invention”.

. . . In my view it is a well established principle that a patent specification is addressed, not to the public generally, but to persons skilled in the particular art. I am further of the opinion that s. 36(1) does not impose upon a patentee the obligation of establishing the utility of the invention.

[Emphasis added; citation omitted; pp. 520-21.]

Since *Consolboard*, the Court has constantly applied the principles stated by Dickson J., which is a testament to the soundness of his reasoning: see, e.g.,

*Monsanto Canada Inc. v. Schmeiser*, 2004 SCC 34, [2004] 1 S.C.R. 902, at para. 18; *Whirlpool Corp. v. Camco Inc.*, 2000 SCC 67, [2000] 2 S.C.R. 1067, at para. 52; *Pioneer Hi-Bred Ltd. v. Canada (Commissioner of Patents)*, [1989] 1 S.C.R. 1623 (“*Pioneer Hi-Bred*”), at p. 1636.

[51] In *Pioneer Hi-Bred*, the Court referred to *Consolboard* in discussing the Act’s disclosure requirements once again. Lamer J. (as he then was), writing for the Court, described those requirements as follows:

In summary, the *Patent Act* requires that the applicant file a specification including disclosure and claims (*Consolboard Inc.*, *supra*, at p. 520). Canadian courts have stated in a number of cases the test to be applied in determining whether disclosure is complete. The applicant must disclose everything that is essential for the invention to function properly. To be complete, it must meet two conditions: it must describe the invention and define the way it is produced or built . . . . The applicant must define the nature of the invention and describe how it is put into operation. A failure to meet the first condition would invalidate the application for ambiguity, while a failure to meet the second invalidates it for insufficiency. The description must be such 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 once the monopoly period is over, to use the invention as successfully as the inventor could at the time of his application (*Minerals Separation*, *supra*, at p. 316). [Emphasis added; citations omitted; pp. 1637-38.]

[52] 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.

F. *Nature of the Invention*

[53] In determining whether the disclosure requirements have been met in this case, the first step is to define the nature of the invention in Patent '446. This must be done in order to comply with s. 27(3) of the Act, which requires, among other things, that the specification “correctly and fully describe the invention”. Therefore, we must ask: What is the invention in Patent '446?

[54] The Federal Court and the Federal Court of Appeal held, based on *Boehringer* and *Apotex ACE* (F.C.A.), that each claim in Patent '446 is a separate invention. As a result, they considered the disclosure requirements with respect to each individual claim, not to the specification as a whole. For example, Kelen J. referred to *Boehringer* and *Apotex ACE* (F.C.A.) and stated on that basis that “sildenafil in Claim 7 should be considered separately” (para. 46). At para. 131, in discussing sufficiency of disclosure, he stated that “[e]ach of the claims, according to the law, represents a separate monopoly and [that] each claim must be viewed separately in relation to the disclosure.” The Federal Court of Appeal upheld Kelen J.’s conclusion. Nadon J.A. stated:

. . . Claim 7 represents a compound (sildenafil) within a class of compounds (those given by formula I) used to treat ED. Accordingly, Claim 7 constitutes a separate invention. The questions of utility and disclosure must therefore be determined on that basis. [para. 69]

[55] In my view, two principles were confused in the reasons of the courts below. One is that the claims define the scope of the exclusive right being sought (s. 27(4) of the Act; see also *Perry and Currier*, at §15.2), and the other is that the

content of the specification determines whether the disclosure requirements have been met (s. 27(3) of the Act). If the first principle were applied, the court would review the claims to determine whether what is being claimed is just a compound, or the compound together with its salts and isotopes. However, what the Act requires is that the courts consider the specification as a whole to determine whether the disclosure of the invention is sufficient.

[56] Pfizer submits that s. 58 of the Act allows courts to consider valid claims separately from those that are not valid. Implicitly, Pfizer is suggesting that under s. 58, where a valid claim exists, the consideration of the disclosure requirements can be limited to that claim. However, this is a misinterpretation of s. 58. Section 58 simply states that valid claims survive in the face of one or more invalid claims. This section is engaged once it has been determined, on the basis of the patent as a whole, whether the requirements, including the disclosure requirements, have been complied with. Section 58 does not allow a court to consider the validity of a single claim — Claim 7 in this case — independently of the rest of the specification, even if the claim in question is the only one that may be valid. This section is engaged only *after* the validity analysis is carried out.

[57] The courts below also concluded that the consideration of the disclosure requirements had to be limited to Claim 7. They came to this conclusion mainly on the basis of the *Boehringer* line of cases. However, the Exchequer Court's decision in *Boehringer* has been misinterpreted. It does not stand for the proposition that every

claim in a patent application is a separate invention. Rather, as Teva points out (A.F., at paras. 106-9), the court in *Boehringer* reached the conclusion that each claim in the patent in question concerned a separate invention only after considering the specification as a whole. The court did not purport to establish a broad proposition that in every case, each claim in a patent application concerns a separate invention. Such a proposition would be contrary to the scheme of the Act.

[58] Section 36(1) makes clear that each patent must contain just one invention:

**36. (1)** A patent shall be granted for one invention only but in an action or other proceeding a patent shall not be deemed to be invalid by reason only that it has been granted for more than one invention.

This provision does have a saving proviso to the effect that, if a patent has more than one invention, it cannot be deemed invalid for that reason only. Nevertheless, the provision clearly states that a patent shall be granted for one invention only.

[59] Further, s. 36(2.1) states,

Where an application (the “original application”) describes and claims more than one invention, the applicant shall, on the direction of the Commissioner, limit the claims to one invention only, and any other invention disclosed may be made the subject of a divisional application, if the divisional application is filed before the issue of a patent on the original application.

[60] The provisions of s. 36 support the conclusion that each claim should not be construed as a separate invention in every case.

[61] In any event, when *Boehringer* was appealed to this Court, the issue of separate inventions was not considered. After stating that the patent application did not meet the disclosure requirements, Martland J., on behalf of the Court, said,

Having reached the conclusion that claim 8 was invalid for failure to comply with s. 41(1), for one of the reasons found by the learned trial judge, it is unnecessary to consider, or express an opinion upon, the other grounds upon which he dismissed the action. [Emphasis added; p. 412.]

[62] The Federal Court considered this same issue in *Apotex ACE*. Considering himself bound by *Boehringer* and *Hoechst Pharmaceuticals of Canada Ltd. v. Gilbert & Co.*, [1965] 1 Ex. C.R. 710 — a decision in which Thurlow J., who had also written the reasons in *Boehringer*, reached a similar conclusion — Hughes J. said the following, at para. 116:

Were I to approach the matter without jurisprudential constraints, I would readily find that the '340 application is directed to but one invention, a class of compounds, of which individual compounds such as lisinopril are but illustrative. However, *Boehringer* and *Hoechst*, *supra*, oblige me to find otherwise, on the slender basis that there was, in the '340 application not only examples but also specific claims to the individual compounds enalapril, enalaprilat and lisinopril, each of which, on the theory of those cases, is a different invention from the class.

Incidentally, *Hoechst* was upheld on appeal by this Court ([1966] S.C.R. 189), but, as in *Boehringer*, the question whether separate claims disclose separate inventions was not considered.

[63] In *Apotex ACE*, the Federal Court of Appeal varied the Federal Court's decision in part, but upheld the conclusion that separate claims disclose separate inventions. However, as I have stated, this broad conclusion is contrary to the provisions of the Act and must be rejected.

[64] It is possible, as in *Boehringer*, for each claim in a patent to disclose a separate invention. Where this issue is raised, however, individual patents must be considered on a case-by-case basis. In my view, the approach Teva advocates for at para. 119 of its factum is useful in this case: “. . . the specification as a whole must be examined to determine whether sildenafil and the other compounds claimed in the patent are linked so as to form a single general inventive concept”. This is consistent with this Court's comment in *Consolboard*, at p. 520: “We must look to the whole of the disclosure and the claims to ascertain the nature of the invention and methods of its performance . . . .”

[65] As required by s. 2 of the Act, an invention must be novel. In the instant case, the invention is not sildenafil, *per se*, because this compound was already known. In fact, Pfizer had been investigating sildenafil as a cardiovascular drug when it first suspected that the compound would be useful in treating ED (R.F., at para. 13). The invention is therefore not sildenafil, but *the use of sildenafil to treat ED*.

[66] In this case, if we consider the specification as a whole, there is nothing to support the view that the use of sildenafil for the treatment of ED is a separate invention from the use of any of the other claimed compounds for that same purpose. No specific attributes or characteristics are ascribed to sildenafil that would set it apart from the other compounds. Even if we take into consideration the fact that sildenafil is an “especially preferred compound”, there is still nothing that distinguishes it from the other eight “especially preferred compounds”. The use of sildenafil and the other compounds for the treatment of ED comprises one inventive concept.

[67] In fact, the patent itself suggests that the entire class of claimed compounds will be effective in treating ED. The first sentence of the specification states: “This invention relates to the use of a series of [compounds] for the treatment of impotence” (A.R. vol. X, at p. 164 (emphasis added)). The following appears on the second page of the specification: “Unexpectedly, it has now been found that these disclosed compounds are useful in the treatment of erectile dysfunction.” And page 11 of the specification contains this statement:

Thus the invention includes a pharmaceutical composition for the curative or prophylactic treatment of erectile dysfunction in a male animal, including man, comprising a compound of formula (I), or a pharmaceutically acceptable salt thereof, together with a pharmaceutically acceptable diluents, or carrier. [Emphasis added; A.R., vol. X, at p. 174.]

The plural word “inventions” does not appear in Patent ’446.

[68] There is no evidence on the record to suggest that Pfizer filed a divisional application under s. 36(2.1). It would be disingenuous for Pfizer to imply that there is one invention in the patent application for the purpose of complying with s. 36(1) and then to submit that each claim concerns a distinct invention for the purposes of this appeal. If Patent '446 is viewed as a whole, there is only one invention: the use of the compound or compounds that are effective in treating ED.

G. *Is the Disclosure in Patent '446 Sufficient?*

[69] In light of s. 27(3), it is the specification and not just the claims that the court must consider to determine whether the patent in question meets the disclosure requirements (see also *Perry and Currier*, at §15.26). Section 27(4) provides that the claim or claims must define the subject-matter of the invention distinctly and explicitly.

[70] As I noted above, this Court made it clear in *Consolboard* that the specification, which includes the claims and the disclosure, must define the “precise and exact extent” of the privilege being claimed so as to ensure that the public can, *having only the specification*, make the same use of the invention as the inventor (p. 520). In my view, the courts below misread *Consolboard* when they stated that the only questions that must be answered are “What is your invention?” and “How does it work?” Dickson J. did not state that those were the only relevant questions. In fact, quoting *Minerals Separation*, he went on to say, at p. 520:

With respect to each question the description must be correct and full in order that . . . :

. . . when the period of monopoly has expired the public will be able, having only the specification, to make the same successful use of the invention as the inventor could at the time of his application. [Emphasis added.]

[71] The Court reiterated this in *Pioneer Hi-Bred*: “The description must be such 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” (p. 1638).

[72] Recall that in this case Pfizer had conducted tests that demonstrated that sildenafil was effective in treating ED. None of the other compounds in Patent '446 had been shown to be effective in doing so. Therefore, the invention was the use of sildenafil for the treatment of ED. This had to be disclosed in order to meet the requirements set out in s. 27(3) of the Act.

[73] Although Patent '446 includes the statement that “one of the especially preferred compounds induces penile erection in impotent males” (A.R., vol. X, at p. 173), the specification does not indicate that sildenafil is the effective compound, that Claim 7 contains the compound that works, or that the remaining compounds in the patent had been found not to be effective in treating ED. The claims were structured as “cascading claims”, with Claim 1 involving over 260 quintillion compounds, Claims 2 to 5 concerning progressively smaller groups of compounds, and Claims 6 and 7 each relating to an individual compound.

[74] The disclosure in the specification would not have enabled the public “to make the same successful use of the invention as the inventor could at the time of his application”, because even if a skilled reader could have narrowed the effective compound down to the ones in Claim 6 and Claim 7, further testing would have been required to determine which of those two compounds was actually effective in treating ED. As the trial judge stated, at para. 146, “[a] skilled reader would then conduct tests on those two compounds and determine which of those compounds worked.” And as he also stated, at para. 135, “the skilled reader must undertake a minor research project to determine which claim is the true invention”.

[75] Pfizer argued in the Court of Appeal that Teva had already been able to make the same use of the invention having only the specification, because it had filed a submission with the Minister of Health for a drug product containing sildenafil (F.C.A. reasons, at para. 48). However, this does not change the fact that the specification required, at a minimum, “a minor research project” in order to determine whether Claim 6 or Claim 7 contained the correct compound. The fact that Teva carried out this minor research project is irrelevant to Pfizer’s obligation to fully disclose the invention. More importantly, what must be considered is whether a skilled reader having only the specification would have been able to put the invention into practice. The trial judge clearly found that the skilled reader would have had to undertake a minor research project to determine what the true invention was.

[76] Pfizer had the information needed to disclose the useful compound and chose not to release it. Even though Pfizer knew that the effective compound was sildenafil at the time it filed the application, it limited its description to the following statement:

In man, certain especially preferred compounds have been tested orally in both single dose and multiple dose volunteer studies. Moreover, patient studies conducted thus far have confirmed that one of the especially preferred compounds induces penile erection in impotent males. [Emphasis added; A.R., vol. X, at p. 173.]

It chose a method of drafting that failed to clearly set out what the invention was. Even now, in its factum to this Court, Pfizer offers no explanation as to why — knowing that Claim 7 contained the tested and thus, the useful, compound — it elected to withhold that information.

[77] This led the application judge to note:

By withholding from the public the identity of the only compound tested and found to work, sildenafil, the patent did not fully describe the invention. Obviously Pfizer made a conscious choice not to disclose the identity of the only compound found to work, and left the skilled reader guessing. This is contrary to the statutory requirement to fully disclose the invention. [Emphasis added; para. 136.]

[78] Perry and Currier agree. They say the following, at §8.55:

. . . an invention that is possessed of novelty, inventiveness and utility will not benefit from patent protection if the specification is insufficient or ambiguous. The description must explain the nature of the invention

failing which the specification is ambiguous, and it must describe how the invention is put into operation failing which the specification is insufficient. In either case, the patent is invalid. [Emphasis added.]

[79] Whether or not a specification is sufficient depends on what a skilled person would consider to be sufficient: see, e.g., Perry and Currier, at §8.57. Expert evidence in this case reveals that there was no basis for a skilled person to determine which of Claim 6 and Claim 7 contained the useful compound. Pfizer's own expert witness admitted that a person skilled in the art who read the patent would not know which compound was shown by the study to be useful in treating ED (F.C. reasons, at para. 123).

[80] I would not make too much of the fact that Claim 1 included over 260 quintillion compounds. The practice of cascading claims — although it may, as in this case, result in claims that are overly broad — is a common one that does not necessarily interfere in every case with the public's right to disclosure. The skilled reader knows that, when a patent contains cascading claims, the useful claim will usually be the one at the end concerning an individual compound. The compounds that do not work are simply deemed invalid. In accordance with s. 58, any valid claim — in this case, Claim 7 — survives despite the existence of invalid claims. However, the public's right to proper disclosure was denied in this case, since the claims ended with two individually claimed compounds, thereby obscuring the true invention. The disclosure failed to state in clear terms what the invention was. Pfizer gained a benefit from the Act — exclusive monopoly rights — while withholding disclosure in spite

of its disclosure obligations under the Act. As a matter of policy and sound statutory interpretation, patentees cannot be allowed to “game” the system in this way. This, in my view, is the key issue in this appeal. It must be resolved against Pfizer.

#### H. *Remedy*

[81] I have reached the conclusion that Patent '446 does not comply with s. 27(3) of the Act. What is the appropriate remedy?

[82] The remedy for inadequate disclosure was stated by this Court in *Pioneer*

*Hi-Bred*:

Canadian courts have stated in a number of cases the test to be applied in determining whether disclosure is complete. The applicant must disclose everything that is essential for the invention to function properly. To be complete, it must meet two conditions: it must describe the invention and define the way it is produced or built [citation omitted]. The applicant must define the nature of the invention and describe how it is put into operation. A failure to meet the first condition would invalidate the application for ambiguity, while a failure to meet the second invalidates it for insufficiency. The description must be such 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 . . . . [Emphasis added; citation omitted; pp. 1637-38.]

[83] In the case at bar, Patent '446 is insufficient, because a skilled reader having only the specification would not be able to put the invention into operation. Therefore, Patent '446 is invalid.

[84] Although s. 27 does not specify a remedy for insufficient disclosure, the logical consequence of a failure to properly disclose the invention and how it works would be to deem the patent in question invalid. This flows from the *quid pro quo* principle underpinning the Act. If there is no *quid* — proper disclosure — then there can be no *quo* — exclusive monopoly rights.

[85] Pfizer, however, appears to argue that the patent cannot be deemed invalid, because Teva did not argue that s. 53 applies (R.F., at para. 82). Section 53 specifically states that a patent will be 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.

[86] Pfizer submits that Teva's argument about "concealment" of the useful compound in the patent is a thinly veiled accusation of fraud, but that Teva has never alleged that Patent '446 contravenes s. 53 (R.F., at para. 79). Further, Pfizer states that, "s. 27(3) . . . [was never] intended to address an allegation of deliberate deception" (R.F., at para. 80).

[87] There is a very simple response to Pfizer's submissions on this point. Even if s. 53 was not raised and its requirements were not met, this does not mean that the disclosure was adequate for the purposes of s. 27(3). These provisions can be

independent of each other, as is the case here. Although wilful intent to mislead has not been alleged or proven in this case, insufficient disclosure has been alleged and I have found that it has been made out. Therefore, in light of the remedy adopted in *Pioneer Hi-Bred*, Patent '446 is invalid.

I. *Other Submissions*

[88] Pfizer and the intervener Canada's Research-Based Pharmaceutical Companies argue that Teva's submissions are incompatible with Canada's international obligations, and more specifically with the *Patent Cooperation Treaty*, Can. T.S. 1990 No. 22, incorporated into Canadian law by the *Intellectual Property Improvement Act*, S.C. 1993, c. 15, s. 29(1). The essence of this argument is that Teva is advocating for an enhanced disclosure requirement which, Pfizer and the intervener says, is contrary to Canada's obligations under the Treaty.

[89] There is no need to address this argument at length. Since, as I have already explained, this is not a case about sound prediction, the Court does not need to consider whether a claim of utility that is based on sound prediction would impose an "enhanced" disclosure obligation on the patentee or whether such an "enhanced" disclosure obligation — if one existed — would be contrary to the Treaty. Neither the parties nor the interveners argue that the disclosure requirements of s. 27(3) violate any international obligations. The only issue in this case is whether the disclosure requirements set out in s. 27 of the Act were met. This argument must therefore fail.

[90] Finally, I will note that the delay of 13 years between the filing of the patent and Teva's challenge is inconsequential. As Nadon J.A. found in the reasons of the Federal Court of Appeal in this case, the relevant question is whether the disclosure was sufficient as of the date of filing. Consequently, the passage of time does not bar Teva's challenge.

V. Conclusion

[91] I would therefore allow the appeal with costs and hold that Patent 2,163,446 is void.

APPENDIX

*Patent Act, R.S.C. 1985, c. P-4*

2. . . .

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

. . .

27. . . .

(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.

(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.

. . .

36. (1) A patent shall be granted for one invention only but in an action or other proceeding patent shall not be deemed to be invalid by reason only that it has been granted for more than one invention.

...

(2.1) Where an application (the “original application”) describes and claims more than one invention, the applicant shall, on the direction of the Commissioner, limit the claims to one invention only, and any other invention disclosed may be made the subject of a divisional application, if the divisional application is filed before the issue of a patent on the original application.

...

**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.

...

(2) Where it appears to a court that the omission or addition referred to in subsection (1) was an involuntary error and it is proved that the patentee is entitled to the remainder of his patent, the court shall render a judgment in accordance with the facts, and shall determine the costs, and the patent shall be held valid for that part of the invention described to which the patentee is so found to be entitled.

...

**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.

*Appeal allowed with costs.*

*Solicitors for the appellant: Osler, Hoskin & Harcourt, Ottawa.*

*Solicitors for the respondents Pfizer Canada Inc., Pfizer Inc., Pfizer Ireland Pharmaceuticals and Pfizer Research and Development Company N.V./S.A.: Torys, Toronto.*

*Solicitors for the intervener the Canadian Generic Pharmaceutical Association: Heenan Blaikie, Toronto.*

*Solicitors for the intervener Canada's Research-Based Pharmaceutical Companies: Gowling Lafleur Henderson, Ottawa.*