Federal Court of Appeal | Cour d'appel fédérale

Date: 20100924

Docket: A-292-09

Citation: 2010 FCA 242

CORAM: **BLAIS C.J.**
NADON J.A.
TRUDEL J.A.

BETWEEN:

NOVOPHARM LIMITED

Appellant

and

PFIZER CANADA INC., PFIZER INC.,
PFIZER IRELAND PHARMACEUTICALS,
PFIZER RESEARCH AND DEVELOPMENT COMPANY N.V./S.A. and
THE MINISTER OF HEALTH

Respondents

Heard at Montreal, Quebec, on March 24, 2010.

Judgment delivered at Ottawa, Ontario, on September 24, 2010.

REASONS FOR JUDGMENT BY: NADON J.A.

CONCURRED IN BY: BLAIS C.J.
TRUDEL, J.A.

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REASONS FOR JUDGMENT

[1] This is an appeal by Novopharm Limited (the "appellant") from an Order of Kelen J. of the Federal Court ("the Judge"), 2009 FC 638, dated June 18, 2009 (the "Decision"), which, pursuant to the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133, prohibited the Minister of Health from issuing a Notice of Compliance (a "NOC") to the appellant for a generic version of sildenafil tablets (marketed commercially by the respondents as Viagra) until the expiry of the

respondents' Canadian Patent No. 2, 163,446 (the " '446 patent"). For the reasons that follow, I conclude that the Judge made no reviewable error in concluding as he did.

The Facts

[2] The '446 Patent is owned by the respondent Pfizer Ireland Pharmaceuticals and licensed to the respondent, Pfizer Canada Ltd. (hereinafter, I will refer to the various respondents as "Pfizer"). The Patent will expire on May 13, 2014.

[3] The '446 Patent claims the use of sildenafil citrate ("sildenafil") for the treatment of erectile dysfunction ("ED"). Sildenafil was initially developed by Pfizer to treat angina and hypertension. However, when testing the drug on patients suffering from angina, Pfizer scientists noticed that patients experienced "prolonged and spontaneous erections." Until that point in time, no oral treatment for ED had been available and existing treatment generally required drugs to be injected directly into the penis.

[4] As a result of its angina studies, Pfizer filed a provisional specification for a patent in the United Kingdom ("UK"). It then conducted a study, known as Study 350, to test the effects of sildenafil on ED. Under Study 350, 16 men diagnosed with ED were administered oral sildenafil for six days. On the sixth day, the patients were admitted to hospital, shown sexually explicit videos, and kept in the hospital overnight. During their stay in the hospital, the rigidity and duration of the patients' erections was measured using a device known as a "RigiScan transducer." The patients also kept diaries. Pfizer concluded, based on this study, that sildenafil could be used to treat ED.

[5] The ‘446 Patent issued on July 7, 1998, subsequent to an application claiming priority filed on May 13, 1994, which, in turn, claimed priority from an application filed in the UK on June 9, 1993.

[6] The ‘446 Patent disclosure states that the patent relates to “the use of a series of pyrazolo [4,3-d]pyrimidin-7-ones for the treatment of impotence.” The disclosure then states that “the present invention concerns the use of a compound of formula I.” Formula I gives rise to approximately 260 quintillion chemical compounds. The disclosure classifies these 260 quintillion compounds into four categories: “a preferred group of compounds,” “a more preferred group of compounds”; “a particularly preferred group of compounds”: and a list of “especially preferred individual compounds of the invention.” Included in the list of especially preferred individual compounds is “5-[2-ethoxy-5-(4-methyl-1-piperazinyl-sulphonyl)-phenyl]-1-methyl-3-n-propyl-1,6-dihydro-7H-pyrazolo[4,3-d]pyrimidin-7-one or a pharmaceutically acceptable salt thereof.” This compound is sildenafil.

[7] The disclosure then refers to Pfizer’s experimentation. At page 10, it states as follows:

> 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.

This is the only reference to Study 350 in the ‘446 Patent. Although the disclosure states that “certain especially preferred compounds” induced erections, it does not specify which one.

[8] The ‘446 Patent then makes 27 claims, the first seven of which relate to the use of formula I for the treatment of ED. Claim 1 lists the use of the entirety of the range of compounds provided by formula I. Claims 2 to 5 successively list smaller ranges of compounds provided by formula I. Claims 6 and 7 each refer to only one compound. The compound found in Claim 7 is sildenafil.

[9] This case is not the first in which the Viagra patent has been litigated. In 2000, the High Court of Justice of England and Wales invalidated the Viagra patent for obviousness (*Lilly Icos Ltd.* v. *Pfizer Ltd.*, 2000 EWHC Patents 49; [2001] F.S.R. 16). The Court of Appeal of England and Wales upheld this decision on appeal (*Lilly Icos Ltd.* v. *Pfizer Ltd.*, [2002] EWCA Civ. 1). In Canada, in 2007, Apotex Inc. challenged the validity of the ‘446 Patent on a number of grounds, most prominently on obviousness. Mosley J. of the Federal Court allowed Pfizer’s application to prohibit the Minister of Health from issuing a NOC to Apotex (*Pfizer Canada Inc.* v. *Apotex Inc.*, 2007 FC 971, [2007] 61 C.P.R. (4th) 305 [*Apotex-Viagra*]). This Court subsequently upheld Mosley J’s decision (*Pfizer Canada Inc.* v. *Apotex Inc.*, 2009 FCA 8; [2009] 72 C.P.R. (4th) 141).

[10] On December 19, 2006, the appellant filed an Abbreviated New Drug Submission for orally administered sildenafil tablets, comparing its tablets to those marketed by Pfizer as Viagra. On July 6, 2007, the appellant served a Notice of Allegation on Pfizer, alleging the invalidity of the ‘446 Patent. Specifically, it claimed that the ‘446 Patent was invalid for obviousness, lack of utility, and insufficient disclosure.

[11] On June 18, 2009, the Judge held that the appellant's allegations of invalidity were not justified.

RELEVANT LEGISLATION

[12] This appeal involves the *Patent Act*, R.S.C. 1985, c. P-4 ("the Act"). Section 2 of the Act defines "invention" to require novelty and utility:

"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	« invention » Toute réalisation, tout procédé, toute machine, fabrication ou composition de matières, ainsi que tout perfectionnement de l'un d'eux, présentant le caractère de la nouveauté et de l'utilité.

[13] Subsection 27(3) lists the requirements of a patent 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	(3) Le mémoire descriptif doit : *a*) décrire d'une façon exacte et complète l'invention et son application ou exploitation, telles que les a conçues son inventeur; *b*) exposer clairement les diverses phases d'un procédé, ou le mode de construction, de confection, de composition ou d'utilisation d'une machine, d'un objet manufacturé ou d'un composé de matières, dans des termes complets, clairs, concis et exacts qui permettent à toute personne versée dans l'art ou la science dont relève l'invention, ou dans l'art ou la science qui s'en rapproche le plus, de confectionner, construire, composer ou utiliser l'invention; *c*) s'il s'agit d'une machine, en expliquer clairement le principe et la meilleure manière dont son inventeur en a conçu

necessary sequence, if any, of the various steps, so as to distinguish the invention from other inventions.	l'application; *d*) s'il s'agit d'un procédé, expliquer la suite nécessaire, le cas échéant, des diverses phases du procédé, de façon à distinguer l'invention en cause d'autres inventions.

[14] Subsection 27(4) adds that a specification must end with the patent's 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.	(4) Le mémoire descriptif se termine par une ou plusieurs revendications définissant distinctement et en des termes explicites l'objet de l'invention dont le demandeur revendique la propriété ou le privilège exclusif.

THE FEDERAL COURT DECISION

(a) Claim Construction:

[15] Before considering the appellant's arguments in support of its allegations of invalidity, the Judge construed Claim 7, the only claim relevant to the application and to this appeal. The Judge endorsed the construction arrived at by Mosley J. in *Apotex-Viagra, supra*, at paragraph 35: "the use of sildenafil (or a salt thereof) in the form of an oral medicine for the treatment of erectile dysfunction in man", which this Court, on appeal, approved at paragraph 11 of its Reasons.

[16] The Judge, at paragraph 42, then accepted Pfizer's submission that "in patents such as the one at bar, each claim should be considered separately for the purposes of determining which claim should be construed." He cited *C.H. Boehringer Sohn* v. *Bell-Craig Ltd.*, [1962] Ex.C.R. 201, 39 C.P.R. 201, aff'd [1963] S.C.R. 410 [*Boehringer*], for the proposition that an individually-claimed

substance represents a separate invention. The Judge followed an earlier Federal Court decision, *Merck & Co.* v. *Apotex*, 2006 FC 524, [2006] 53 C.P.R. (4th) 1 [*Apotex ACE* (FC)], which gave effect to *Boehringer*. In *Apotex ACE* (FC), the patent at issue related to the use of angiotensin-converting enzyme inhibitors ("ACE inhibitors") for the treatment of hypertension. The formula stated in the patent covered billions of individual compounds. Among these compounds were linisopril, enalapril, and enalaprilat, each of which was individually claimed. Citing *Boehringer*, Hughes J. found that "there was, in the 340 application not only examples but also specific claims to the individual compounds enalapril, enalaprilat and linisopril, each of which… is a different invention from the class" (*Apotex ACE* (FC) at paragraph 116 /Decision at paragraph 45).

[17] In turn, this Court upheld Justice Hughes' interpretation (*Merck & Co* v. *Apotex Inc.*, 2006 FCA 323, [2007] 3 F.C.R. 588 [*Apotex ACE* (FCA)]. Accordingly, at paragraph 46 of his Decision, the Judge held:

> As the '446 Patent specifically claims and describes sildenafil in claim 7, the Federal Court of Appeal's ruling [in *Merck & Co*. v. *Apotex Inc*., 2006 FCA 323, [2007] 3 FCR 588] is applicable here and sildenafil in Claim 7 should be considered separately.

b) Obviousness:

[18] Pfizer argued that the appellant's attempt to invalidate the patent for obviousness was an abuse of process. The Judge disagreed, holding that the appellant had raised new distinguishing arguments. However, the Judge determined that the '446 Patent was not obvious. There is no appeal of that part of the Judge's Decision.

c) Utility:

[19] The appellant argued that as of the filing date, Pfizer had neither demonstrated nor soundly predicted the utility of sildenafil. It argued that the '446 Patent did not demonstrate utility because the patent itself did not disclose the utility of sildenafil. It further argued that the '446 Patent did not soundly predict the utility of sildenafil because it did not name sildenafil as the "active pharmaceutical ingredient" in the patent, because the results of Study 350 were not disclosed therein and because Study 350 contained serious flaws. Further, the appellant argued that the '446 Patent lacked utility because it included inoperative species, to wit the quintillions of compounds that do not treat ED.

[20] The Judge found that the '446 Patent was not invalid for lack of utility. He held that for an invention to be useful, it must do what the patent says it will do. He cited *Consolboard Inc.* v. *MacMillan Bloedel (Saskatchewan Ltd.)*, [1981] 1 S.C.R. 504 [*Consolboard*] for the proposition that an inventor need only demonstrate a low level of utility and also cited *Aventis Pharma* v. *Apotex Inc.*, 2005 FC 1283, [2005] 43 C.P.R. (4th) 161 [*Aventis*] for the proposition that "[w]here the specification does not promise a particular result… a 'mere scintilla' of utility will suffice" (paragraph 271 of *Aventis*; Decision at paragraph 78).

[21] The Judge held that the '446 Patent did demonstrate utility. He dismissed the appellant's contention that where a patent issues on the basis of demonstrated utility, the patent must include evidence of demonstrated utility. He further held that the brief reference to Study 350 (excerpted at

paragraph 7 of these Reasons) was sufficient to find that the ‘446 Patent issued based on demonstrated utility. At paragraph 82 of his Reasons, he stated:

> [82] The Court finds that there is no requirement in patent law that evidence of the demonstrated utility of the patent must be included in the patent. It is sufficient that the patent states that the invention has been demonstrated to be useful, as the ‘446 Patent does by making reference to the clinical testing of the compound (Study 350) and that the patent-holder is able to show evidence of demonstrated utility if the validity of the patent is challenged.

[22] The validity of the patent being challenged, the Judge then considered whether the invention was useful. The appellant argued that Study 350 was flawed in three ways. First, it used erections as an endpoint, rather than sexual intercourse; second, the diary data of patients were not statistically significant; and third, RigiScan results did not necessarily indicate an ability to engage in sexual intercourse.

[23] The Judge dealt with these arguments as follows at paragraph 86:

> [86] Having reviewed the data, the Court is satisfied that the results of Study 350 indicate that the patients who received sildenafil showed a significant improvement in erectile function. The expert evidence is that RigiScan is the best available tool for measuring the rigidity and duration of an erection, which is the only objective method of determining whether an erection is adequate for intercourse. The RigiScan results were statistically significant. Moreover, the diary results, although not statistically significant, nonetheless indicated a subjective measure of improved function. The small size of the study, which was objected to by Novopharm, is accounted for in the p-values measuring the statistical significance of the result.

[24] Additionally, at paragraph 87 of his Decision, the Judge stressed that a valid patent need not demonstrate utility to the same degree required by health regulators. For this proposition, he relied

on the decision of Wetston J. in *Apotex v. Wellcome*, (1998) 79 C.P.R. (3d) 193 (F.C.) [*Wellcome* (FC)] at paragraphs 105-106.

[25] The Judge then dismissed the appellant's inoperative species argument. The appellant argued that since only one of the compounds claimed by the '446 Patent treated ED, the entire patent had to be considered invalid. Relying on section 58 of the Act, which provides that where one claim is invalid, the others shall be construed as if the patent contained only the valid claims, the Judge dismissed the appellant's arguments. Thus, in the Judge's view, even if claims 1 to 6 are invalid, the '446 Patent must be construed as if they were not included (Decision at paragraph 91).

d) Disclosure:

[26] The appellant alleged that the '446 Patent did not adequately describe the invention and how to practice it. The Judge began his analysis by referring to this Court's decision in *Pfizer Canada v. Ranbaxy Laboratories Ltd*., 2008 FCA 108, [2009] 1 F.C.R. 253 [*Ranbaxy*], which in turn relied on *Consolboard, supra,* for the following proposition: "Only two questions are relevant for the purpose of subsection 27(3) of the Act. What is the invention? How does it work?" (Decision at paragraph 103; *Ranbaxy* at paragraph 59; *Consolboard* at 157).

[27] The Judge also referred, at paragraph 106 of his Reasons, to *Hughes & Woodley on Patents*, 2nd ed., looseleaf (Markham, ON: LexisNexis Canada, 2005) at §34, cited by this Court in *Ranbaxy* at paragraph 36, where the learned authors, Rogers T. Hughes and Dino P. Clarizio, write as follows:

> Insufficiency is directed to whether the specification is sufficient to enable a person skilled in the art to understand how the subject matter of the patent is to be made… An allegation of insufficiency is a technical attack that should not operate to defeat a patent for a meritorious invention; such attack will succeed where a person skilled in the art could not put the invention into practice.

[28] The Judge then stated, at paragraph 107, the following requirements for sufficient disclosure:

> [107] The jurisprudence also states that the language in the patent cannot obfuscate, obscure or bewilder the skilled reader of the patent. The description in the patent must be "free from avoidable obscurity or ambiguity and be as simple and distinct as the difficulty of the description permits." 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.
>
> [Citations omitted]

[29] With those principles in mind, the Judge reviewed the expert evidence on what the '446 Patent teaches a person skilled in the art. The appellant adduced evidence to the effect that a person skilled in the art would not be able to select sildenafil from the patent as a whole. As to Pfizer, it adduced evidence to the effect that a person skilled in the art would look only to the nine "especially preferred compounds" in the disclosure and would then notice that only two of these compounds were specifically claimed, and could therefore narrow his or her focus appropriately.

[30] The Judge then made two observations. First, he noted that the case before him raised a novel issue because he could not find any prior case which had considered the issue of sufficiency with respect to a patent which contains many claims but does not disclose the claim embodied in the

invention found to be the commercial product. Second, he held that "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" (Decision at paragraph 133).

[31] Before making his findings on the issue of disclosure, the Judge, at paragraphs 135 and 136 of his Reasons, made the following remarks *in obiter*, expressing his uneasiness with the relevant case law:

> [135] In my mind, the disclosure plays games with the reader. Why did the disclosure not simply state that that 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.
>
> [136] 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.

[32] Having expressed his reservations, the Judge nevertheless declined to invalidate the '446 Patent for want of sufficient disclosure. In so doing, he made, at paragraphs 141 to 146 of his Reasons, the following comments:

1. He cited the present popularity of Viagra as evidence that sildenafil is a meritorious invention.

2. He noted the 13-year delay in initiating invalidity proceedings.

3. He concluded from the delay that "surely that patent would have been attacked on this basis before 2007 if there [had been] any possibility of success" (Decision at paragraph 143).

4. He held that any skilled reader now knows sildenafil is the active ingredient and that the '446 Patent will expire in 2014.

5. He found that the jurisprudence dictates that the relevant claim be considered as a separate invention.

6. Finally, he accepted the evidence that a person skilled in the art would narrow the 260 quintillion compounds down to the two especially preferred compounds claimed separately. "A skilled reader would then conduct tests on those two compounds and determine which of those compounds worked. In this case, Claim 7 is the compound which works and Claim 7 does sufficiently and clearly describe sildenafil" (Decision at paragraph 146).

THE ISSUES

[33] The appeal raises two issues, each with two parts:

1. Was the Judge correct in concluding that the disclosure of the invention in the '446 Patent was sufficient under section 27 of the Act?

    (a) What is the relevant invention?

    (b) Given the determination of the invention, was there sufficient disclosure?

2. Was the Judge correct in concluding that the '446 Patent met the requirement of utility under section 2 of the Act?

    (a) Was the respondent required to demonstrate utility in the patent disclosure?

    (b) If not, does the evidence disclose that the invention was useful?

THE PARTIES' SUBMISSIONS

1.(a) Disclosure: What is the relevant invention?

[34] The appellant submits that the Judge erred in concluding that the patent was not invalid for lack of sufficient disclosure. I begin with its submission in regard to what is the relevant invention.

[35] The appellant notes that the *Consolboard, supra* test for sufficiency of disclosure requires that a patent answer two questions: What is the invention? How does it work? The appellant submits that Pfizer failed to disclose its invention by concealing which compound in the patent was sildenafil.

[36] The appellant submits that Pfizer's disclosure obligations relate to the '446 Patent in its entirety and, therefore, it asserts that the Judge was wrong when he stated that the invention in question, in relation to the disclosure requirements, was Claim 7 specifically. Rather, the appellant maintains that the disclosure requirements apply broadly to the patent as a whole.

[37] First, the appellant says that the Judge erred by failing to require that Pfizer disclose the best mode of practice. It relies on the disclosure requirements outlined by Thorson P. in *Minerals Separation North American Corp.* v. *Noranda Mines Ltd.* [1947] Ex. C.R. 106, 12 C.P.R. 99 at 112 [*Minerals Separation* (Ex. Ct.)]:

> The description must also give all information that is necessary for successful operation or use of the invention, without leaving such result to the chance of successful experiment, and if warnings are required in order to avert failure such warnings must be given. Moreover, the inventor must act *uberrima fide* and give all information known to him that will enable the invention to be carried out to its best effect as contemplated by him.

[38] The appellant submits that Pfizer was required to disclose the "best mode" of its invention. While the appellant concedes that under paragraph 27(3)(*c*) of the Act, best mode requirements only apply to machines, it submits, however, that some of the case law has applied the best mode requirement more broadly. For example, in *Lido* v. *Teledyne* (1981) 57 C.P.R. (2d) 29 (F.C.A.), Chief Justice Thurlow, dissenting in part but concurring with respect to the issue of validity, quoted from the 1969 edition of Fox on *Canadian Law and Practice Relating to Letters Patent for Inventions*, which states that an inventor is "required to describe fully and correctly what is his invention. This necessarily involves the duty of disclosing the best method of doing so as contemplated by him" (*Lido* at 44; Fox at 180).

[39] Second, the appellant argues that when the Judge held that Claim 7 should be read as an invention on its own for the purpose of disclosure requirements, he conflated the disclosure requirements in subsection 27(3) with the claim description requirements in subsection 27(4). While the sufficiency of a specification is a requirement imposed by subsection 27(3), the requirement that a claim clearly describe an invention is found separately in subsection 27(4) of the Act.

[40] Third, the appellant argues that the Judge misapplied the test from *Consolboard, supra,* and *Ranbaxy, supra,* when he concluded that the '446 Patent answers the question "what is the invention?" because Claim 7 is clear, regardless of the rest of the patent. At paragraph 58 of its Memorandum, the appellant states:

> 58. In [*Ranbaxy*] there was no issue that the public was able, with only the specification, to use the invention as successfully as the inventor could himself. In contrast, the 446 Patent fails to identify the only PDE5 inhibitor that was ever found to allegedly induce erections. The 446 Patent simply fails to answer the question "What is the invention?"

[41] Fourth, the appellant argues that the judge based his finding on "impermissible hindsight." Specifically, a patent disclosure must enable the public to make immediate use of the invention (*Kirin-Amgen Inc.* v. *Hoechst Marion Roussel Ltd.* [2005] R.P.C. 9 (H.L.) at paragraph 77). In this case, however, the Judge stated that "The skilled reader knows… that sildenafil is the active ingredient in the invention and will be able to make the invention when the patent expires in 2014" (Decision at paragraph 144). The appellant therefore submits that the Judge was not entitled to rely on what the skilled reader knows now, but was required to rely on what the skilled reader knew at the time of filing. It submits that at the time of filing, a skilled reader would not have been able to discern which compound was sildenafil.

[42] Pfizer responds to the appellant's arguments as follows. It offers two arguments. First, it relies on *Consolboard, supra,* to argue that attacks on the validity of a patent because of its specification are technical in nature and ought not to defeat a meritorious invention.

[43] Second, Pfizer argues that the Act does not impose a "best mode" requirement except with respect to machines, nor does it not impose a requirement to distinguish inventions, except for processes. It notes that in *Sanofi Aventis Canada Inc.* v. *Apotex Inc.*, 2009 FC 676, [2009] 77 C.P.R. (4th) 99 [*Sanofi*], Snider J. of the Federal Court explicitly considered and rejected the proposition that *Minerals Separation* (Ex. Ct.), *supra*, imposes a best mode requirement on inventions other than machines.

*1.(b) **Disclosure: Given the determination of the invention, was there sufficient disclosure?***

[44] Two of the appellant's arguments on sufficiency relate more to whether the Judge accurately assessed the evidence than whether the disclosure requirements pertain to the '446 Patent as a whole or Claim 7 in particular.

[45] The appellant first argues that the Judge erred when he held that "… Claim 7 and sildenafil is the relevant invention" (Decision at paragraph 131). The appellant contends that the expert evidence was to the effect that it was not possible to discern which compound was sildenafil. To support this view, the appellant points to the fact that the judge, at paragraph 135 of his Reasons, states that "… the skilled reader must undertake a minor research project to determine which claim is the true invention."

[46] Second, the appellant asserts that the Judge took into account irrelevant and extraneous factors, specifically that the appellant waited 13 years to challenge the validity of the patent (until 2007), that Pfizer identified sildenafil as the active ingredient 11 years ago and that Viagra was introduced in the United States nine years ago.

[47] Pfizer's response is as follows. First, it argues that even if the invention were to be interpreted in light of the entire patent and not just Claim 7, "a patent should not be interpreted *contra proferentem*." Rather, it should be interpreted purposely, with a mind willing to understand and with a judicial anxiety to support a very useful invention" (Citing *Mobil Oil Corp.* v. *Hercules Canada Inc.* (1994), 57 C.P.R. (3d) 488 at paragraph 62 (F.C.T.D.), rev'd on other grounds (1995)

63 C.P.R. (3d) 473 (C.A.)). Pfizer argues that disclosure is sufficient because there is enough evidence to support the finding that the person skilled in the art would select one of the especially preferred compounds and, in particular, focus on the two compounds claimed individually in claims 6 and 7 of the '446 Patent. The person skilled in the art would then conduct a 'minor research project' (i.e., not experimentation).

[48] Second, Pfizer relies on *Consolboard, supra*, at page 520, for the proposition that the consideration given by the patentee in the patent bargain is that "after the period of monopoly has expired the public will be able, with only the specification, to put the invention to the same successful use as the inventor himself could do it." In this case, according to Pfizer, the appellant had already been able to do this because it had filed a submission with the Minister of Health for a drug product containing sildenafil.

2.(a) Utility: Was the respondent required to demonstrate utility in the patent disclosure?

[49] The appellant argues that the '446 Patent issued based on sound prediction rather than demonstrated utility. It maintains that this Court has confirmed that the question of whether a patent is based on demonstrated utility is to be determined on the basis of what the patent discloses, not on what the patentee may have done in secret and failed to disclose. For authority, it relies on this Court's decision in *Eli Lilly Canada Inc.* v. *Apotex Inc.*, 2007 FCA 97, [2007] 78 C.P.R. (4th) 388 [*Eli Lilly*]: "the question to be asked… is whether the disclosure in the patent was adequate to tell a person skilled in the art how to practice the invention or whether it discloses enough information so

that a person skilled in the art could soundly predict that it would work" (Appellant's Memorandum, paragraph 7).

[50] Since the '446 Patent disclosure does not identify which of the compounds was clinically tested, a person skilled in the art would have to select one compound from among the quintillions of options. A person skilled in the art who selects a compound will therefore not know if that compound is sildenafil. For the appellant, "the selection must be made on the basis of a prediction that every compound referred to in the '446 Patent will have the same utility as the unidentified compound" (Appellant's Memorandum at paragraph 74).

[51] The appellant further argues that the Judge did not refer to any case that supported the view "that the statutory requirement for sufficiency of specification can be satisfied by a bald statement in the patent that promised utility has been demonstrated coupled with the ability to adduce evidence of demonstrated utility at some undefined later date" (Appellant's Memorandum at paragraph 102). The appellant takes the view that the Judge never considered "whether the '446 Patent provides practical readers with knowledge that sildenafil in fact works to treat ED" (Appellant's Memorandum at paragraph 104).

[52] Pfizer responds to the appellant by arguing that it misinterprets the ratio of *Eli Lilly*, *supra*, and that the determination of whether a patent demonstrates utility is a question of fact answered by what the inventors actually did. It argues that in *Eli Lilly*, the Judge first determined that the invention was based on sound prediction, and then determined that the basis for the prediction was

not sufficiently disclosed. Therefore, the case does not stand for the proposition that the determination of whether or not an invention is based on sound prediction or demonstrated utility must be made on the basis of the disclosure alone. Rather, it stands for the proposition that once a court concludes a patent is based on sound prediction, then it must ensure that the basis of the prediction is properly disclosed.

[53] Pfizer also submits that the appellant conflates the section 2 requirement that an invention be useful with the section 27 requirement that the patent disclose the use to which the inventor conceived the invention would be put. It notes that the Supreme Court specifically warned against mixing up these two concepts in *Consolboard*, *supra*, as did this Court more recently in *Ranbaxy*, *supra*. In *Consolboard*, the Supreme Court specifically stated that the utility requirement is a "condition precedent to an invention", whereas the section 27 requirement is "a disclosure requirement, independent of the [utility requirement]" (*Consolboard*, at page 162).

2.(b) Utility: Does Study 350 actually disclose utility?

[54] The appellant argues that, as of the date of filing, Pfizer had neither demonstrated nor soundly predicted the utility of the invention. First, it argues that the Judge used the wrong standard of required utility. Second, it argues that the Judge should have come to a different conclusion based on the evidence.

[55] With respect to the standard of utility, the appellant argues that the Judge misdirected himself when he used the "mere scintilla" standard. It argues that the "mere scintilla" test applies

only where a patent does not promise a specific result. Where a patent promises a specific result, the invention must accomplish that result in order to demonstrate utility. Furthermore, the appellant argues that the Judge was not entitled to rely on *Wellcome* (FC), *supra*, for the proposition that utility in the context of patent law is a lower standard than utility in the context of testing for regulatory standards, as *Wellcome* (FC) was overturned by the Supreme Court in *Apotex Inc.* v. *Wellcome Foundation Ltd.*, 2002 SCC 77, [2002] 4 S.C.R. 153 [*Wellcome* (SCC)].

[56] As to the Judge's factual findings, the appellant argues that Study 350 did not in fact demonstrate utility in treating ED. The appellant characterizes Study 350 as merely a "pilot study" and notes that its sample size was limited to 16 patients. It points to evidence which shows that the purpose of the study was only a "preliminary assessment of the potential efficacy" of sildenafil. According to the appellant, one of Pfizer's experts, Dr. Brock, admitted on cross-examination that Study 350 was only intended to provide a "signal" that further research was required.

[57] The appellant also takes issue with the efficacy endpoints used in Study 350. The data obtained from patients' diaries failed to reach statistical significance, and the most that the RigiScan revealed was a statistically significant increase in duration of erections. The appellant also notes that RigiScan measurements showed that patients in the placebo group attained erections objectively measured to be sufficient for sexual intercourse, and they did so more often than those patients who were taking sildenafil, during the two-hour period of visual sexual stimulation. Furthermore, the appellant challenges the RigiScan data generally, noting that one of Pfizer's experts testified in cross-examination that it is "not a good predictor of therapeutic response." Finally, the appellant

points to admissions on cross-examination from two of Pfizer's experts, Drs. Gerald B. Brock and George Christ, that merely inducing an erection does not itself demonstrate efficacy in treating ED.

[58] Pfizer submits that the Judge was aware that the "mere scintilla" standard did not apply directly and appreciated the distinction. It further submits that the Supreme Court did not overrule that part of *Wellcome* (FC), *supra*, which dictated the difference between regulatory and patent utility standards. Pfizer also argues that there is not a high threshold for demonstrated utility and that utility means useful for the purpose claimed – not useful in the sense of commercial approval or acceptance.

[59] With respect to the Judge's factual findings, Pfizer argues that there is no palpable and overriding error. First, it submits that erections are indeed a clinically appropriate endpoint and cites expert testimony that a person skilled in the art would understand that a compound that induces erections is useful to treat ED.

[60] Second, Pfizer argues that the diary card evidence did not need to reach a level of statistical significance to be significant for the purpose of demonstrating utility. Statistical significance requires a p-value of 0.005 or lower. A p-value of 0.005 would mean that there is a 95 percent chance that the erections observed in the study were a result of the drug and not a random effect. The p-value actually observed was 0.0692. This means that there was a 93.1 percent chance that the results observed were not random. While this does not reach statistical significance, Pfizer argues it is nevertheless worthy of consideration.

[61] Third, Pfizer submits that the appellant's contentions regarding the small sample size of Study 350 are without substance, since small studies were common at the time and the Judge found that Pfizer accounted for small sample size in the p-values used to measure the results.

[62] Finally, Pfizer submits that much of the appellant's arguments are based on un-contextualized quotes from its expert, Dr. Brock. Pfizer states that the Judge had an opportunity to review the full transcript, and appreciated that Dr. Brock did not waiver from his conclusion that Study 350 demonstrated the utility of sildenafil in treating ED, but recognized that the Study, on its own, could not lead to regulatory approval.

ANALYSIS

[63] I will first consider the issue of disclosure: Was the Judge correct in concluding that the disclosure of the invention in the '446 Patent was sufficient pursuant to the requirements of subsections 27(3) and 27(4) of the Act? To answer this question, we must define the invention and then determine how it works.

1.(a) Disclosure: What is the relevant invention?

[64] This is a question of pure law. The dispute before us pertains to whether the invention is defined by the '446 Patent as a whole, or whether Claim 7 must be considered as a stand-alone invention. The Judge's Decision in regard to this point is reviewable on the standard of correctness (*Housen* v. *Nikolaisen*, [2002] 2 S.C.R. 235, 2002 SCC 33 [*Housen*] at paragraph 8).

[65] After careful consideration of this Court's decisions in *Apotex ACE* (FCA), *supra*, and *Boehringer, supra*, I conclude that the Judge was correct to limit the invention to that described in Claim 7.

[66] In *Boehringer, supra,* the patent addressed a class of "substituted morpholines." Claim 8 of the patent, however, was a claim for a specific compound, "2-phenyl-3-methylmorpholine." The specification did not mention 2-phenyl-3-methylmorpholine alone, but rather described "in general terms certain processes for the production of a class of substituted morpholines large enough to include many billions of them most of which have never been made or tested by anyone" (at 210). Thurlow J. (as he then was) of the Exchequer Court held as follows at page 214:

> As I view the matter, it becomes necessary because of the presence of claim 8 to read the specification not only to see what it says that refers to and describes an alleged invention of processes for the preparation of the class of substances but also to see what, if anything, it says that refers to and describes an invention of 2-phenyl-3-methyl morpholine and processes for its production. For, if the requirements of s. 36 of the Patent Act in respect of the description, etc., of the invention of 2-phenyl-3-methylmorpholine are complied with, the mere fact that the required information is mixed with and included as part of the description of another alleged invention will not by itself render claim 8 invalid.
>
> [Emphasis added]

[67] In *Apotex ACE* (FC), *supra*, Hughes J., albeit reluctantly, followed *Boehringer, supra*, and stated at paragraph 116:

> [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 linisopril, each of which, on the theory of those cases, is a different invention from the class. A higher court may be persuaded otherwise however, for jurisprudential integrity in this Court, I must find that the '340 application discloses separate inventions to each of the class, to linisopril, to enalapril and to enalaprilat.

[68] On appeal to this Court, in *Apotex ACE* (FCA), *supra*, Hughes J.'s reasoning was upheld, at paragraph 31, in the following terms:

> [31] Nowhere does [Justice Hughes] state that those cases stand for the broad proposition that each claim in a patent represents a separate invention. Rather, his holding is much narrower; namely, in cases as in the present, where a single patent application separately claims a class of chemical compounds and a single compound within that class, each separate claim discloses a separate invention.
>
> [Emphasis added]

[69] In the present matter, the Judge adopted the construction of Claim 7 of the '446 Patent endorsed by this Court in *Apotex-Viagra*, *supra*. Pursuant to this construction, 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.

[70] The appellant's attempt to distinguish between subsections 27(3) and 27(4) of the Act does not impact the appropriate approach to take. Paragraph 27(3)(*a*) provides that "[t]he specification of an invention must… correctly and fully describe the invention and its operation or use as contemplated by the inventor" [Emphasis added]. As to subsection 27(4), it states: "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." While it is true, as

the appellant argues, that the fact that a claim meets the requirements of subsection 27(4) does not necessarily mean the invention will meet the subsection 27(3) disclosure requirements, in this case, the two requirements are the same: Claim 7 is the invention. Therefore, when paragraph 27(3)(*a*) states that the invention must be fully described, it should be read as requiring that Claim 7 be fully described. In the patent, Claim 7 clearly states the formula for sildenafil and accordingly is clearly described.

[71] The interpretation of the relevant invention as Claim 7 rather than the ‘446 Patent as a whole also answers the appellant’s argument that the Judge misapplied the *Consolboard/Ranbaxy* test. The appellant argues that the Judge was not entitled to find that the patent was clear because Claim 7 was clear. However, the Judge was never actually required to find that the ‘446 Patent itself was clear. Rather, he was required to find that the ‘446 Patent clearly revealed the invention disclosed by Claim 7. He did so, and in so doing, he did not err.

[72] The appellant’s contention that best mode requirements apply is without merit. In *Sanofi*, *supra*, Snider J. carefully examined the Act and concluded, in my view correctly, as follows:

> [329] As can be seen from the words of the statute, the "best mode" obligation only arises in the case of a patent to a machine. Neither the words nor the underlying concept that a patentee must set out the best available manner of putting the invention into practice are used elsewhere in s. 34(1) or in the Patent Act.
>
> [330] Where Parliament has chosen to include a "best mode" obligation in respect of machine patents only, the courts must respect that choice. Accordingly, reading such a requirement into non-machine patents would be contrary to the principles of statutory interpretation.
>
> […]

> [332] I also note that the words of President Thorson in *Mineral Separation*, above, must be placed in context. President Thorson's words were obiter only; nowhere in the decision, did President Thorson apply the concept of best mode or good faith to his decision. Further, Justice Dickson's words referred to above, in the *Consolboard* decision, were addressed to the issue of sufficiency. In brief, I do not read either of these cases as importing a "best mode" requirement into a patent for a compound.

[73] In concluding as she did, Snider J. took note of the Supreme Court's decision in *Apotex Inc.* v. *Sanofi-Synthelabo Canada Inc.*, 2008 SCC 61, [2008] 3 S.C.R. 265, wherein Rothstein J. stressed the importance of fidelity to the Act, at paragraph 12:

> [12] At the outset, it is appropriate to refer to the words of Judson J. for this Court in *Commissioner of Patents v. Farbwerke Hoechst Aktiengesellschaft Vormals Meister Lucius & Braning*, [1964], S.C.R. 19, at p. 57:
>
> > There is no inherent common law right to a patent. An inventor gets his patent according to the terms of the Patent Act, no more and no less.
>
> The most recent reference to the law of patents being wholly statutory are the words of Lord Walker in *Synthon B.V. v. SmithKline Beecham plc*, [2006] 1 All E.R. 685, [2005] UKHL 59, at paras. 57-58:
>
> > The law of patents is wholly statutory, and has a surprisingly long history. In the interpretation and application of patent statutes judge-made doctrine has over the years done much to clarify the abstract generalities of the statutes and to secure uniformity in their application.
> >
> > Nevertheless it is salutary to be reminded, from time to time, that the general concepts which are the common currency of patent lawyers are founded on a statutory text, and cannot have any other firm foundation.

[74] I therefore conclude that the scope of disclosure requirements is limited to Claim 7. Consequently, the Judge was correct in finding that Claim 7 was the invention.

1.(b) Sufficiency of Disclosure: Given the determination of the invention, was there sufficient disclosure?

[75] This question is one of mixed fact and law, as the Judge was required to assess the evidence before him against a legal standard – sufficiency. The Judge's findings can only be overturned if he made a palpable and overriding error (*Housen, supra,* at paragraphs 28 and 36).

[76] For a patent to be valid, an invention must be sufficiently disclosed. The specification represents the bargain between the Crown on behalf of the public and the inventor (*Consolboard, supra*). Accordingly, the patent must contain enough information to allow a person skilled in the art to make the invention. The claims must be precisely laid out, without being overbroad. If the disclosure requirements are not met, the patent will be invalid even if it is new, useful and not obvious. These requirements for a patent specification are set out in subsections 27(3) and 27(4) of the Act.

[77] In my view, the Judge did not err. The invention herein is found in the compound disclosed in Claim 7, not in the patent as a whole. This approach clarifies the answers to the *Consolboard, supra,* questions: "What is your invention?" and "How does it work?" The invention is the compound in Claim 7. The Judge adopted Mosley J.'s construction of Claim 7 from *Apotex-Viagra, supra,* at paragraph 35, which this Court upheld on appeal at paragraph 11: "the use of sildenafil (or a salt thereof) in the form of an oral medicine for the treatment of erectile dysfunction in man" (Decision at paragraphs 40 and 41). Therefore, there is no difficulty in answering the first question:

the invention is the use of sildenafil to treat ED. The question “How does it work?” is answered by the rest of the patent, which describes the mechanism of action.

[78] Furthermore, the Judge also found that even if the ‘446 Patent were taken as a whole, a skilled reader would be able to narrow the range of listed compounds down to two: the “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 those two compounds worked. In this case, Claim 7 is the compound which works and Claim 7 does sufficiently and clearly describe sildenafil” (Decision at paragraph 146). Though the appellant argues that the Judge erred in coming to this finding, the Judge’s Decision clearly demonstrate that he turned his mind to the relevant expert evidence and came to a conclusion open to him on the evidence. Consequently, in my view, he made no palpable and overriding error.

[79] As to the appellant’s arguments regarding certain of the Judge’s comments, which the appellant labels “extraneous”, I have no difficulty agreeing with the Pfizer that these comments do not lead to a reviewable error. Pfizer correctly points out that the Judge was required to determine whether the disclosure was sufficient as of the date of filing. As a result, anything which occurred subsequent thereto is of no relevance. Nevertheless, in my view, the Judge’s comments, although misguided in the circumstances, do not form the basis of a reviewable error. As the relevant invention is the compound found in Claim 7, the disclosure is sufficient.

2.(a) Utility: Was the respondent required to demonstrate utility in the patent disclosure?

[80] I now turn to the second issue, whether the Judge was correct in concluding that the '446 Patent met the requirement of utility under section 2 of the Act, which requires that the subject matter of a patent be new and useful. The general principle is that, as of the relevant date (the date of filing), there must have been either demonstration of utility of the invention or a sound prediction of the utility. Evidence beyond that set out in the specification can and, normally, will be necessary.

[81] Whether or not Pfizer was required to include proof of utility in the patent is a question of law, and therefore reviewable on the standard of correctness (*Housen, supra,* at paragraph 8).

[82] I agree with Pfizer's submission and with the Judge's finding that there is no requirement for a patent to demonstrate utility in the patent disclosure, so long as the trier of fact finds it to be proven upon a legal challenge.

[83] On the one hand, I do not agree with the appellant's interpretation of *Eli Lilly, supra,* where this Court and the Federal Court were of the view that the invention was based on sound prediction. The focus of the debate was not on determining whether the invention demonstrated utility, but rather on determining the standard of disclosure required where a patent is based on sound prediction. Accordingly, *Eli Lilly* is not directed at determining the basis of utility but, rather, it is directed to determining whether, given the basis of sound prediction, an invention has in fact been soundly predicted.

[84] On the other hand, I cannot entirely accept Pfizer's interpretations of *Consolboard, supra,* and *Ranbaxy, supra*. In *Consolboard,* the Supreme Court addressed whether the patent was required to disclose the use to which the inventor intended the invention to be put: in other words, it differentiated between utility *qua* fulfilling what is promised and utility *qua* practical utility. That is why Justice Dickson (as he then was), at page 525, quoted from *Halsbury's Laws of England,* (3rd ed.), vol. 29, at p. 59, for the proposition that "the practical usefulness of the invention does not matter, nor does its commercial utility… " and concluded, at page 526, that the inventor:

> … must say what it is he claims to have invented. He is not obliged to extol the effect or advantage of his discovery, if he describes his invention so as to produce it.

[85] Similarly, in *Ranbaxy*, this Court addressed the subsection 27(3) disclosure requirements. There, I wrote as follows at paragraphs 56 and 57:

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

[86] The point of *Ranbaxy*, therefore, was not to dictate the section 2 utility requirements, but rather to elaborate on the section 27(3) disclosure requirements. *Ranbaxy* says that as far as disclosure requirements are concerned, the patentee need only provide enough information to allow

someone else to practice the invention; it does not state that the patentee must demonstrate utility in the patent.

[87] Although there is no jurisprudence dictating whether or not utility need be demonstrated in the patent disclosure, I am of the view that the answer is that it need not be demonstrated in the patent disclosure. First, there is nothing in the Act which leads one to conclude that such a demonstration is necessary. Second, there is no *a priori* reason to think that the patent disclosure should contain proof of all the elements required to obtain the patent. *Hughes &Woodley, supra*, describe the goal of the disclosure as follows at §25:

> The description of the invention… is to give the public adequate 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. In essence what is called for in the specification (including both disclosure and claims) is a description of the invention and the method of producing and constructing it, coupled with a claim or claims which state those novel features in which the applicant wants the exclusive right; the specification must define the precise and exact extent of the exclusive property and privilege claimed.

[88] In other words, the disclosure provides direction, not proof: it tells practitioners how to practice the invention. It does not prove to them its utility, though they can require proof through invalidity proceedings.

[89] Indeed, the Supreme Court's most recent decision on utility, *Wellcome* (SCC), *supra*, makes no mention of any requirement to prove utility in the disclosure. At paragraph 56 of his Reasons, Binnie J. wrote as follows:

> [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 available. If a patent sought to be supported on the basis of sound prediction is subsequently challenged, the challenge will succeed if, *per* Pigeon J. in *Monsanto Co.* v. *Commissioner of Patents*, [1979] 2 S.C.R. 1108, at p. 1117, the prediction at the date of the 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."

[90] The appellant's argument that Pfizer was required to include evidence of demonstrated utility in the patent disclosure is without merit. The requirements for demonstrated utility can be provided in evidence during invalidity proceedings as opposed to in the patent itself. So long as the disclosure makes reference to a study demonstrating utility, there do not appear to be any other requirements to fulfil section 2.

2.(b) <u>Utility: Does Study 350 actually disclose utility?</u>

[91] The question of whether the Judge used the wrong standard to determine utility is a question of law reviewable on a correctness standard. With respect to the Judge's ultimate conclusion, the appellant argues that "promised utility is a question of law," citing *Laboratoires Servier* v. *Apotex Inc.*, 2009 FCA 222, [2009] 74 C.P.R. (4th) 443. However, in my view, this is an incorrect reading of the case. At paragraph 101 of her Reasons for the Court, Layden-Stevenson J.A. made the following remarks:

> [101] Determining the promise of a patent is an aspect of claims construction, a question of law.

[92] As Pfizer points out, the case does not state that the question of whether or not an invention lives up to the promise contained in the patent is a question of law. To the contrary, in *French's*

Complex Ore Reduction Co. v. *Electrolytic Zinc Process Co.*, [1930] S.C.R. 462, Justice Rinfret wrote as follows at page 466:

> Whether in a particular case there is invention, novelty or utility is always a question of fact depending on the special circumstances and stands to be decided on the evidence of those having the technical skill and knowledge enabling them to understand the new art, machine, manufacture, process or composition of matter or the improvement thereon for which the patent was granted.

[93] Therefore, provided the Judge did not misdirect himself with respect to the appropriate test, his findings on utility can only be overturned in the presence of a palpable and overriding error.

[94] I am satisfied that the Judge did not commit a reviewable error. With respect to the standard of utility, the Judge stated that "usefulness, while essential for patentability, need only satisfy a low threshold" (Decision at paragraph 77). He then quoted from *Consolboard, supra*, which in turn cites *Halsbury's, supra,* for the proposition that practical utility does not matter. He then referred to paragraph 271 of *Aventis, supra,* where Mactavish J. stated: "In order to be patentable, an invention must be novel, inventive and useful. Where the specification does not promise a specific result, no particular level of utility is required – a 'mere scintilla' of utility will suffice" (Decision at paragraph 78). He later reiterated "As Mactavish J. stated in *Aventis, supra*, a 'scintilla of utility' is sufficient for the purposes of patentability" (Decision at paragraph 87).

[95] Although the Judge's pronouncements seem to denote some confusion on his part with regard to the appropriate standard of utility, this does not constitute a reviewable error. First, the Judge noted that apart from the "scintilla of utility" standard, there had to be evidence that the

invention produced that result, but that there was no requirement that the result be commercially useful. At paragraph 75 of his Decision, he then quoted the following passage from *Hughes and Woodley, supra*:

> §11. An essential condition to the validity of a patent is that the invention as claimed should possess utility…Utility means primarily that the invention, as described in the patent, will work in the manner as promised by the patent.

[96] Furthermore, the Judge found that "patients who received sildenafil showed a significant improvement in erectile function" [Emphasis added]. A finding of significant improvement is, in my view, an indication that the Judge found that there was more than a "scintilla of utility."

[97] The Judge was also correct in finding that an inventor is not required to meet regulatory testing standards in order to demonstrate utility. In support of that proposition, he adopted the view expressed by Wetston J. in *Wellcome* (FC), *supra*, at paragraph 104:

> [104] A&N argues that the standard of utility to which a pharmaceutical invention must be held is safety and effectiveness … In my opinion, these requirements are excessive in order for pharmaceuticals to be patentable and create too high a standard for a patent. Indeed, what would the effect of such a standard have on drug research?

[98] The appellant submits that the Supreme Court overruled Wetston J. on this point in *Wellcome* (SCC), *supra*, but the Court's Reasons show otherwise. At paragraph 77, Binnie J. wrote as follows:

> The appellants take issue with the trial judge's conclusion. In their factum … they argue that utility must be demonstrated by prior human clinical trials establishing toxicity, metabolic features, bioavailability and other factors. These factors track the requirements of the Minister of Health when dealing with a new drug submission to assess its "safety" and "effectiveness"…

> The prerequisites of proof for a manufacturer who wishes to market a new drug are directed to a different purpose than patent law. The former deals with safety and effectiveness. The latter looks at utility, but in the context of inventiveness. The doctrine of sound prediction, in its nature, presupposes that further work remains to be done.

[99] *Wellcome* (SCC) did not therefore overturn *Wellcome* (FC) on the required standard of utility. Furthermore, *Wellcome* is a case which pertains to the doctrine of sound prediction, in regard to which the appellant concedes that a higher standard of utility is required than where an inventor can point to demonstrated utility.

[100] Consequently, although the Judge may have misapplied the "mere scintilla" test because in the present matter, there had been a specific promise that sildenafil would work to treat ED, his error is, in the end, inconsequential. The Judge found that Study 350 revealed a "significant" improvement in treating ED. Furthermore, he correctly stated that the test for utility in this case was whether the invention did what it promised, and that the level of proof need not reach the level required by clinical testing. Accordingly, he found there to be more than a scintilla of utility, and so his error does not attract our intervention.

[101] As to the Judge's findings of fact, he explicitly turned his mind to all of the appellant's grounds of criticism: whether erections are an appropriate clinical endpoint, the utility of statistically insignificant diary data, and the RigiScan data. He held first that the RigiScan is the "best available tool for measuring the rigidity and duration of an erection, which is the only objective method of determining whether an erection is adequate for intercourse" (Decision at paragraph 86). He then addressed the problems relating to statistical significance, outlined above, and held that "[w]hile the

study may not have met the standards for regulatory approval, the Court is satisfied that it is sufficient for the purposes of establishing the demonstrated utility of the invention" (Decision at paragraph 88).

[102] I am of the opinion that these findings were open to the Judge on the record and that, as a consequence, he made no palpable and overriding error in determining that Study 350 disclosed utility.

DISPOSITION

[103] I would therefore dismiss the appeal with costs to Pfizer, both in this Court and in the Court below.

"M. Nadon"
J.A.

"I agree.
Pierre Blais C.J."

"I agree.
Johanne Trudel J.A.

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

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