Federal Court  Cour fédérale

Date: 20140128

Docket: T-609-12

Citation: 2014 FC 38

Ottawa, Ontario, January 28, 2014

PRESENT: The Honourable Mr. Justice Harrington

BETWEEN:

PFIZER CANADA INC.
AND G.D. SEARLE & CO.

Applicants

and

MYLAN PHARMACEUTICALS ULC
AND THE MINISTER OF HEALTH

Respondents

PUBLIC REASONS FOR ORDER
(Identical to Confidential Reasons for Order Issued January 14, 2014)

"Ah, but a man's reach should exceed his grasp. Or what's a heaven for?"
(Robert Browning)

[1] This case is about whether a promise was made and, if so, whether it was kept. Did Canadian Patent No. 2,177,576 ('576) promise that Celecoxib, better known under the brand name Celebrex®, would be useful in significantly reducing harmful side effects in humans, as compared to other Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)? If so, and if it has now been established that that promise has not been met, then for the purposes of this application

under the *Patented Medicine (Notice of Compliance) Regulations*, Mylan's allegation that the patent is not useful is justified. It follows that the Minister, who took no part in these proceedings, shall not be prohibited from issuing Mylan a Notice of Compliance which would allow it to market its generic version of Celecoxib before the expiry of patent '576.

[2] Conversely, if that promise was not made, Mylan's allegation of inutility would not be justified, and the Minister shall be prohibited from issuing it a Notice of Compliance before the expiry of the patent.

[3] To be patentable, an invention must be both new and useful. However, its usefulness need not be demonstrated. It is sufficient that its usefulness be promised, provided that there is a sound basis for making that prediction. If, over the course of time, it turns out that the prediction was wrong, then the patent is invalid.

[4] It is not in issue that Celebrex® is both new and useful in the treatment of inflammation. Mylan asserts, however, that the patent also promised to be useful in significantly reducing harmful side effects in humans. According to Mylan, the evidence has now established that that promise has not been met. It follows that the patent is invalid. Consequently, it should be permitted to market its own version of Celecoxib.

[5] For their part, Pfizer and Searle say:

a. the patent did not promise the invention would be useful in significantly reducing harmful side effects;

b. alternatively, if it did, that promise did not extend to humans; and

c. in any event, the evidence establishes that Celebrex® in fact has significantly reduced harmful side effects in humans.

[6] For almost two years now, Mylan has been thwarted by Pfizer and Searle in its efforts to obtain regulatory approval to market its generic version of Celecoxib. It filed an Abbreviated New Drug Submission with the Minister of Health so as to obtain the required Notice of Compliance. It claims that its product is the bioequivalent of Celebrex®, a point not before the Court in this application.

[7] Pfizer, as successor to *G.D. Searle and Co.*, the patent holder, had submitted Canadian Patent No. 2,177,576 ('576) to the Minister for listing on the Register of Patents maintained under the *Patented Medicine (NOC) Regulations*

[8] In order to obtain a Notice of Compliance before the expiry of the patent on 14 November 2014, Mylan was first required to file and serve a Notice of Allegation under s. 5 of the Regulations. It gave notice that the patent was invalid.

[9] Pfizer responded by filing a Notice of Application in this Court on 23 March 2012 for an order prohibiting the Minister from issuing a Notice of Compliance until the patent expires.

[10] Under the *Patented Medicine (NOC) Regulations*, this application has the effect of enjoining the Minister from issuing a NOC for two years or until the Court declares that the

patent is invalid or will not be infringed. The process is complicated and counterintuitive. It is well known to those in the pharmaceutical industry and need not be set out in detail here. Reference is made to the decisions of the Supreme Court in *Merck Frosst Canada Inc v Canada (Minister of National Health and Welfare)*, [1998] 2 SCR 193, 80 CPR (3d) 368, [1998] SCJ No 58 (QL); *Bristol-Myers Squibb Co v Canada (Attorney General)*, 2005 SCC 26, [2005] 1 SCR 533, 39 CPR (4th) 449, [2005] SCJ No 26 (QL) at paras 5-24 (*Biolyse*) and *Apotex Inc v Sanofi-Synthelabo Canada Inc.*, 2008 SCC 61, [2008] 3 SCR 265, 69 CPR. (4th) 251, [2008] SCJ No 63 (QL) at paras 7 and 12-17, as well as to the decision of Mr. Justice Hughes in *Ferring Inc v Canada (Health)*, 2007 FC 300, 55 CPR (4th) 271, [2007] FCJ No 420(QL).

[11] The stage was set and the issues were framed by Mylan in its Notice of Allegation. As it only alleged invalidity, the legally rebuttable presumption under s. 43(2) of the *Patent Act* must be kept in mind. It provides that "after the patent is issued, it shall, in the absence of any evidence to the contrary, be valid…" This is not a particularly strong presumption.

[12] Thus, although the burden is upon the applicants to prove, on the balance of probabilities, that Mylan's allegations are not "justified"; given the presumption of the patent's validity, Mylan should, at the very least, lead evidence to put validity in play (*Abbott Laboratories v Canada (Health)*, 2007 FCA 153, 59 CPR (4th) 30, [2007] FCJ No. 543 (QL) and *Pfizer Canada Inc. v. Apotex Inc.*, 2007 FC 971, 61 CPR (4th) 305, [2007] FCJ No 1271 (QL) per Mr. Justice Mosley at paras 44-51).

[13] Another issue in this case is abuse of process. According to Mylan, it does not lie in Pfizer's mouth to assert that the patent did not promise reduced side effects in humans. That point, it says, was decided in *G. D. Searle & Co v Novopharm Limited,* 2007 FC 81, 56 CPR (4th) 1, [2007] FCJ No 120 (QL). Mr. Justice Hughes held that the utility of the '576 patent was "the duality of treatment of inflammation and reduction of unwanted side effects such as ulcers of the gastrointestinal system."(para 27) Although he found that Novopharm's allegations as to invalidity were not justified, other allegations were justified, and so the Minister was not prevented from issuing a Notice of Compliance. Mr. Justice Hughes was reversed on those other issues by the Federal Court of Appeal, 2007 FCA 173, 58 CPR (4th) 1,[2007] FCJ No 625 (QL), but his findings with respect to utility were not disturbed.

[14] Mylan submits that Pfizer is attempting to relitigate, which constitutes an abuse of process. It relies on *Toronto (City) v C.U.P.*E., *Local 79,* 2003 SCC 63, [2003] 3 SCR 77, [2003] SCJ No 64 (QL), which was applied by the Federal Court of Appeal in PM (NOC) Proceedings in *Sanofi-Aventis Canada Inc v Novopharm Limited,* 2007 FCA 163, 59 CPR (4th) 416, [2007] FCJ No 548 (QL). The Court of Appeal held that in NOC proceedings, the innovator must put his best foot forward. If it does not first succeed with the first generic, it cannot relitigate the same issue with a second generic.

I. Background

[15] Celecoxib, which I shall call Celebrex, is a NSAID (non-steroidal anti-inflammatory drug). The first NSAID was Aspirin, developed over a century ago. Ibuprofen is another NSAID,

marketed under such well-known names as Advil and Motrin. Still another, of the many, is Naproxen, one brand name of which is Aleve.

[16] Inflammation is caused by prostaglandins which the body produces as an aid in healing. However, they also cause pain. Prostaglandins are produced by the enzyme cyclooxygenase (COX). Prostaglandins not only promote inflammation and pain, but also protect the stomach from the acid therein. NSAIDs inhibit the COX enzymes. They therefore not only reduce inflammation and pain, but also leave the stomach vulnerable to the acids therein, which can lead to ulcers and internal bleeding.

[17] It was discovered in the 1970s that there are in fact two cyclooxygenases, now known as COX-1 and COX-2. While COX-1 is ever present, COX-2 is only generated when there is an injury or an inflammation, such as arthritis. The theory is that if one could inhibit COX-2, while leaving COX-1 alone, there would be fewer side effects than with the traditional NSAIDS, which are non-selective in the sense that they attack both COX-1 and COX-2.

[18] This led to the development of Celebrex®.

II. The Patent

[19] The ‘576 patent is titled *Substituted Pyrazolyl Benzenesulfonamides for the Treatment of Inflammation*.

[20] The application for the patent was filed 14 November 1994. It was issued 26 October 1999 and, as mentioned above, expires 14 November 2014.

[21] In its Notice of Allegation, Mylan did not allege that the patent is invalid for treatment of symptoms associated with such conditions as osteoarthritis and adult rheumatoid arthritis. Rather, it alleges that the patent also promised, to use the words of the patent, "the additional benefit of having significantly less harmful side effects." For the purpose of its Notice, Mylan does not contest that Searle had a sound basis for predicting that Celebrex® would have significantly less harmful side effects. However, it says that it has not met that promise. It alleges that it has now been proven that Celebrex® does not have significantly less side effects. It follows that the patent is invalid. Thus, this is a case of patent construction.

[22] The invention, for which the patent was issued, is described in a specification which is 194 pages in length. It ends with 16 claims.

[23] Subsections 27(3) and (4) of the *Patent Act* provide in part:

(3) The specification of an invention must	(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 in a process, or the method of constructing, making, compounding or using a machine, manufacture or	b) exposer clairement les diverses phases d'un procédé, ou le mode de construction, de confection, de composition ou d'utilisation d'une machine,

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; […]	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; …
(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.

It is not alleged that the specification fails to set out clearly what is required to enable the skilled addressee to make Celebrex®.

[24] Nearly all of the specification is incomprehensible except to the skilled readers to whom it is addressed. Chemical formulas after chemical formulas are described in detail, and some 262 examples are given.

[25] The specification is broken down as follows:

Field of the invention	Page 1
Background of the invention	Pages 1-3
Description of the invention	Pages 4-63
General synthetic procedures	Pages 64 and 175
Biological evaluation	Pages 175-183
Claims	Pages 184-194

[26] However, only a few pages of the patent are in issue. At first glance, they appear to be in perfectly comprehensible English.

[27] The Field of the Invention is described as:

> This invention is in the field of anti-inflammatory pharmaceutical agents and specifically relates to compounds, compositions and methods for treating inflammation and inflammation-associated disorders, such as arthritis.

[28] In the background of the invention, it is stated that:

> Thus, use of high doses of most common NSAIDs can produce severe side effects, including life threatening ulcers, that limit their therapeutic potential. An alternative to NSAIDs is the use of corticosteroids, which have even more drastic side effects, especially when long term therapy is involved.
>
> Previous NSAIDs have been found to prevent the production of prostaglandins by inhibiting enzymes in the human arachidonic acid/prostaglandin pathway, including the enzyme cyclooxygenase (COX). The recent discovery of an inducible enzyme associated with inflammation (named "cyclooxygenase II (COX II)" or "prostaglandin G/H synthase II") provides a viable target of inhibition which more effectively reduces inflammation and produces fewer and less drastic side effects.

[29] In the Description of the Invention portion of the specification, in a very lengthy paragraph, it is stated that: "Compounds of Formula I would be useful for […] the treatment of inflammation in a subject". Various examples are given such as the treatment of several forms of arthritis, asthma, bronchitis, menstrual cramps, eczema, gastrointestinal conditions, type I diabetes, and the list goes on.

[30] The paragraph ends as follows: "The compounds are useful as antiinflammatory agents, such as for the treatment of arthritis, with the additional benefit of having significantly less harmful side effects."

[31] Mylan places great emphasis on the "additional benefit".

[32] As much as Mylan emphasizes that paragraph, Pfizer and Searle rely on the next paragraph which states that the invention preferably includes compounds which selectively inhibit COX-2 over COX-1: "Such preferred selectivity may indicate an ability to reduce the incidents of common NSAID-induced side effects." (My emphasis)

[33] Under its Biological Evaluation heading, the specification describes *in vivo* and *in vitro* tests. The *in vivo* testing was on rats. The *in vitro* evaluation was based on either human or murine (mouse) cloned enzymes.

[34] Of the 16 claims, claims 4 and 8 through 13 are at issue. Claim 4 claims Celecoxib or Celebrex®, itself. Claims 8 through 13 claim the use of Celebrex® for inflammation or inflammation-associated disorders, arthritis and pain. There is no mention of reduced side effects.

III. Some Principles of Patent Construction

[35] Although letters patent are strictly a matter of statute, statutes in one form or another in England and in Canada have been in place for centuries. It is inevitable that the courts have developed canons of construction, some of which are relevant to the present application.

[36] One of the prerequisites of the issuance of letters patent is that the invention be useful. However, no particular utility need be claimed. An objective scintilla of utility will suffice. On the other hand, if a particular utility is claimed, the invention had better deliver. The utility asserted need not be demonstrated. It suffices if it is promised. However, not every promise will do. The promise must not be speculative. It must be based on a sound prediction. The leading case is *Apotex Inc v Wellcome Foundation Ltd*, 2002 SCC 77, [2002] 4 SCR 153, [2002] SCJ No78 (QL) (AZT).

[37] It was held in AZT that the inventor must establish utility as of the date the patent is applied for, either by demonstration or by sound prediction based on the information and expertise then available. The doctrine of sound prediction has three components:

a. there must be a factual basis for it;

b. the inventor must have had at that time an articulate and "sound" line of reasoning from which the desired result can be inferred from the factual basis; and

c. there must be proper disclosure.

[38] Mylan asserts that the patent application did not demonstrate, but rather promised reduced side effects in humans. It does not dispute that as of the time of the patent application in 1994, there was a sound basis for predicting such utility. However, it says the promise has not been met.

[39] If a sound prediction has "subsequently been shown to be wrong, the patent would have been invalidated for want of utility." (AZT, para 76)

[40] Since the soundness of a prediction is a question of fact (AZT), this leads to another principle of patent construction, the skilled addressee.

[41] While an invention in the world of pharmaceuticals may be intended to treat human frailties of one sort or another, utility under the *Patent Act* and utility for the purposes of obtaining food and drug regulatory approval for administration of the invention to humans are two separate things. As Mr. Justice Binnie noted at para 77 of AZT, regulatory approval:

> […] deals with safety and effectiveness. The later 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.

[42] The patent is notionally addressed to a person skilled in the art or science of the subject matter and is read as such a person would have read it when it first became public:

> The involvement in claims construction of the skilled addressee holds out to the patentee the comfort that the claims will be read in light of the knowledge provided to the court by expert evidence on the technical meanings of the terms and concepts used in the claims. (*Free World Trust v ÉlectroSanté Inc.*, 2000 SCC 66, [2000] 2 SCR 1024, [2000] SCJ No (QL) at para 51)

> and
>
> The key to purposive construction is therefore the identification by the court, with the assistance of the skilled reader, of the particular words or phrases in the claims that describe what the inventor considered to be the "essential" elements of his invention. (*Whirlpool Corp. v Camco Inc.*, 2000 SCC 67, [2000] 2 SCR 1067, para 45)

[43] The patent specification contains a disclosure followed by the claims over which a monopoly is sought. The claim portion of the patent specification takes precedence over the disclosure portion in the sense that the disclosure is read to understand what is meant by a word in the claims "but not to enlarge or contract the scope of the claim as written and thus understood" (*Whirlpool,* para 52).

[44] In the same vein, as stated in *Whirlpool* at para 42: "An inventor is not obliged to claim a monopoly on everything new, ingenious and useful disclosed in the specification. The usual rule is that what is not claimed is considered disclaimed."

[45] When the patent is issued, it is not just another "writing". It is an enactment within the definition of "regulation" in s. 2(1) of the *Interpretation Act* (*Whirlpool*, para 49(e)):

> Claims construction is a matter of law for the judge, and he was quite entitled to adopt a construction of the claims that differed from that put forward by the parties. (*Whirlpool*, para 61)

IV. Skilled Addressee

[46] "[…] The inventor must, in return for the grant of a patent, give to the public an adequate description of the invention with sufficiently complete and accurate details as will enable a workman, skilled in the art to which the invention relates, to construct or use that invention when the period of the monopoly has expired." (Fox, *Canadian Patent Law and Practice*, (4th ed), page 163, as quoted by Mr. Justice Dickson, as he then was, in *Consolboard Inc. v MacMillan Bloedel (Saskatchewan) Ltd.*, [1981] 1 SCR 504, at p 517)

[47] Not much was said by the parties about the skilled addressee, perhaps because the language in issue is not technical, although words which have a certain meaning in ordinary parlance, may take on a different meaning to a skilled reader in a particular context.

[48] In its Notice of Allegation, Mylan states that inasmuch as the '576 patent relates to the synthesis of a new class of compounds, the skilled addressee is a medicinal chemist in a team with a biologist and/or biochemist and would have input from a formulator and pharmacologist. In terms of the specific side effect profile, it is directed to an experienced prescribing clinician or research scientist with training in epidemiology with at least a PhD and/or an MD, and well-versed with anti-inflammatory medications.

[49] It its Memorandum of Argument, Pfizer does not deal with the skilled addressee, although two of the experts it called, Professor Robert N. Young and Doctor Stephen B. Abramson, do, as do Professor John L. Wallace and Doctor Sanford H. Roth, called by Mylan.

[50] In its Memorandum of Fact and Law, Mylan accurately describes the situation at para 51:

> **Person Skilled in the Art:** The parties agree that the skilled person in the art includes a chemist and pharmacologist with experience pertaining to anti-inflammatory drugs and COX. Mylan includes a clinician treating arthritis within the definition, but Pfizer does not.

[51] In oral argument, Pfizer reiterated that it did not think the patent was addressed to a medical doctor, as they are not in the habit of reading patents. However, nothing turns on this point as it has not been said that a medical doctor would read the patent any differently from a medicinal chemist.

V. The Promise of the Patent

[52] Nearly all of the evidence filed and oral argument focused on whether Celebrex® significantly reduces harmful side effects in humans, compared to other NSAIDs. No evidence was led as to whether it reduces side effects in other mammals. As to the promise of the patent, as considered by a skilled addressee, the position of the parties is best set out in the evidence of Professor John L. Wallace and Professor Robert N. Young.

[53] Professor Wallace, called by Mylan, is a professor of pharmacology and therapeutics at the Department of Medicine at McMaster University. He is considered an expert in pharmacology with an emphasis on NSAIDs and the mechanism of gastrointestinal injury and repair. He read the patent as addressing a problem and describing a solution. The problem was that traditional or non-selective NSAIDs could create severe side effects at high doses, including life threatening ulcers. The solution was that selective inhibition of COX-2 would produce fewer

and less drastic side effects than other NSAIDs. The heart of his opinion is found at para 73 of his affidavit:

> Although I understand that my views are not determinative, I think this patent does contain a promise of "significantly less harmful side effects". Otherwise, the patent would merely be offering another in a large class of compounds in a crowded field. My view is based on my recollection of the prevailing side effect challenges that existed at the time of the patent, and the focus of the patent on solving these side effects challenges. Although the patent claims do not mention side effects explicitly, side effect reduction appears to me to be the entire point of the patent and is therefore implicit.

[54] This point of view is not shared by Professor Young, called by Pfizer. He spent most of his career as a medicinal chemist at Merck, where he was involved in the discovery of rofecoxib, the active ingredient in Vioxx, which is another COX-2 inhibitor. Vioxx has been withdrawn from the market. He is a professor of chemistry in the Department of Chemistry and the Merck-Frosst BC leadership chair in Pharmaceutical Genomics Bioinformatics and Drug Discovery at Simon Fraser University, and adjunct professor of chemistry at the University of British Columbia.

[55] The essence of his opinion is found at para 28 of his affidavit:

> In my opinion, reading the patent as a whole, from the perspective of a person of ordinary skill in the art in 1995, the 576 Patent is generally promising that the claimed compounds will be useful in the treating inflammation and/or inflammation-associated disorder (depending on the particular claim). More specific utilities are set out in individual claims. In addition, a skilled person would understand that, by virtue of their COX2 selectivity, they may reduce the incident of common NSAID-induced side effects. […]

[56] He considers the meaning of the term "viable target", found under the background of the invention heading, as setting a goal, "something to shoot for", as opposed to any promise of particular utility.

[57] "The additional benefit of having significantly less harmful side effects" would be considered, by the skilled addressee, as being a possible benefit, and not a promised use. He emphasizes the next paragraph in the disclosure which says that: the "preferred selectivity may indicate an ability to reduce the incidence of common NSAID-induced side effects."

[58] In his opinion, the promised utility of the specific claims in issue relates to inflammation and inflammation-associated disorders.

[59] In his view, the skilled addressee would not, in any event, consider that any promise was made with respect to treatment of humans. Given that a new compound has to be tested in test tubes and rodents before being clinically tested in humans, by reading the claims, a skilled addressee would not expect the compounds to be claimed to be effective in humans. He emphasizes that the patent refers to the invention as being useful to treat inflammation "in a subject" and not in a "human". A number of COX-2 selective NSAIDs have been used to treat animals, such as horses and dogs.

VI. Decision

[60] I have come to the conclusion that patent ‘576 did not promise reduced side effects in humans. Therefore, it would be inappropriate to make any finding as to whether Celebrex® in fact has fewer side effects than other NSAIDs.

[61] This conclusion was reached by two routes. As a matter of interpretation, and given that the language in question is not technical (*Whirlpool*, above), I can find no such promise. If it is necessary to read the patent as the skilled addressee would have in 1994, I am in broad agreement with Professor Young.

[62] As a skilled addressee, Professor Young seizes on the word “may”. While I accept that words may take on different meanings in different contexts, nevertheless there are grammatical limits: “When I use a word, Humpty Dumpty said, in a rather scornful tone, it means just what I choose it to mean - neither more nor less.” (Lewis Caroll, *Through the Looking-Glass*).

[63] The patent falls within the definition of a regulation. As such, the following passage from the reasons of Madam Justice Deschamps in *Glykis v Hydro-Quebec*, 2004 SCC 60, [2004] 3 SCR 285, [2004] SCJ No 56 (QL), is *à propos*:

> The approach to statutory interpretation is well-known (*Bell ExpressVu Limited Partnership v. Rex*, [2002] 2 S.C.R. 559, 2002 SCC 42). A statutory provision must be read in its entire context, taking into consideration not only the ordinary and grammatical sense of the words, but also the scheme and object of the statute, and the intention of the legislature. This approach to statutory

> interpretation must also be followed, with necessary adaptations, in interpreting regulations.

[64] The patent says: "such preferred selectivity may indicate an ability to reduce." It does not say such preferred selectivity "reduces" or "indicates" an ability to reduce.

[65] The word "may" connotes a possibility; maybe yes, maybe no. While it was hoped the selectivity would reduce side effects, no such claim was made.

[66] Professor Wallace speaks of problems and solutions, and points out that Celebrex® was entering a "crowded field". There would be no point to it were it not for the promised reduced side effects. However, it does not matter how crowded a field may be. If Celebrex® was new, which it was, and useful in treating inflammation, which it is, then the invention is entitled to letters patent. No specific level of utility was claimed. A scintilla of utility would do. It would not matter if other pain relievers were far more effective.

[67] There is not a word of reduced side effects in the claims. What is usually not claimed is disclaimed. The claims take precedence of the disclosure portion of the specification, as the disclosure may lead to an understanding of what is meant by a word in the claims but neither contracts nor enlarges its scope.

[68] Professor Wallace infers a promise. The Court of Appeal does not. In *Sanofi-Aventis v Apotex Inc*, 2013 FCA 186, 114 CPR (4th) 1 , [2013] FCJ No 856 (QL) (*Plavex*), the Court of

Appeal, per Mr. Justice Pelletier, at para 67 specifically drew a distinction between the potential use of an invention and an explicit promise to achieve a specific result.

> The frailty of the Trial Judge's conclusion is even more apparent when the distinction drawn in the jurisprudence between the potential use of an invention and an explicit promise to achieve a specific result is considered. […] The pharmaceutical industry's interest of the invention obviously lay in its potential use in humans which the invention foreshadowed. The person skilled in the art would understand that in alluding to this possibility, the inventors were not promising that this result had been or would be achieved. As was held in *AstraZeneca Canada Inc. v. Mylan Pharmaceuticals ULC*, 2011 FC 1023 at paragraph 61:
>
> > I accept AstraZeneca's argument that not all statements of advantage in a patent rise to the level of a promise. A goal is not necessarily a promise. The third paragraph of the 420 Patent refers to a forward looking goal, a hoped-for advantage of the invention. (my emphasis)
> >
> > *AstraZeneca Canada Inc. v. Mylan Pharmaceuticals ULC*, 2011 FC 1023, [2011] F.C.J. No. 1262 (Q.L.) at paragraph 139. For other examples of this distinction, see *Pfizer Canada Inc. v. Mylan Pharmaceuticals ULC*, 2012 FCA 103, [2012] F.C.J. No. 386, at paragraph 61, *Mylan Pharmaceuticals ULC v. Canada (Minister of Health)*, 2012 FCA 109, [2012] F.C.J. No. 422, at paragraphs 32-33.

See also *Pfizer Canada Inc v Mylan Pharmaceuticals ULC*, 2012 FCA 103, 100 CPR (4th) 203, [2012] FCJ No 386 at paras 57-59.

[69] In her concurring reasons in *Plavex*, above, Madam Justice Gauthier wondered "Why an inventor would include comments relating to a practical purpose to which an invention may be applied when such statements are not necessary under Canadian law." (para 124) She was commenting with respect to utility and obviousness. Searle was under no obligation to state why

it made a disclosure with respect to a potential reduction in side effects. It may be that it was not confident enough to claim reduced side effects on the basis of a sound prediction. Since the theory of COX-2 inhibition was well known, the disclosure may have prevented others from patenting a new use on the grounds that such use was anticipated by the patent.

[70] As stated by Mr. Justice Zinn in *Fournier Pharma Inc. v Canada (Health)*, 2012 FC 741, 107 CPR (4th) 32, [2012] FCJ No 901, at para 126, a utility not expressed in the claim portion of the specification "[…] should be presumed to be a mere statement of advantage unless the inventor clearly and unequivocally states that it is part of the promised utility."

[71] Mylan relies on another recent decision of the Federal Court of Appeal, *Eurocopter v Bell Helicopter Textron Canada Limitée*, 2012 FC 113, 100 CPR (4th) 87, [2012] FCJ No 107 (QL), aff'd 2013 FCA 219, [2013] FCJ No 1043 (QL). The patent in issue related to a particular type of helicopter landing gear. In first instance, at para 214, Mr. Justice Martineau stated that: "The specification mentions a number of advantages […]" Mylan submits that a promise need not be explicit and need not be set out in the claims portion of the specification. However, as noted by Mr. Justice Mainville, speaking for the Court of Appeal, at para 26, the advantage "was principally embodied in claim 1 of the […] Patent." Thus, I do not see two competing schools of thought in the Court of Appeal. *Eurocopter* is not a departure from other decisions of the Federal Court of Appeal, which follow *Whirlpool*, above.

VII. Abuse of Process

[72] Given Mr. Justice Hughes' decision in *G. D. Searle*, above, Mylan submits that Pfizer is attempting to relitigate, which constitutes an abuse of process, as referred to in paras 13 and 14 hereof.

[73] It must be borne in mind that utility is a matter of fact, while patent construction is a matter of law.

[74] The *G.D. Searle* case was quite different from *Sanofi-Aventis*, above. At para 14 of his decision, Mr. Justice Hughes stated: "After some discussion, Counsel for the Applicants conceded that both the anti-inflammatory properties and lesser side effects were necessary to the utility of the claimed invention." He added at para 27: "[…] as conceded by Counsel for the Applicants, the utility of that compound is set out in the specification as being the duality of treatment of inflammation and reduction of unwanted side effects such as ulcers of the gastrointestinal system." Pfizer made no such concession in this application.

[75] Mylan's case is based on a prediction which, although sound when made, it says has been proven to be wrong. However, Mr. Justice Hughes held that the utility of the invention was demonstrated, not soundly predicted. He said at paras 101 to 103:

> [101] The Canadian patent application, as filed effective November 14, 1994, makes ample disclosure as to the utility of celecoxib; it is described, a process for preparing it is disclosed as Example *2* and data demonstrating effectiveness in dealing with

> inflammation and having appropriate COX II selectivity is all disclosed.
>
> [102] The law is clear as to utility. There must have been, as of the relevant date, a demonstration of utility or, lacking that, a sound prediction of utility based on the information and science available at the time of the prediction (*Merck & Co. v. Apotex Inc.*, (2003), 41 C.P R. (4th) 35 (FC), at paragraph 121; *Pfizer Canada Inc. v. Apotex Inc.*, 2007 FC 26, at paragraphs 36 to 40).
>
> [103] I find that, certainly by the Canadian filing date, Searle had determined and articulated sufficient utility. Since the work had actually been done, there is no need to consider the law as to sound prediction, which comes into play only when the work has not been done.

[76] In appeal, at paras 44 and 45, Mr. Justice Malone said there had been a finding of utility, which was a finding of fact not in issue.

[77] What exactly was demonstrated in the specification? Counsel for Pfizer submits that what was demonstrated was utility in rats, not humans. Certainly, Mr. Justice Hughes did not state that the evidence before him demonstrated reduced side effects in humans.

[78] A concession made by Pfizer in one NOC proceeding is not an admission binding upon it in another. Mylan finds itself in a somewhat of a delicate position. If the *G.D. Searle* case turned on the construction of the patent, a pure question of law, I would be bound by the decision of the Court of Appeal on the basis of *stari decisis* (*Apotex Inc. v Pfizer Ireland Pharmaceuticals*, 2012 FC 1339, a decision of Mr. Justice Zinn, currently in appeal). However, utility, whether demonstrated or predicted, is a matter of fact.

[79] Neither Pfizer nor Mylan are engaged in abuse of process in litigating this matter.

VIII. Pfizer's Motion to Strike

[80] Pfizer brought on a motion, heard concurrently with its application, that portions of Mylan's material be struck from the record. Since I reached the conclusion I have without recourse to that material, the motion shall be dismissed on the grounds of mootness, without costs.

IX. Confidentiality

[81] As portions of the record were covered by a confidentiality order, the parties shall have seven days from the date hereof to make written representations as to whether any part of these reasons should be redacted before they are made public. If necessary, each shall then have five days to respond.

"Sean Harrington"

Judge

Ottawa, Ontario
Confidential Reasons for Order dated January 14, 2014
Public Reasons for Order (Identical to Confidential Reasons for Order) dated January 28, 2014

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-609-12
STYLE OF CAUSE:	PFIZER CANADA INC. AND G.D. SEARLE & CO. v MYLAN PHARMACEUTICALS ULC AND THE MINISTER OF HEALTH
PLACE OF HEARING:	TORONTO, ONTARIO
DATE OF HEARING:	DECEMBER 9, 2013
REASONS FOR ORDER:	HARRINGTON J.
CONFIDENTIAL REASONS FOR ORDER DATED:	JANUARY 14, 2014
PUBLIC REASONS FOR ORDER (IDENTICAL TO CONFIDENTIAL REASONS FOR ORDER) DATED:	JANUARY 28, 2014

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No one appearing	FOR THE RESPONDENT THE MINISTER OF HEALTH

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