Federal Court  Cour fédérale

Date: 20160401

Docket: T-852-14

Citation: 2016 FC 344

Ottawa, Ontario, April 1, 2016

PRESENT: The Honourable Mr. Justice Zinn

BETWEEN:

ALLERGAN INC.

Applicant

and

APOTEX INC. AND
THE MINISTER OF HEALTH

Respondents

and

SENJU PHARMACEUTICAL CO., LTD AND
KYORIN PHARMACEUTICAL CO., LTD.

Respondents/Patentees

PUBLIC JUDGMENT AND REASONS
(Confidential Judgment and Reasons released March 22, 2016)

[1] Allergan Inc. [Allergan] seeks an Order, pursuant to the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133, prohibiting the Minister of Health from issuing a Notice

of Compliance to Apotex Inc. [Apotex] for its gatifloxacin ophthalmic product until after the expiration of Canadian Patent No. 2,307,632 [the 632 Patent].

[2] The 632 Patent claims aqueous liquid pharmaceutical compositions (in the form of eye drops, ear drops, or nasal drops) containing gatifloxacin and disodium edetate [EDTA]. It has a priority date of August 21, 1998, a filing date of August 20, 1999, and a publication date of March 3, 2000.

[3] The 632 Patent contains 10 claims. Claims 6-8 are method claims that relate to positive effects that can be brought about by adding EDTA to gatifloxacin. Claim 6 covers a method for raising gatifloxacin's corneal permeability by adding EDTA. Claim 7 covers a method for preventing the precipitation of gatifloxacin crystals in solution by adding EDTA. Claim 8 covers a method for preventing the coloration of a gatifloxacin solution by adding EDTA.

[4] Claims 1-5, 9, and 10 are pharmaceutical composition claims involving variations in the amount of gatifloxacin claimed, the amount of EDTA claimed, the pH level of the solution, and the form of delivery (eye drops, ear drops, or nasal drops).

[5] In this application, Allergan relies solely on Claim 10 of the 632 Patent, as it reads on Claims 9, 3, 2, and 1. These claims are as follows:

> 1. An aqueous liquid pharmaceutical composition which comprises Gatifloxacin or its salt and disodium edetate.
>
> 2. The aqueous liquid pharmaceutical composition according to claim 1, wherein pH of the composition is within the range of 5 to 8.

> 3. The aqueous liquid pharmaceutical composition according to claim 1 or 2, where the composition is in the form of eye drops.
>
> 9. The aqueous liquid composition according to any one of claims 1 to 5, wherein Gatifloxacin or its pharmaceutically acceptable salt is contained in an amount of 0.1 to 1.0 w/v% and disodium edetate is contained in an amount of 0.001 to 0.2 w/v%.
>
> 10. The aqueous liquid composition according to claim 9, wherein the amount of disodium edetate is 0.01 to 0.1 w/v%.

[6] Allergan submits, and I agree, that when read in conjunction with Claims 9, 3, 2, and 1, Claim 10 covers:

> An aqueous liquid pharmaceutical composition in the form of eye drops wherein the pH of the composition is within the range of 5 to 8 which comprises Gatifloxacin or its pharmaceutically acceptable salt in an amount of 0.1 to 1.0 w/v% and [EDTA] in an amount of 0.01 to 0.1 w/v% [the Invention].

[7] Apotex alleged in its Notice of Allegation [NOA] and in its submissions that the 632 Patent is invalid because it is obvious and lacks utility. The issue is whether either allegation is justified. Apotex must show that there is evidence that, if accepted, is capable of rebutting the presumption of patent validity enshrined in subsection 43(2) of the *Patent Act*, RSC, 1985, c P-4. If Apotex does that, then Allergan must demonstrate on a balance of probabilities that the allegations of obviousness and inutility are not justified: *Abbott Laboratories v Canada (Minister of Health)*, 2007 FCA 153 at paras 9-10; *Allergan Inc v Canada (Minister of Health)*, 2012 FC 767 at para 42.

[8] In light of the few issues raised and my preference for the evidence of one of the expert witnesses, only brief reasons are required to explain my finding that Allergan has not demonstrated that Apotex's allegations are not justified.

THE EVIDENCE

[9] Allergan relied on the expert evidence of Dr. Joseph Fix, who attests that he has expertise in "the area of drug delivery and formulation."

[10] Apotex relied on the expert evidence of Dr. Paul Myrdal, a formulator, and Dr. Heather Sheardown, "a chemical engineer with a focus on studying and developing delivery formulations for ophthalmic applications."

[11] Apotex urges that little weight be given to the evidence of Dr. Fix:

> His evidence is flawed: (a) he was not "blinded" to the issues, having reviewed the NOA and the 632 Patent prior to preparing his opinion; (b) he was not properly instructed on obviousness and utility; (c) he construed the patent from his perspective (with over 30 years' experience) rather than a skilled person; (d) he construed the inventive concept and the promise by determining what would make the 632 Patent different than the prior art; (d) he was out of touch with the state of the art in formulating ophthalmic products in 1998, *e.g.*, he opined that EDTA was not then a conventional excipient used in ophthalmic formulations when the evidence clearly shows that it was; (f) he reviewed each reference in isolation instead of construing a mosaic of the prior art; and (h) he did not closely review all the documents relied on by Apotex in its NOA and, consequently, missed or ignored critical aspects of the prior art. [references omitted]

[12] While I am not convinced that all of these alleged flaws are made out, I am satisfied, for the following reasons, that the evidence of Dr. Sheardown is to be preferred and given more weight than that of Dr. Fix and Dr. Myrdal.

[13] As noted by Apotex, Dr. Fix was not blinded; he offered his opinion after having read the 632 Patent and Apotex's NOA and after having discussed both with Allergan. The Supreme Court of Canada in *Apotex Inc v Sanofi-Synthelabo Canada Inc*, 2008 SCC 61, [2008] 3 SCR 265 [*Plavix SCC*] at para 67, directs that an obviousness assessment is to be made "without any knowledge of the alleged invention as claimed." Relying on this observation, this Court has recognized that evidence from experts who have not seen the patent nor been apprised of the positions of the litigants is to be given greater weight on issues going to obviousness and patent construction than the evidence of an expert with full knowledge of the patent's disclosure and the positions of the parties: *AstraZeneca Canada Inc v Apotex Inc*, 2014 FC 638 [*Esomeprazole FC*] at para 321; *Teva Canada Innovation v Apotex Inc*, 2014 FC 1070 at paras 94-97; *Takeda Canada Inc v Canada (Minister of Health)*, 2015 FC 570 at paras 27-29.

[14] Like Dr. Fix, Dr. Myrdal had prior knowledge of the 632 Patent (or the U.S. equivalent) and the positions of the parties. As acknowledged by Apotex, "[Dr. Myrdal] testified in a United States case on the corresponding patent and his evidence … in the present proceeding was consistent with his U.S. evidence."

[15] Apotex brought to the Court's attention two proceedings before the United States Court for the District of Delaware, in which Dr. Myrdal testified. Apotex submits that in both cases,

the court concluded that the U.S. equivalent to the 632 Patent was found invalid for obviousness. Those findings are clearly not binding on this Court, nor are those decisions of any persuasive value in the absence of expert evidence as to the relevant law in that jurisdiction and its similarity, if any, to the jurisprudence binding on this Court. In any event, even if the patents are "equivalent," their language is not identical.

[16] Unlike the other experts in pharmaceutical formulation, Dr. Sheardown expressed her opinion on the common general knowledge and the prior art with no knowledge of the patent at issue or the positions of the parties. As such, her responses to the questions asked of her came without any influence, conscious or unconscious. Moreover, of the three, only Dr. Sheardown's expertise focused on "studying and developing delivery formulations for ophthalmic applications." Dr. Fix and Dr. Myrdal are expert formulators. However, given that the alleged invention in the claims at issue is specifically directed to an ophthalmic medication in the form of an eye drop, I am of the view that the evidence of the one expert specializing in that area, whose opinion is offered with no possible influence, is to be preferred.

OBVIOUSNESS

[17] If a claimed invention is obvious, then it is not patentable because it fails to meet the definition of "invention" in section 2 of the *Patent Act*, and it fails to meet the test set out in section 28.3 of being "subject-matter that would not have been obvious on the claim date to a person skilled in the art or science to which it pertains."

[18] The Supreme Court of Canada in *Plavix SCC* at para 67 set out a four-step approach to assessing whether a claimed invention is obvious:

> (1) (a) Identify the notional "person skilled in the art";
>
> (b) Identify the relevant common general knowledge of that person;
>
> (2) Identify the inventive concept of the claim in question or if that cannot readily be done, construe it;
>
> (3) Identify what, if any, differences exist between the matter cited as forming part of the "state of the art" and the inventive concept of the claim or the claim as construed;
>
> (4) Viewed without any knowledge of the alleged invention as claimed, do those differences constitute steps which would have been obvious to the person skilled in the art or do they require any degree of invention?

Step 1: Person of Skill in the Art and Common General Knowledge

[19] The parties agree that the person of skill in the art [POSITA] would have expertise in drug formulation and delivery and pharmaceutical chemistry, be able to follow the instructions of the prior art to make formulations, and would have some knowledge of statistics by virtue of their scientific education.

[20] Allergan submits that the 49 references cited in Apotex's NOA are not representative of the common general knowledge because they were collected by Apotex, with the benefit of hindsight, and with a view to invalidating the 632 Patent. Moreover, it notes that Apotex's two experts did no independent prior art search.

[21] I agree with Apotex that these objections are without merit. Apotex's experts provided reasons as to why these references would have been easily located during a prior art search or stated that they would already have been known to the POSITA. Dr. Sheardown attests that "many of the documents are well-known references in the field of pharmaceutical formulation, in particular the field of ophthalmic formulations," that she is familiar with many of the articles and texts, and that any of the others would have been easily located by a formulator conducting a diligent search in 1998. More importantly, Allergan has offered no evidence that there are other material references constituting the prior art that are not included in the NOA, or that those referenced in the NOA do not constitute the common general knowledge.

[22] Much of the relevant common general knowledge is set out in the specification of the 632 Patent, and may be summarized as follows:

- Gatifloxacin is a quinolone;
- Gatifloxacin is an antimicrobial agent which is known to have strong antimicrobial activity against Gram-negative and Gram-positive bacteria, anaerobes and mycoplasmas;
- Gatifloxacin had been proposed to treat ophthalmic infectious diseases;
- Passage of the active ingredient in eye drops is inhibited by tearing and by the barrier function of the cornea and thus increasing corneal permeability by using an absorption enhancer is advantageous;
- EDTA lowers "the calcium concentration in corneal epithelium cells and expand[s] intercellular spaces, thereby accelerating passing of a water-soluble medicament into the inside of eyes;" and

- "[T]he solubility of gatifloxacin depends on its pH and its solubility at about physiological pH is very low."

[23] In addition, I accept the evidence of Dr. Sheardown that the following is also part of the common general knowledge:

- That fluoroquinolones (other than gatifloxacin) were being used in ophthalmic formulations;
- That the ophthalmic fluoroquinolone formulations on the market were Ciloxan (ciprofloxacin), Chibroxin (norfloxacin), and Ocuflox (ofloxacin);
- That two of these fluoroquinolone formulations, Ciloxan and Chibroxin, contained EDTA;
- That Ciloxan contained a 0.3% concentration of ciprofloxacin and a 0.05% concentration of EDTA; and
- That EDTA was an approved excipient used in FDA approved ophthalmic solutions; and
- That EDTA was a metal chelator.

Step 2: The Inventive Concept

[24] Step two requires that the Court discern the inventive concept of the claim, starting with the claim itself. However, if the inventive concept is not readily discernable from the claim, the Court may look to the specification, provided that, in doing so, it does not construe the claim more narrowly or broadly than the text of the claim will allow (*Plavix SCC* at para 77).

[25] Allergan submits that the incentive concept of Claim 10 is not discernible from the claim itself but submits that the disclosure shows that the inventive concept, as attested by Dr. Fix, "is the finding that formulating gatifloxacin in the amount of 0.1 to 1.0 w/v% with EDTA concentrations in the range of 0.01 to 0.1 w/v% increases the corneal permeability of gatifloxacin, or prevents the precipitation of gatifloxacin, or prevents discoloration of the formulation."

[26] Apotex submits, as Dr. Myrdal attests, that the inventive concept of Claim 10 is discernible from the claim itself and is "an aqueous composition containing from 0.1 to 1.0% gatifloxacin and from 0.01 to 0.1% EDTA for use as an eye drop solution."

[27] Dr. Sheardown's evidence, which I prefer and accept, closely accords with the submission of Allergan. She attests that:

> The inventive concept of claims 1 to 3 of the 632 Patent is an aqueous composition containing some amount of gatifloxacin and EDTA. The 632 Patent says that these compositions are useful to provide one of the three purposes stated in the 632 Patent, namely, to: increase corneal permeability of gatifloxacin; prevent precipitation of gatifloxacin crystals; and prevent coloration of the gatifloxacin solution.
>
> …
>
> The inventive concept of claim 9 and 10 is similar to that of claims 1 to 3 above, except that the amount of gatifloxacin is between 0.1 and 1.0% and the amount of EDTA is either 0.001 to 0.2% (claim 9) or 0.01 to 0.1% (claim 10).

Step 3: The Difference Between the State of the Art and the Inventive Concept

[28] It is not disputed that combining gatifloxacin and EDTA in the amounts set out in Claim 10 for use as an eye drop was novel. Although, as attested by Dr. Sheardown, U.S. Patent 4,980,470 dated December 25, 1990, disclosed that "gatifloxacin can be formulated as eye drops" and it was also known that "EDTA was a conventional excipient used in ophthalmic solutions as of August 1998."

[29] The parties differ on whether it was known in the art that combining gatifloxacin and EDTA would increase corneal permeability of gatifloxacin, prevent precipitation of gatifloxacin crystals, and prevent coloration of the gatifloxacin solution.

[30] Dr. Sheardown attests that penetration enhancers improve corneal permeability thus permitting more of the active ingredient to cross the cornea and enter the aqueous humour. As noted above, EDTA was known as one such penetration enhancer.

[31] She attests that a skilled person would have expected that EDTA "in some circumstances" would have prevented precipitation:

> [S]ince ETDA has some surfactant-like properties, a skilled person would have expected that its addition to an aqueous solution could assist in solubilizing a poorly soluble compound and thus, in some circumstances, prevent precipitation.

[32] She further attests that it was known that EDTA was a chelating agent and that adding such an agent would prevent a gatifloxacin solution from changing colour.

[33] Thus, while the three advantages of the Invention were not known with absolute certainty to be a consequence of combining EDTA and gatifloxacin in the amounts set out in Claim 10, each was known to some degree and was not an unexpected consequence of the combination.

Step 4: Do the differences constitute steps which would have been obvious to the POSITA or do they require any degree of invention?

[34] Dr. Sheardown opines that there is nothing inventive:

> There is no practical difference between the inventive concept of the claims of the 632 Patent and the common general knowledge. Any differences between the inventive concept and the claims of the 632 Patent and what was known to the skilled person as of August 1998 constituted steps that would have been obvious to the skilled person. There was nothing inventive to formulate gatifloxacin as a topical ophthalmic solution with EDTA. The skilled person knew that EDTA in an ophthalmic solution would have the effect of increasing the corneal permeability of polar compounds. Gatifloxacin is a polar compound, and thus the skilled person would have expected that incorporating EDTA into a gatifloxacin would serve to increase the corneal permeability of gatifloxacin. The skilled person would also have expected that incorporating EDTA into gatifloxacin solution would prevent precipitation of gatifloxacin and prevent colorization due to complexing of gatifloxacin with metal ions. [emphasis added]

[35] Allergan's counsel submits that the emphasized passages show that this expert is using the utility test of "reasonable inference" rather than the obviousness test of "ought to work." With respect, counsel's parsing of the words of this expert's affidavit results in a conclusion that is not warranted and it is telling that this interpretation was not ever put to her in cross-examination.

[36] I begin by noting that obviousness is "largely concerned with how a skilled worker would have acted in the light of the prior art:" *Plavix SCC* at para 70. That inquiry proceeds using the four-step approach adopted by the Supreme Court cited above at para 18. It is at the last step, when assessing whether the differences between the claimed invention and the prior art constitute steps which would have been obvious or that require a degree of invention, that the "obvious to try" test may be used when answering the question.

[37] The United States law on the obvious to try test in *KSR International Co v Teleflex Inc*, 127 S Ct 1727 (2007) at 1742, as recited in *Plavix SCC* at para 58, provides an excellent statement, in my view, of the use of the obvious to try test when assessing obviousness:

> When there is a design need or a market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious…

[38] Where the obvious to try test is used, then one must ask whether the step taken from the prior art to the claimed invention was obvious in that there was a fair or reasonable expectation of success in obtaining the invention: *Eli Lilly Canada Inc v Mylan Pharmaceuticals ULC*, 2015 FC 178 at para 150; *Janssen Inc v Teva Canada Ltd*, 2015 FC 184 at paras 12-13; *Pfizer Canada Inc v Apotex Inc*, 2009 FCA 8 at para 44.

[39] Dr. Sheardown opines, and I agree, that a POSITA would have a fair and reasonable expectation that combining gatifloxacin with EDTA would produce an effective ophthalmic compound that would have the three advantages set out in the 632 Patent. It would not be a

certainty, but it would be higher than a fair expectation of success. In my view, it rises to the level of being more or less self-evident: *Eli Lilly Canada Inc v Mylan Pharmaceuticals ULC*, 2015 FCA 286.

[40] I reach that conclusion based on the following being known at the time:

- That gatifloxacin, a fluoroquinolone, is an antimicrobial agent which had been proposed to treat ophthalmic infectious diseases;
- That corneal permeability is enhanced using an absorption enhancer and EDTA is an absorption enhancer;
- That EDTA is an excipient that was used in two other ophthalmic fluoroquinolone formulations on the market - Ciloxan and Chibroxin;
- That Ciloxan contained a 0.3% concentration of ciprofloxacin and 0.05% concentration of EDTA;
- That the Handbook of Professional Excipients describes the application of EDTA in pharmaceutical formulations and states that it is commonly used in amounts between 0.005 to 0.1%;
- That EDTA is a known metal chelator; and
- That adding EDTA to an aqueous solution could assist in solubilizing a poorly soluble compound, such as gatifloxacin, and thus, in some circumstances, prevent precipitation.

[41] Given the state of the art, a person of ordinary skill had good reason to pursue the known options within his or her technical grasp; namely, combining gatifloxacin with EDTA in an ophthalmic solution. Admittedly, the amount of each to include in the solution required testing, but the nature of the testing was of the usual sort routinely carried out when developing ophthalmic solutions and the range of concentrations was well within that known in the literature. As such, the anticipated success was the product, not of innovation but of ordinary skill and common sense.

UTILITY

[42] To be patentable, the invention must be useful: *Patent Act*, s 2.

[43] The law as it currently stands is that an invention need only possess a scintilla of utility and there is no requirement that an inventor describe any particular utility for the invention. However, if an inventor explicitly, using clear and unambiguous language, promises a specific result, then he or she will be held to that promise and utility will be assessed against that promise: *Pfizer Canada Inc v Canada (Minister of Health)*, 2008 FCA 108, [2009] 1 FCR 253 at para 53; *Astrazeneca Canada Inc v Mylan Pharaceuticals ULC*, 2012 FCA 109 at para 7; *Apotex Inc v Pfizer Canada Inc*, 2014 FCA 250 at paras 65-66.

[44] Apotex submits that the 632 Patent "provides an explicit promise of a specific result, namely, that the composition of Claim 10 will result in increased corneal permeability, will not precipitate and will not discolour." Allergan, in oral submissions, stated that the utility of the 632 Patent is that "it's an effective antibiotic" thus taking the position that increased corneal

permeability, the prevention of precipitation, and the prevention of colorization, are "objects" or "goals" of the patent, but not promises.

[45] The Federal Court of Appeal in *Pfizer Canada Inc v Canada (Minister of Health)*, 2011 FCA 236 at para 17 instructs me that, assisted by expert evidence, I am to purposively ascertain the promise of the patent within the context of the patent as a whole, through the eyes of the POSITA in relation to the science and information available at the time of filing.

[46] Dr. Sheardown, the POSITA whose evidence I prefer, offers her opinion that the promised utility encompasses the three advantages which Allergan submits are mere goals:

> The promised utility is clearly and unequivocally described in the 632 Patent. The skilled person would understand that the patent explicitly states that the gatifloxacin and EDTA compositions of the invention are useful as follows: to increased or raise corneal permeability of gatifloxacin compared to an aqueous solution that does not contain EDTA; to prevent precipitation of gatifloxacin crystals compared to an aqueous solution that does not contain EDTA; and to prevent colorization of gatifloxacin compared to an aqueous solution that does not contain EDTA.

I agree.

[47] The patent as a whole makes it clear that these three items are promises of the invention. Aside from Claims 6, 7 and 8 where these three results are method claims, the disclosure of the 632 Patent contains statements that promise these when the patent is used:

> …the present invention provides a method for increasing corneal permeability of Gatifloxacin … a method for preventing precipitation of Gatifloxacin crystals …and a method for preventing colorization of Gatifloxacin …

Moreover, when describing the three experiments conducted, similar statements of promised utility are made:

> …these results show that corneal permeability of Gatifloxacin has been improved…
>
> These results show that precipitation of Gatifloxacin crystals under storage conditions at a low temperature is prevented …
>
> …these results show that addition of disodium edetate can prevent coloration of Gatifloxacin.

[48] The most telling statement in the 632 Patent leading to the conclusion that these three aspects of the invention are promises of utility, is the final statement in the specification:

> As shown in Experiment 1, according to the eye drops of the present invention, corneal permeability of the effective component, Gatifloxacin, can be improved even by using disodium edetate in 1/10 amount as much as normally used. Further, as shown in Experiment 2, the aqueous liquid preparation of the present invention can prevent precipitation of Gatifloxacin crystals under storage as [sic] a low temperature. Furthermore, as shown in Experiment 2, colorization of Gatifloxacin by a metal ion can be prevented. Thus the aqueous liquid preparation of the present invention is very useful. [emphasis added]

In using the words "thus" and "useful" the inventor provides a clear statement that he is promising the three aspects of the invention under discussion. These are promises of utility.

[49] Were these promises of utility established by the filing date of August 20, 1999, or were they soundly predicted?

[50] Given the many compositions covered by Claim 10, and the very limited testing done by the inventors, Allergan's witness, Dr. Fix, correctly conceded that this is not a case where the utility, as I have described it, was demonstrated. Was it soundly predicted?

[51] Allergan urges the Court to follow the decision of Justice Rennie in *Esomeprazole FC*; aff'd 2015 FCA 158, wherein he expressed his view that there is no disclosure requirement in cases of sound prediction except in new use patents, that is to say, the factual basis for a sound prediction of utility does not need to be disclosed in the patent itself. I note that his discussion of his view on this was not necessary for the disposition he reached (see para 139) and was not addressed by the Federal Court of Appeal.

[52] Apotex submits that the Federal Court of Appeal in a number of prior cases and the Supreme Court of Canada in 2002, concluded in cases of sound prediction, that the patentee may only rely on the facts and line of reasoning disclosed in the patent: *Apotex Inc v Wellcome Foundation Ltd*, 2002 SCC 77, [2002] 4 SCR 153 at paras 70-72; *Eli Lilly Canada v Apotex Inc*, 2009 FCA 97 at paras 12-15; *Eli Lilly and Company v Teva Canada Limited*, 2011 FCA 220 at paras 47 & 50; *Apotex Inc v Pfizer Canada Inc*, 2011 FCA 236 at paras 42-44 & 51-52. It argues that this remains the law in Canada unless, as is suggested by Justice Rennie and Allergan, it was reversed by the Supreme Court of Canada in *Teva Canada Ltd v Pfizer Canada Inc*, 2012 SCC 60, [2012] 3 SCR 625 [*Teva sildenafil*].

[53] Justice Rennie acknowledges at paragraph 142 of his Reasons that the passage in *Teva sildenafil* he relies upon is an *obiter* remark. Indeed at paragraph 43 of his Reasons, Justice

LeBel states that sound prediction is not an issue in the case and "whether there is an 'enhanced' or 'heightened' disclosure requirement does not arise in this case and need not be addressed." He repeats this observation at paragraph 89.

[54] The Federal Court of Appeal in *Bell Helicopter Textron Canada Limitée v Eurocopter*, 2013 FCA 219, which was decided after *Teva sildenafil* and referenced that decision, in my view held that, with the exception of matters of common general knowledge, the factual basis and the line of reasoning must be included in the patent:

> [151] In *Teva Canada Ltd. v. Pfizer Canada Inc.*, 2012 SCC 60, [2012] 3 S.C.R. 625 ("Teva"), LeBel J. recently noted (at para. 37) that "[t]he lack of certainty that comes from predicting rather than demonstrating an invention's utility has led some courts to conclude that there is a 'heightened' or 'enhanced' disclosure requirement in cases in which a claim of utility is based on sound prediction: see e.g. *Eli Lilly Canada Inc. v. Apotex Inc.*, 2009 FCA 97, 78 C.P.R. (4th) 388 (F.C.A.), at paras. 14-15." However, LeBel J. refused to address the question since the issue did not arise in that case (*Teva* at para. 43). He nevertheless made comments (at paras. 38 to 40 of *Teva*) suggesting that nothing in the *Patent Act* requires that the utility of the invention be disclosed, and he referred approvingly to the comments of Dickson J. in *Consolboard*, at p. 521, "that s. 36(1) [now s.27(3)] [of the *Patent Act*] does not impose upon a patentee the obligation of establishing the utility of the invention." In *Sanofi-Aventis v. Apotex Inc.*, 2013 FCA 186 at paras. 47-49, Pelletier J.A. recently also noted that while an inventor need not describe the utility of his invention in the patent, if he does so, he will be held to the promise he made.
>
> [152] In my opinion, the factual basis, the line of reasoning and the level of disclosure required by the doctrine of sound prediction are to be assessed as a function of the knowledge that the skilled person would have to base that prediction on, and as a function of what that skilled person would understand as a logical line of reasoning leading to the utility of the invention.
>
> [153] Where the factual basis can be found in scientifically accepted laws or principles or in information forming part of the common general knowledge of the skilled person, then no disclosure of such factual basis may be required in the

> specification. On the other hand, where the factual basis is reliant on data which does not form part of the common general knowledge, then disclosure in the specification may indeed be required to support a sound prediction.
>
> [154] As noted in the Manual of Patent Office Practice issued by the Canadian Patent Office (at paras. 12.08.04b and 12.08.04c), since a sound line of reasoning is directed to a skilled person, those elements of the doctrine of sound prediction that would be self-evident to that person in view of the common general knowledge need not be explicitly disclosed in the specification. The soundness of a line of reasoning can also be effectively assessed by asking whether the skilled person would accept the logic presented in the specification and derive from the sound prediction as a whole an expectation that the invention will provide the promised utility.
>
> [155] As a result, where the sound prediction is based on knowledge forming part of the common general knowledge and on a line of reasoning which would be apparent to the skilled person (which is often the case in mechanical inventions), the requirements of disclosure may readily be met by simply describing the invention in sufficient detail such that it can be practiced. A contextual approach is thus appropriate in each case. [emphasis added]

[55] Indeed, the observation at paragraph 155 above is precisely the situation Justice Gauthier spoke of in *Sanofi-Aventis v Apotex Inc*, 2013 FCA 186, [2015] 2 FCR 644, referenced and relied upon by Justice Rennie, where she said at para 134: "In contradistinction with the situation in AZT, where the invention claimed was the new use/utility and thus the quid pro quo for the grant of the monopoly was a full disclosure in respect of such utility, the public here received all the information necessary to make and use clopidogrel, the invention claimed in the '777 Patent" [emphasis added]. As was the case in *Teva sildenafil*, these are *obiter* comments (see para 123).

[56] After these decisions, this Court has applied the law as it stood prior to *Teva sildenafil*: see *Laboratoires Servier v Canada (Minister of Health)*, 2015 FC 108 at paras 219-225.

[57] With the greatest of respect to the views of Justice Rennie, I am not prepared to depart from established jurisprudence directly on point from the higher courts by relying on *obiter* statements of a few judges in cases where the issue of utility was not fully and thoughtfully addressed. In my view, until the Federal Court of Appeal or the Supreme Court of Canada rules otherwise, Canadian jurisprudence is that, with the exception of matters of common general knowledge, the factual basis and the line of reasoning must be included in the patent.

[58] Apotex in its Notice of Allegation detailed why, in its view, the inventors had no sound basis to predict that the composition of Claim 10 would prevent precipitation. Dr. Sheardown offered evidence to this effect:

> According to Experiment 2 in the 632 Patent, three formulations were tested (Formulations B, C and D) and the two formulations that contained ETDA (C and D) did not precipitate after ten freeze/thaw cycles, whereas precipitation occurred after three cycles with Formulation B. Although these data suggest that the inventors could have predicted that EDTA concentrations equal to or greater than 0.05% [being the amount of EDTA in Formulation C, while Formulation D had 0.1%] will prevent precipitation of gatifloxacin, it is my opinion that the inventors could not have predicted that lower concentrations, such as 0.01% or 0.001% would have prevented precipitation of gatifloxacin. There is no basis discussed in the patent from which a prediction could be made that these lower concentrations of EDTA would prevent precipitation.

[59] In response, Allergan offered the evidence of Dr. Fix. After observing that the only difference in the three formulations tested was the presence of EDTA in formulations C and D, he states that "a skilled person would infer that EDTA was the component of the formulation impacting gatifloxacin's precipitation."

[60] In my view, Dr. Fix is saying no more than Dr. Sheardown; i.e. in the amounts in the tested formulations (0.05% and 0.1%), the skilled person would infer that EDTA was the component impacting on precipitation. What he does not say in his affidavit is that the skilled person would also infer or know that this result would be obtained with the much lower levels of ETDA specified in Claim 10. Nowhere does Dr. Fix assert that it would be inferred that precipitation would be prevented if any amount of ETDA within the range set out in Claim 10 was added to the solution, let alone provide the basis for such a conclusion.

[61] For these reasons, I find that the utility of the 632 Patent is not established by Allergan.

[62] Allergan has failed to disprove the allegations of Apotex in respect of Claim 10 of the 632 Patent, namely that it is obvious and lacks utility. Accordingly, this application for a prohibition order must be dismissed with costs to Apotex.

[63] If the parties are unable to agree on costs, they may exchange and file submissions with the Court within 20 days of the release to them on a confidential basis of the Judgment and Reasons.

JUDGMENT

THIS COURT'S JUDGMENT is that this application is dismissed with costs to Apotex, the quantum of which is reserved in accordance with the Reasons.

"Russel W. Zinn"

Judge

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-852-14
STYLE OF CAUSE:	ALLERGAN INC v APOTEX INC ET AL
PLACE OF HEARING:	OTTAWA, ONTARIO
DATES OF HEARING:	DECEMBER 14 - 17, 2015
PUBLIC JUDGMENT AND REASONS:	ZINN J.
DATED:	APRIL 1, 2016

APPEARANCES:

Anthony Creber, John Norman, Alex Gloor	FOR THE APPLICANT
Andrew R. Brodkin, Dino Clarizio, Michelle Schneer	FOR THE RESPONDENT APOTEX INC.

SOLICITORS OF RECORD:

Gowling LaFleur Henderson LLP Barristers & Solicitors Ottawa, Ontario	FOR THE APPLICANT
Goodmans LLP Barristers & Solicitors Toronto, Ontario	FOR THE RESPONDENT APOTEX INC.
William F. Pentney Deputy Attorney General of Canada Ottawa Ontario	FOR THE RESPONDENT THE MINISTER OF HEALTH