Federal Court of Appeal | Cour d'appel fédérale

Date: 20140122

Docket: A-560-12

Citation: 2014 FCA 13

CORAM: **SHARLOW J.A.**
DAWSON J.A.
MAINVILLE J.A.

BETWEEN:

PFIZER IRELAND PHARMACEUTICALS

Appellant

and

APOTEX INC.

Respondent

Heard at Toronto, on October 15, 2013.

Judgment delivered at Ottawa, Ontario, on January 22, 2014.

REASONS FOR JUDGMENT BY: SHARLOW J.A.

CONCURRED IN BY: DAWSON J.A.
MAINVILLE J.A.

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REASONS FOR JUDGMENT

SHARLOW J.A.

[1] In the judgment under appeal (2012 FC 1339), Justice Zinn granted the motion of the respondent Apotex Inc. for summary judgment in its action to impeach Canadian Patent No. 2,163,446. Based on *Teva Canada Ltd. v. Pfizer Canada Inc.*, 2012 SCC 60, [2012] 3 S.C.R. 625 ("*Teva 2012*"), he declared that the 446 patent is invalid and is not infringed by the sildenafil tablets produced by Apotex. The judgment is appealed by Pfizer Ireland Pharmaceuticals ("Pfizer"), the registered owner of the 446 patent. For the following reasons, I would dismiss the appeal.

The 446 patent

[2] Pfizer and its affiliates have relied on the 446 patent for many years to protect the Canadian monopoly on sildenafil. It is the active medicinal ingredient in Viagra, a commercially successful drug used to treat erectile dysfunction. A licensed affiliate of Pfizer produces and sells Viagra in Canada pursuant to a notice of compliance issued in 1999 under the *Food and Drug Regulations*, C.R.C. 1978, c. 870.

[3] The title of the 446 patent is "Pyrazolopyrimidinones for the treatment of impotence". The application was filed in 1994. It issued on July 7, 1998 with an expiry date of May 13, 2014.

[4] The 446 patent contains 27 claims. In this appeal, the parties have addressed directly only Claims 5, 6 and 7, and by necessary implication the preceding claims upon which they are dependent. Neither party has suggested that anything in this appeal turns on Claims 8 through 27, or the disclaimers filed in respect of the 446 patent. For that reason, this discussion will refer only to claims 1 through 7.

[5] Claim 1, read literally, claims the use of:

> … a compound of formula (I) [the chemical description of which is stated] or a pharmaceutically acceptable salt thereof, or a pharmaceutical composition containing either entity, for the manufacture of a medicament for the curative or prophylactic treatment of an erectile dysfunction in a male animal or sexual dysfunction in a female animal.

[6] There are approximately 260 quintillion compounds included within Claim 1. Claims 2, 3, 4 and 5 are cascading claims based on Claim 1. That is, each of them claims the use according to Claim 1 for a group of compounds that is a subset of the group in the immediately preceding claim.

[7] The successively smaller groups of compounds are the "preferred group" (Claim 2 – approximately 60 billion compounds), the "more preferred group" (Claim 3 – approximately 1.8 million compounds), the "particularly preferred group" (Claim 4 – 768 compounds), and the "especially preferred group" (Claim 5 – nine compounds) (affidavit of Dr. Robert Gristwood, paragraphs 8.9 and 8.21, Appeal Book Volume II, pages 155 and 157).

[8] Claim 6 and Claim 7 each claim the same use for a single compound within the group of compounds described in Claim 4, or a pharmaceutically acceptable salt thereof.

[9] The single compound specified in Claim 6 is designated UK-114,542. The single compound specified in Claim 7 is sildenafil. UK-114,542 and sildenafil are among the nine compounds listed in Claim 5.

Teva 2012

[10] There has been much litigation relating to the 446 patent. However, for the purpose of this appeal the most important case is *Teva 2012*.

[11] *Teva 2012* originated with proceedings in which a corporate predecessor of Teva Canada Ltd. ("Teva"), a generic drug manufacturer, filed with the Minister of Health an abbreviated new

drug submission under the *Food and Drug Regulations* in which Teva sought a notice of compliance for its generic version of Viagra.

[12] As permitted under the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 (the *NOC Regulations*), Teva served Pfizer and certain of its affiliates (collectively, the "Pfizer group") with a notice of allegation that the 446 patent was invalid on the basis of obviousness, lack of utility, and insufficient disclosure. That prompted the Pfizer group to commence an application under the *NOC Regulations* for an order prohibiting the Minister from issuing a notice of compliance for the Teva generic version of Viagra until after the expiry of the 446 patent.

[13] The application was granted by the Federal Court on June 18, 2009, with the result that Teva was unable to receive its notice of compliance (2009 FC 638). Teva appealed to this Court, without success (2010 FCA 242, [2012] 2 F.C.R. 69). Teva then sought and obtained leave to appeal to the Supreme Court of Canada. Teva's appeal was allowed on November 8, 2012. Within a day, the Minister issued notices of compliance for sildenafil drugs to Teva and to a number of other drug manufacturers, including Apotex.

[14] Teva was successful in *Teva 2012* because the Supreme Court of Canada concluded that Teva's allegation of invalidity on the basis of insufficient disclosure was justified. The reason for that conclusion is encapsulated in paragraph 5 of the reasons of Justice LeBel, writing for the Court:

> 5. At the time of Pfizer's patent application, Pfizer had conducted tests that demonstrated that sildenafil was effective in treating [erectile dysfunction]. 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" […], 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 [erectile dysfunction].

[15] I summarize as follows the reasoning of Justice LeBel in support of the conclusion that the 446 patent was invalid because of insufficient disclosure:

Principles

(a) The patent system is based on a bargain in which the inventor is granted exclusive rights to a new and useful invention for a limited period in exchange for disclosing the invention so that society can benefit from the knowledge when that period expires (*Apotex Inc. v. Wellcome Foundation Ltd.*, 2002 SCC 77, [2002] 4 S.C.R. 153, at paragraph 37, and *Consolboard Inc. v. MacMillan Bloedel (Sask.) Ltd.*, [1981] 1 S.C.R. 504, at page 523).

(b) The bargain underlying the patent system is reflected in subsections 27(1) to 27(3) of the *Patent Act*, R.S.C. 1985, c.P-4. The disclosure requirement is stated in subsection 27(3), which reads in relevant part as follows:

27. (3) The specification of an invention must	**27.** (3) Le mémoire descriptif doit :
(*a*) correctly and fully describe the invention and its operation or use as contemplated by the inventor;	*a*) décrire d'une façon exacte et complète l'invention et son application ou exploitation, telles que les a conçues son inventeur;
(*b*) set out clearly the various steps	*b*) exposer clairement les diverses

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;	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*) 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	*c*) s'il s'agit d'une machine, en expliquer clairement le principe et la meilleure manière dont son inventeur en a conçu l'application ;
(*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.	*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.

(c) Adequate disclosure in the specification is a precondition for the granting of a patent (*Eli Lilly Canada Inc. v. Apotex Inc*., 2008 FC 142, at paragraph 74).

(d) Where the sufficiency of a patent disclosure is challenged, the question to be asked is whether the public is getting the information it needs to be getting in exchange for the exclusive monopoly rights.

(e) The leading case on the sufficiency of disclosure is *Consolboard* (cited above), confirmed by the Supreme Court of Canada in *Monsanto Canada Inc. v. Schmeiser*, 2004

SCC 34, [2004] 1 S.C.R. 902, at paragraph 18, *Whirlpool Corp. v. Camco Inc.*, 2000 SCC 67, [2000] 2 S.C.R. 1067, at paragraph 52, and *Pioneer Hi-Bred Ltd. v. Canada (Commissioner of Patents)*, [1989] 1 S.C.R. 1623 at page 1636. The principles in *Consolboard* should be applied in this case.

(f) *Consolboard* establishes 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 the disclosure was sufficient.

(g) *Consolboard* also establishes (at page 520, citing *Minerals Separation North American Corp. v. Noranda Mines, Ltd.*, [1947] Ex. C.R. 306) that the disclosure is sufficient if the public, using only the specification, can make the same use of the invention as the inventor. A similar statement appears in *Pioneer Hi-Bred* (cited above) at page 1638.

(h) Contrary to the statements in the courts below, *Consolboard* does not stand for the proposition that in determining the sufficiency of the disclosure, the only relevant questions are "What is your invention?" and "How does it work?"

Application of the principles in the Teva 2012 case

(i) It does not matter that Claim 1 includes 260 quintillion compounds. The practice of cascading claims, even if it results in claims that are overly broad, does not necessarily interfere with the public's right to disclosure. The skilled reader knows that when a patent contains cascading claims, the useful claim usually is the one at the end of the cascade that

names a single compound. Provided the disclosure is sufficient, section 58 of the *Patent Act* ensures that any valid claim survives despite the existence of invalid claims.

(j) Since Pfizer had conducted tests that demonstrated that sildenafil was effective in treating erectile dysfunction, and none of the other compounds in the 446 patent had been shown to be effective in doing so, the invention was the use of sildenafil for the treatment of erectile dysfunction. That is what had to be disclosed in order to meet the requirements of subsection 27(3) of the *Patent Act*.

(k) However, that disclosure was not made. The 446 patent includes the statement that "one of the especially preferred compounds induces penile erection in impotent males", but the specification does not say that sildenafil is the effective compound, that Claim 7 contains the effective compound, or that the remaining compounds in the patent had not been found to be effective.

(l) Whether or not a specification is sufficient depends on what a skilled person would consider to be sufficient. Expert evidence in this case reveals that there was no basis for a skilled person to determine which of Claim 6 or Claim 7 describes the compound found to be useful in treating erectile dysfunction. 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.

(m) Even if a skilled reader could have discerned that the effective compound must be one of the two compounds named in Claim 6 and Claim 7, further testing would have been required to determine which of the two was actually effective. On the facts as found by the trial judge, that would require a minor research project.

(n) The public's right to sufficient disclosure was denied in this case because the claims ended with two individually claimed compounds, obscuring the true invention. Pfizer gained a benefit from the *Patent Act* — exclusive monopoly rights — while withholding disclosure as required by the *Patent Act*. Therefore, the question as to whether the disclosure was sufficient must be answered in the negative.

The *Teva 2012* remedy

[16] The formal order in *Teva 2012* as originally issued read as follows (Bulletin of Proceedings, Supreme Court of Canada, November 9, 2012, page 1728):

The appeal from the judgment of the Federal Court of Appeal, Number A-292-09, 2010 FCA 242, dated September 24, 2010, heard on April 18, 2012, is allowed with costs and Patent 2,163,446 is declared void.	L'appel interjeté contre l'arrêt de la Cour d'appel fédérale, numéro A-292-09, 2010 CAF 242, en date du 24 septembre 2010, entendu le 18 avril 2012, est accueilli avec dépens et le brevet 2,163,446 est déclaré nul.

[17] The declaration of invalidity was surprising because the appeal originated with an application for a prohibition order under the *NOC Regulations*. There is a long and consistent line of jurisprudence to the effect that such a proceeding cannot, as a matter of law, result in a final determination as to the validity or infringement of a patent. The earliest authorities are *Merck Frosst*

Canada Inc. v. Canada (Minister of National Health and Welfare) (1994), 55 C.P.R. (3d) 302 (F.C.A.) and *David Bull Laboratories (Canada) Inc. v. Pharmacia Inc.*, [1995] 1 F.C. 588 (F.C.A.), both cited with approval in *Eli Lilly & Co. v. Novopharm Ltd.; Eli Lilly & Co. v. Apotex Ltd.*, [1998] 2 S.C.R. 129, at paragraphs 95 to 97.

[18] On November 9, 2012, the day after the issuance of *Teva 2012*, the Pfizer affiliates filed a motion in the Supreme Court of Canada to seek amendments to the reasons and the formal order, essentially to give effect to the jurisprudence mentioned in the previous paragraph. The motion was granted in part by an order dated June 4, 2013. The amendment to the formal order is described in paragraph 5 of the amending order, which reads as follows (Bulletin of Proceedings, Supreme Court of Canada, June 14, 2013, at page 1098-9):

5. The formal order is amended to read as follows: "The appeal from the judgment of the Federal Court of Appeal, Number A-292-09, 2010 FCA 242, dated September 24, 2010, heard on April 18, 2012, is allowed with costs and Teva having established its allegation that Patent 2,163,446 is not valid, the application of Pfizer for an order of prohibition under s. 55.2(4) of the *Patent Act*, R.S.C. 1985, c. P-4, and s. 6 of the *Patent Medicines (Notice of Compliance) Regulations*, SOR/93-133, is dismissed" ….	5. « L'appel du jugement de la Cour d'appel fédérale, numéro A-292-09, 2010 CAF 242, en date du 24 septembre 2010, entendu le 18 avril 2012, est accueilli avec dépens et, Teva ayant fait la preuve de son allégation portant que le brevet 2 163 446 n'est pas valide, la demande de Pfizer pour que soit prononcée une ordonnance d'interdiction en application du par. 55.2(4) de la *Loi sur les brevets*, L.R.C. 1985, ch. P-4, et de l'art. 6 du *Règlement sur les médicaments brevetés (avis de conformité)*, DORS/93-133, est rejetée. »

The impeachment action of Apotex

[19] On May 13, 2009, Apotex filed a statement of claim seeking, among other things, a declaration that the 446 patent is invalid and that its sildenafil tablets will not infringe any valid claim of the 446 patent. The statement was amended several times, most recently on September 7, 2012. The statement of claim as it read on September 7, 2012 asserts numerous grounds for impeaching the 446 patent, but for the purpose of this appeal it is enough to say that Apotex alleges insufficient disclosure. Pfizer defended the claim on all grounds, specifically disputing the claim that the disclosure is insufficient. The trial was scheduled to begin on November 26, 2012.

The summary judgment motion

[20] On November 9, 2012, the day after the issuance of the initial judgment in *Teva 2012*, Apotex filed a motion in the Federal Court seeking summary judgment of its action to impeach the 446 patent, relying on *Teva 2012*. The order granting that motion is the order now under appeal.

[21] A respondent opposing a motion for summary judgment must present evidence aimed at establishing that there is a genuine issue for trial (*MacNeil Estate* v. *Canada (Department of Indian and Northern Affairs)*, [2004] 3 F.C.R. 3, 2004 FCA 50, at paragraph 25, citing what was then Rule 215 and is now Rule 214). In this case, it was incumbent on Pfizer to adduce evidence capable of establishing that the sufficiency of the disclosure in the 446 patent cannot fairly be determined without a trial.

[22] That is what Pfizer attempted to do, but without success. The judge concluded that he was bound by *Teva 2012* to find the 446 patent invalid because the disclosure is insufficient whether or

not the Supreme Court of Canada amended its judgment and removed the declaration of invalidity, as it eventually did.

[23] The issue for this Court is whether the judge erred in law or misapplied the test for summary judgment when he concluded as he did. For the following reasons, I have concluded that the judge made no error warranting the intervention of this Court.

Analysis

[24] Pfizer argues that *Teva 2012* is based on a particular construction of the 446 patent which cannot be conclusive for all purposes because, in the context of an application under the *NOC Regulations* for a prohibition order, any conclusion on the construction of the patent is necessarily provisional. I agree, based on the authorities cited above in paragraph 17 (*Merck Frosst* (F.C.A. 1994), *David Bull* (F.C.A. 1995), *Eli Lilly* (S.C.C. 1998)).

[25] However, to establish that there is a triable issue with respect to the construction of the 446 patent, it was incumbent on Pfizer to adduce evidence or to refer to evidence already adduced in this matter. In particular, Pfizer should have adduced or referred to evidence that addresses how the skilled reader would construe the specification, and why that construction casts doubt on the correctness of the construction adopted in *Teva 2012*. The record contains no such evidence.

[26] Pfizer points to evidence that UK-114,542, the compound named in Claim 6, was in fact tested before the Canadian filing date and found to be useful for treating erectile dysfunction. However, what the patent discloses is that as of the filing date studies had confirmed that one of the

compounds in the especially preferred group induces penile erection in impotent males. There is no disclosure that UK-114,542 was tested, and Pfizer has adduced no evidence that is capable of establishing that the skilled reader should have discerned from the specification that it was tested. Therefore, evidence that UK-114,542 was tested is not capable of establishing a genuine issue for trial on the question of the sufficiency of the disclosure.

[27] Pfizer pointed out in argument that it had little time to gather evidence to respond to the summary judgment motion. I note that this is not a ground of appeal that is before this Court. However, even if it were, I would reject it. The summary judgment motion was made in November of 2012. The argument in the Supreme Court of Canada in *Teva 2012* was heard in April of 2012, and Pfizer was a party to that proceeding. The issue of the sufficiency of disclosure appears in the latest version of the statement of claim in this case, which was filed in September of 2012. Therefore, for a considerable time before the summary judgment motion was made, it should have been apparent to Pfizer that it could be a problem that the disclosure in the 446 patent does not mention the testing of UK-114,542.

Relevant date for determining the sufficiency of the disclosure

[28] The argument of the parties discloses a possible debate as to whether the relevant date for determining the sufficiency of the disclosure is the date of the Canadian patent application, or the date on which the patent application becomes public. That issue was not fully argued in the parties' memoranda of fact and law, and additional written submissions were requested and received. However, given my conclusion that the state of the record on the status of tests conducted on UK-

114,542 is incapable of establishing a genuine issue for trial on the question of the sufficiency of the disclosure, I do not consider it necessary in this appeal to attempt to resolve that debate.

Conclusion

[29] For these reasons, I would dismiss the appeal with costs.

"K. Sharlow"
J.A.

"I agree
Eleanor R. Dawson J.A."

"I agree
Robert M. Mainville J.A."

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKET: A-560-12

(APPEAL FROM A JUDGMENT OR ORDER OF JUSTICE ZINN OF THE FEDERAL COURT DATED NOVEMBER 20, 2012 (DOCKET NUMBER T-772-09))

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DATED:	JANUARY 22, 2014

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