Federal Court of Appeal  Cour d'appel fédérale

Date: 20170411

Docket: A-191-16

Citation: 2017 FCA 76

CORAM: **PELLETIER J.A.**
NEAR J.A.
RENNIE J.A.

BETWEEN:

BRISTOL-MYERS SQUIBB CANADA CO., BRISTOL-MYERS SQUIBB HOLDINGS IRELAND and NOVARTIS AG

Appellants

and

TEVA CANADA LIMITED

Respondent

and

THE MINISTER OF HEALTH

Respondent

Heard at Toronto, Ontario, on January 16, 2017.

Judgment delivered at Ottawa, Ontario, on April 11, 2017.

REASONS FOR JUDGMENT BY: PELLETIER J.A.

CONCURRED IN BY: NEAR J.A.
RENNIE J.A.

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REASONS FOR JUDGMENT

PELLETIER J.A.

I. INTRODUCTION

[1] In 1997, Novartis AG (then known as Ciba-Geigy Ltd.) filed a Canadian patent application for a complex molecule known as atazanavir and its pharmaceutically acceptable salts. It was granted Canadian Letters Patent No. 2,250,840 (the '840 patent) in 2006. Atazanavir's potential as a treatment for HIV (human immunodeficiency virus) and AIDS (acquired immunodeficiency syndrome) is limited by its poor bioavailability. In 1998, Bristol-Myers Squibb Canada Co. (BMS), having acquired rights to the atazanavir molecule, filed a patent application for Type-I atazanavir bisulfate, a salt of atazanavir whose superior bioavailability makes it useful in the formulation of an oral dosage of atazanavir. BMS obtained Canadian Letters Patent No. 2,317,736 (the '736 patent) in 2004.

[2] In proceedings under the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133, the Federal Court found that Teva Canada Limited's (Teva) allegation that the '736 patent was invalid for obviousness was justified and dismissed BMS' application for a writ of prohibition. This is an appeal from that decision.

[3] BMS argues that the Federal Court erred in its application of the "obvious to try" test set out in *Apotex Inc. v. Sanofi-Synthelabo Canada Inc.*, 2008 SCC 61, [2008] 3 S.C.R. 265, [*Plavix 1*] and applied by this Court in *Sanofi-Aventis v. Apotex Inc.*, 2013 FCA 186, [2015] 2 F.C.R. 644 [*Plavix 2*]. Specifically, BMS argues that the Federal Court erred in concluding that Teva's allegation of obviousness was justified in spite of the fact that it found that some of the properties of Type-I atazanavir bisulfate were not predictable before it was made and tested.

[4] I come to the same conclusion as the Federal Court though for somewhat different reasons. I would dismiss the appeal.

II. THE DECISION UNDER APPEAL

[5] As these proceedings arise under the *Patented Medicines (Notice of Compliance) Regulations*, the issue is whether Teva's allegation of obviousness in its Notice of Allegation has been shown to be justified. Any question as to the validity of the '736 patent will have to be decided in an action brought for that purpose.

[6] The Federal Court began its analysis on the issue of obviousness by noting that the free base of atazanavir is not very soluble and that the person skilled in the art [the Skilled Person] would know that one way of improving a compound's solubility and its bioavailability is to convert it to a salt using a salt screen: Reasons at paras. 406-07. A salt screen is a process in which a chemist uses various acids and solvents to produce salts of a compound.

[7] Different salts of a compound may have different properties when compared to each other and when compared to the compound itself: Reasons at para. 411. It was not contested that the Skilled Person would have expected a salt screen to identify at least one salt with improved pharmaceutical properties over the free base: Reasons at para. 412.

[8] The parties were agreed that the '840 patent disclosed the atazanavir molecule and that salts of atazanavir could be made with a variety of acids including sulfuric acid: Reasons at

para. 408. However, the properties of the resulting salts would not have been known prior to their being made: Reasons at para. 411.

[9] The Federal Court then applied the framework for the analysis of obviousness set out at paragraph 67 of *Plavix 1*.

[10] After having identified the Skilled Person and the relevant common general knowledge, the Federal Court turned to the inventive concept of the '736 patent. BMS argued that the inventive concept of the '736 patent had four aspects: crystallinity, oral bioavailability, stability and *in situ* transformation behaviour: Reasons at para. 416. Teva's evidence was that the inventive concept of the patent was a pharmaceutical salt, Type-I atazanavir bisulfate and a pharmaceutical formulation of Type-I atazanavir bisulfate. By way of background, the '736 patent has only two claims, claim 1 which claims the bisulfate salt of atazanavir and claim 2 which claims a pharmaceutical dosage form comprising Type-I atazanavir bisulfate and a pharmaceutically acceptable carrier. Teva argued, in effect, that the inventive concept was the compound claimed in claims 1 and 2 of the '736 patent.

[11] The Federal Court relied on paragraph 77 of *Plavix 1* for the proposition that "where the inventive concept of the claims in a patent is not readily discernable from the claims themselves (as may be the case with a bare chemical formula), it is appropriate to read the specification in the patent to determine the inventive concept of the claims": Reasons at para. 421.

[12] The Federal Court reviewed the disclosure of the ‘736 patent and the evidence of each party’s experts and concluded at paragraph 446 that the inventive concept of the ‘736 patent included:

i) the improved oral bioavailability of Type-I atazanavir bisulfate over the free base of atazanavir;

ii) the anhydrous crystalline solid form of Type-I atazanavir bisulfate salts; and

iii) the stability of Type-I atazanavir bisulfate salts.

[13] The next step in the analysis is to identify the differences between the “state of the art” and the inventive concept. The Federal Court disposed of this question by noting that none of the properties found to be part of the inventive concept were disclosed in the prior art: Reasons at para. 448.

[14] The last step of the obviousness analysis asks whether the differences between the prior art and the inventive concept represent steps that would have been obvious to the Skilled Person, or whether those steps would have required any inventiveness. The Federal Court began its analysis of this issue by inquiring into the extent to which a Skilled Person has to be able to predict the advantageous properties of a compound in order for the invention of that compound to be obvious. This led to a review of the jurisprudence, in particular the decisions in *Plavix 1* and *Plavix 2*.

[15] Referring to *Plavix 1*, the Federal Court noted, at paragraph 456, the Supreme Court’s endorsement of the “obvious to try” test and its comment that it might well be appropriate in areas such as the pharmaceutical industry where advances are often won by experimentation:

Plavix 1 at para. 68. The Federal Court then paraphrased paragraphs 65-66 of *Plavix 1*, stating that "to be 'obvious to try', there must be evidence to convince a judge on a balance of probabilities that it was 'very plain' or 'more or less self-evident' that what is being tested ought to work. The mere possibility that something might turn up will not be enough": Reasons at para. 456.

[16] The Federal Court next set out the non-exhaustive list of factors to be considered, depending on the evidence in the case, when a court determines that the "obvious to try" test is appropriate. These factors are set out at paragraph 69 of *Plavix 1* as follows:

1. Is it more or less self-evident that what is being tried ought to work? Are there a finite number of identified predictable solutions known to persons skilled in the art?

2. What is the extent, nature and amount of effort required to achieve the invention? Are routine trials carried out or is the experimentation prolonged and arduous, such that the trials would not be considered routine?

3. Is there a motive provided in the prior art to find the solution the patent addresses?

[17] The Federal Court then addressed this Court's decision in *Plavix 2*, which was cited to it as authority for the proposition that the lack of knowledge of the properties of a compound meant that it was not obvious to try to obtain that compound. BMS argued that the Skilled Person could not have predicted the properties of the anhydrous form of atazanavir sulfate and therefore it was not obvious to try to obtain a salt with those properties.

[18] The Federal Court, however, considered *Plavix 2* in the context of *Plavix 1*. It noted that in *Plavix 1*, the key factor on the question of obviousness was the lack of knowledge of the

properties of the enantiomers of the compounds of the genus patent, including its racemate. While the technique for resolving racemates was well known, having no knowledge of the properties of the racemate meant that it was not possible to predict what the properties of its enantiomers would be, therefore, it was not obvious to try to resolve the racemate to obtain the enantiomer: Reasons at paras. 464-65; *Plavix 2* at paras. 73-75. BMS argued that this was precisely the case with respect to the bisulfate salt of atazanavir.

[19] The Federal Court pointed out an important difference between the facts in the Plavix litigation and the present case. The Plavix litigation involved a selection patent where the genus patent disclosed over 250,000 different compounds with some utility in inhibiting platelet aggregation in blood. The genus patent identified 21 specific examples of compounds coming within its scope, one of which was a racemate known at PCR 4099. The Federal Court noted that the trial judge in *Plavix 2* found as a fact that the genus patent did not point directly or indirectly to PCR 4099 so that the Skilled Person would have had no motivation to focus on it over other compounds disclosed in the genus patent: Reasons at para. 473.

[20] The Federal Court concluded its comparison of *Plavix 1* and *Plavix 2* as follows:

> I do not understand the finding of the Federal Court of Appeal in *Plavix #*2 that, on the facts of that case, it was not obvious to try to resolve the PCR 4099 racemate to stand for the blanket proposition that in every case where a skilled person cannot predict the properties of a compound in advance of making it, it will not be obvious to try to obtain that compound.
>
> Reasons at para. 475.

[21] The balance of the Federal Court's analysis consisted of applying the principles derived from the jurisprudence to the facts of the case before it.

[22] While there was a difference in the expert evidence on the point, the Federal Court found that even though increasing solubility of a compound would not necessarily increase its bioavailability, it would generally have that effect. Thus the increase in bioavailability as a result of an increase in solubility was more than a possibility and would have been more or less self-evident to the Skilled Person: Reasons at para. 496.

[23] As for the question of motivation to find the claimed solution, the Federal Court found that the limited bioavailability of atazanavir would have given the skilled person every reason to try to improve its solubility – and therefore its bioavailability – by making its salts: Reasons at paras. 483, 497.

[24] After reviewing the common general knowledge and known techniques for salt formation, the Federal Court concluded that the Skilled Person would have come directly and without difficulty to the bisulfate salts of atazanavir: Reasons at para. 501. The Court was confirmed in this view by the fact that BMS' personnel succeeded in making atazanavir salts, including Type-I atazanavir bisulfate salt, on the very first day of their drug development project. Using routine techniques, they were then able to characterize both Type-I and Type-II atazanavir bisulfate salts insofar as solubility, crystallinity, melting points, hygroscopicity and short term solid-state stability were concerned. The Federal Court found that this process was neither prolonged nor arduous: Reasons at para. 502. To the contrary, BMS' personnel arrived at Type-I atazanavir bisulfate "quickly, easily, directly and relatively inexpensively": Reasons at para. 503, citing *Plavix 1* at para. 71.

[25] The Federal Court concluded that, to the extent that the inventive concept of the ‘736 patent was the improved bioavailability of Type-I atazanavir bisulfate salts over the free base of atazanavir, the invention was obvious: Reasons at para. 505.

[26] As for the other elements of the inventive concept, namely the anhydrous non-hygroscopic crystalline solid form, and solid state stability of Type-I atazanavir bisulfate, the Federal Court found that the discovery of these inherent characteristics of Type-I atazanavir bisulfate salt added nothing to the “inventive work” of BMS’ personnel: Reasons at para. 507. To that extent, the determination that this salt had these characteristics was a serendipitous discovery, made without prolonged or arduous work, and was not an invention: Reasons at para. 508.

[27] As a result, the Federal Court concluded that the invention of the Type-I atazanavir bisulfate salt claimed in the ‘736 patent was obvious.

III. Issues in the appeal

[28] BMS challenges the Federal Court’s conclusion as to the obviousness of Type-I atazanavir bisulfate salt on the basis of the Court’s failure to properly apply the “obvious to try” test as set out by the Supreme Court in *Plavix 1*. The substance of BMS’ argument is that the Court’s finding that each of the elements of the inventive concept could not be predicted is fatal to the finding of obviousness.

[29] This argument is encapsulated in paragraphs 77-78 of BMS' memorandum of fact and law:

> 77. The 'obvious to try' test involves a hypothetical cognitive exercise done before the claimed invention is made, and without the benefit of hindsight. To use the words of the Supreme Court in *Plavix #1*, it requires a finding, prospectively, that it would have been "more or less self-evident to try to obtain the invention".
>
> 78. To be satisfied in this case, the legal standard requires the prospective finding (which was never made) that it would have been more or less self-evident that a routine salt screen would generate Type-I atazanavir bisulfate, and that it would have the properties the Applications Judge found were included in the inventive concept.
>
> (citations and emphasis omitted)

[30] Teva counters this argument by pointing out that *Plavix 1* does not stand for the proposition for which it is cited and that this Court's decision in *Plavix 2* does not expand the scope of *Plavix 1*.

IV. Analysis

[31] While the proceeding below is in the form of an application for judicial review – because it was brought by notice of application – it is in substance a summary trial on affidavit evidence. No administrative action is being assessed against a legal standard as would be the case in an application for judicial review. As a result, I find that the appellate standard of review applies; correctness for errors of law and palpable and overriding error for fact or mixed fact and law (absent an extricable error of law): *Agraira v. Canada (Public Safety and Emergency Preparedness)*, 2013 SCC 36, [2013] 2 S.C.R. 559 at para. 45; *Pharmascience Inc. v. Canada (Health)*, 2014 FCA 133, 460 N.R. 343 at para. 31.

[32] The determinative issue in this appeal is whether the Federal Court erred when it found that the development of Type-I atazanavir bisulfate was obvious in spite of the fact that only one of the three elements of the inventive concept, improved bioavailability over the free base of atazanavir, was predictable and the uncontradicted evidence was that the other two elements, crystallinity and stability, were not.

[33] The basis for BMS' argument is the Supreme Court's decision in *Plavix 1* and this Court's elaboration of its rationale in *Plavix 2*. It is therefore useful to review those two cases to see if they support BMS' position.

[34] The innovative feature of the Supreme Court's decision in *Plavix 1* in relation to obviousness was its adoption of the "obvious to try" test, which it linked to the framework set out in jurisprudence in the United Kingdom, namely *Windsurfing International Inc. v. Tabur Marine (Great Britain) Ltd.*, [1985] R.P.C. 59 (Eng. C.A.) [*Windsurfing*] and *Pozzoli SPA v. BDMO SA*, [2007] EWCA Civ. 588, [2007] F.S.R. 37 [*Pozzoli*]. I will refer to this framework as the *Windsurfing/Pozzoli* framework.

[35] Prior to *Plavix 1*, the leading case on obviousness was this Court's decision in *Beloit Canada Ltd. v. Valmet OY* (1986), 64 N.R. 287, 8 C.P.R. (3d) 289 at 294 (F.C.A.) [*Beloit* cited to C.P.R.] where the well-known comparison to the "Man on the Clapham omnibus" was drawn:

> The classical touchstone for obviousness is the technician skilled in the art but having no scintilla of inventiveness or imagination; a paragon of deduction and dexterity, wholly devoid of intuition; a triumph of the left hemisphere over the right. The question to be asked is whether this mythical creature (the man in the

> Clapham omnibus of patent law) would, in the light of the state of the art and of common general knowledge as at the claimed date of invention, have come directly and without difficulty to the solution taught by the patent.

[36] In *Plavix 1*, the Supreme Court addressed "the restrictiveness with which the *Beloit* test has been interpreted in Canada", noting that the application judge had found that the *Beloit* test would not accommodate the "worth a try" test: *Plavix 1* at paras. 52. The Supreme Court reviewed the English and American jurisprudence on the "obvious to try" test, finding that it had been accepted in both jurisdictions. This convergence influenced the Supreme Court in its decision to endorse the "obvious to try" test.

[37] The Supreme Court then noted that the English jurisprudence identified the following non-exhaustive list of factors as "useful guides in deciding whether a particular step was 'obvious to try'" (*Plavix 1* at para. 59):

> The question of obviousness must be considered on the facts of each case. The court must consider the weight to be attached to any particular factor in the light of all the relevant circumstances. These may include such matters as the motive to find a solution to the problem the patent addresses, the number and extent of the possible avenues of research, the effort involved in pursuing them and the expectation of success.
>
> *H. Lundbeck A/S v. Generics (UK) Ltd.*, [2008] EWCA Civ. 311, [2008] R.P.C. 19 at paras. 24-25 [*Lundbeck*], citing *Angiotech Pharmaceuticals Inc. v. Conor Medsystems Inc.*, [2007] EWCA Civ. 5, [2007] R.P.C. 20 at para. 45, rev'd on other grounds [2008] UKHL 49, [2008] R.P.C. 28.

[38] Having noted these factors, the Supreme Court was quick to add that "the 'obvious to try' test must be approached cautiously" because it "is only one factor to assist in the obviousness inquiry": *Plavix 1* at para. 64.

[39] After a brief digression into the meaning of “obvious”, the Supreme Court offered its view as to the threshold for the “obvious to try” test:

> For a finding that an invention was “obvious to try”, there must be evidence to convince a judge on a balance of probabilities that it was more or less self-evident to try to obtain the invention. Mere possibility that something might turn up is not enough.
>
> *Plavix 1* at para. 66.

[40] This led the Court to the next step in its reasoning, which was to say that it would be useful in an obviousness inquiry “to follow the four-step approach first outlined by Oliver L.J.” in *Windsurfing* as updated in *Pozzoli*, [i.e. the *Windsurfing/Pozzoli* framework], reproduced below:

> (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?
>
> *Plavix 1* at para. 67.

[41] The Supreme Court then stated that “[i]t will be at the fourth step of the *Windsurfing/Pozzoli* approach to obviousness that the issue of ‘obvious to try’ will arise”: *Plavix 1* at para. 67.

[42] The Supreme Court, immediately following its articulation of the *Windsurfing/Pozzoli* framework, asked when the "obvious to try" test might be appropriate. Its discussion of this question is reproduced below:

> In areas of endeavour where advances are often won by experimentation, an "obvious to try" test *might* be appropriate. In such areas, there may be numerous interrelated variables with which to experiment. For example, some inventions in the pharmaceutical industry *might* warrant an "obvious to try" test since there may be many chemically similar structures that can elicit different biological responses and offer the potential for significant therapeutic advances.
>
> *Plavix 1* at para. 68 (my emphasis).

[43] The contingency that the "obvious to try" test might not apply in any given case is underlined at the next step of the Supreme Court's reasoning, where it identifies the factors that <u>should</u> be considered <u>if</u> an "obvious to try" test is warranted. The Court then rephrased the non-exhaustive list of factors set out in *Lundbeck* [the *Lundbeck* factors] that apply in accordance with the evidence in a given case:

> 1. Is it more or less self-evident that what is being tried ought to work? Are there a finite number of identified predictable solutions known to persons skilled in the art?
>
> 2. What is the extent, nature and amount of effort required to achieve the invention? Are routine trials carried out or is the experimentation prolonged and arduous, such that the trials would not be considered routine?
>
> 3. Is there a motive provided in the prior art to find the solution the patent addresses?
>
> *Plavix 1* at para. 69.

[44] The Court suggested another factor which, it seems to me, is essentially an elaboration of the second factor. After pointing out that "obviousness is largely concerned with how a skilled worker would have acted in the light of the prior art", the Court commented that this was "no

reason to exclude evidence of the history of the invention, particularly where the knowledge of those involved in finding the invention is no lower than what would be expected of the skilled person": *Plavix 1* at para. 70. If the inventors, operating at the same level as a Skilled Person, came to the invention quickly and easily in light of the prior art and the common general knowledge, this would suggest that a Skilled Person would have acted in much the same way and come to the same conclusion: *Plavix 1* at para. 71.

[45] Having set out the applicable principles, the Supreme Court undertook the "obvious to try" analysis at first instance. The trial judge had not done so and the Supreme Court considered it preferable to avoid remitting the matter to the trial judge for redetermination so as to avoid further delay: *Plavix 1* at para. 73.

[46] The first two elements of the *Windsurfing/Pozzoli* framework, the identification of the person skilled in the art and the common general knowledge, were straightforward. The person skilled in the art was a trained pharmachemist and the common general knowledge included the fact that that there were five well-known methods to separate the relevant racemate, PC 4099, into its isomers but did not include the relative advantages of the dextro-rotatory isomer: *Plavix 1* at paras. 74-75.

[47] The identification of the inventive concept was also straightforward. The Supreme Court construed the claims of the '777 patent as constituting "the dextro-rotatory isomer of the racemate and its pharmaceutically acceptable salts and processes for obtaining them": *Plavix 1* at para. 76. The inventive concept was not readily discernable from the claims, thus the

Supreme Court construed it as "a compound useful in inhibiting platelet aggregation which has greater therapeutic effect and less toxicity than the other compounds of the '875 patent and the methods for obtaining that compound": *Plavix 1* at paras. 77-78.

[48] In the third step the Supreme Court departed from the *Windsurfing/Pozzoli* framework which calls for the identification of the differences between the common general knowledge and the inventive concept. Instead, the Supreme Court compared the '875 patent (the genus patent) to the '777 patent (the selection patent). It concluded that, unlike the '875 patent, the '777 patent disclosed "that the invention of the dextro−rotatory isomer of the racemate, clopidogrel, and its bisulfate salt discloses their beneficial properties over the levo-rotatory isomer and the racemate and expressly describes how to separate the racemate into its isomers": *Plavix 1* at paras. 79-80.

[49] This took the Supreme Court to the fourth and final step of the *Windsurfing/Pozzoli* framework, inquiring whether the differences between the common general knowledge and the inventive concept would have been obvious to the Skilled Person. The Supreme Court first asked if recourse to the "obvious to try" test was warranted. Referring to the expert evidence as to the discovery of the beneficial properties of the dextro-rotatory isomer and its bisulfate salts, it concluded that recourse to the "obvious to try" test was warranted and that the application judge had erred in not applying the "obvious to try" test: *Plavix 1* at paras. 81-82.

[50] Applying the "obvious to try" factors, the Supreme Court first asked whether it was self-evident that what was being tried ought to work. It noted that the Skilled Person would not

know, before isolating and testing them, that the properties of the dextro-rotatory isomer would be different from the properties of the racemate or the levo-rotatory isomer: Reasons at paras. 84-85. The focus on the properties of the isomers was dictated by the fact that it is the special properties of the selection which make it inventive.

[51] The Court went on to find that the mere fact that there were well know techniques for isolating isomers did not mean that it was evident to apply those techniques, even if it was known that the properties of the isomers and the racemate might be different: *Plavix 1* at para. 85.

[52] Turning to the "extent, nature and amount of effort required to achieve the invention", the Supreme Court noted that it would have small significance in light of the Court's observations on the actual course of conduct leading to the invention. When considering the latter factor, the Supreme Court observed that Sanofi had spent several millions of dollars to develop the racemate in issue – not its isomers – for several years, to the point of testing it in its salified form in clinical trials, before attempting to see if the dextro-rotary isomer had advantageous properties compared to the racemate. If it had been obvious to separate the racemate and test the properties of the dextro-rotary isomer, the Court reasoned that Sanofi would not have wasted the time and money it did in attempting to commercialize the racemate: *Plavix 1* at paras. 91-92.

[53] The Court found that while it could be assumed that there was a general motive to find an effective and non-toxic product to inhibit platelet aggregation, there was nothing in the '875

patent or common general knowledge to motivate the Skilled Person to pursue the invention of the ‘777 patent: *Plavix 1* at para. 90.

[54] The Supreme Court summarized its conclusions on obviousness as follows:

> …it was not self-evident from the '875 patent or common general knowledge what the properties of the dextro-rotatory isomer of this racemate would be or what the bisulfate salt's beneficial properties would be and therefore that what was being tried ought to work. *The course of conduct and the time involved throughout demonstrate that the advantage of the dextro-rotatory isomer was not quickly or easily predictable. Had the dextro-rotatory isomer been “obvious to try”, it is difficult to believe that Sanofi would not have opted for it before unnecessary time and investment were spent on the racemate.* I conclude that the prior art and common general knowledge of persons skilled in the art at the relevant time were not sufficient for it to be more or less self-evident to try to find the dextro-rotatory isomer.
>
> *Plavix 1* at para. 92 (my emphasis).

[55] BMS did not limit its argument to *Plavix 1* but also relied on this Court’s decision in *Plavix 2*. It is worth underlining what this Court decided on the issue of obviousness in *Plavix 2*:

> Given that the Trial Judge applied the test for obviousness set out in *Plavix* [*Plavix 1*], and given that he applied it to the same material facts as the Supreme Court, he ought to have come to the same conclusion.
>
> *Plavix 2* at para. 81.

[56] Having said that the trial judge in *Plavix 2* erred in coming to a different conclusion than did the Supreme Court in *Plavix 1* when he applied the same law to the same facts, this Court was hardly in a position to argue that some other test should have been applied. I am therefore of the view that one should be wary of seeing things in *Plavix 2* that have no foundation in

Plavix 1. The governing authority remains *Plavix 1*. I also agree with the distinction which the Federal Court drew between the facts of *Plavix 1* and the facts of this case.

[57] It is useful, at this point, to take stock and to review what *Plavix 1* teaches and what it leaves for the lower courts to work out.

[58] As noted earlier, the novel feature of *Plavix 1* is its endorsement of the "obvious to try" test which it linked to the *Windsurfing/Pozzoli* framework. The impetus for this endorsement was the "acontextual" application of the *Beloit* test to all classes of claims. It noted that "the courts have often tended to treat the word formulation of Beloit as if it were a statutory prescription that limits the obviousness inquiry": *Plavix 1* at para. 61. Along the same lines, it expressed its view that in matters where courts must make factual determinations, rigid rules are inappropriate unless mandated by statute.

[59] At the same time, the Supreme Court showed itself to be very cautious about substituting one rigid rule for another. Its discussion leading to its endorsement of the "obvious to try" test is replete with cautionary notes, including the observation that the "obvious to try" test is not mandatory in England and the United States: *Plavix 1* at para. 62. It made the point that the "obvious to try" test was to be approached cautiously as it was only one factor in the obviousness inquiry, from which one might conclude that it is not mandatory in Canada either: *Plavix 1* at para. 64. After having set out the *Windsurfing/Pozzoli* framework, the Court asked when the "obviousness to try" test might be appropriate, which suggests that it might not always be appropriate. The Supreme Court went on to conclude that it *might* be so in

pharmaceutical litigation. In introducing the *Lundbeck* factors, the Supreme Court was careful to stipulate that those factors should be considered *if* the "obvious to try" test was warranted. In applying the *Windsurfing/Pozzoli* framework to the case before it, the Supreme Court began its consideration of the last step by asking "whether the nature of the invention in this case is such as to warrant an 'obvious to try' test": *Plavix 1* at para. 81.

[60] The reasonable conclusion to be drawn from these expressions of caution is that the "obvious to try" test has not displaced all other inquiries into obviousness. Indeed, that is what this Court concluded in *Wenzel Downhole Tools Ltd. v. National-Oilwell Canada Ltd*., 2012 FCA 333, [2014] 2 F.C.R. 459 at para. 105. In a passage referring to the adoption of the "obvious to try test", this Court wrote:

> Finally, one must recall that the Supreme Court of Canada in *Sanofi* clearly indicated that there is no single or mandatory approach in the obviousness inquiry. Indeed, accepting that the "obvious to try" approach might be useful depending on the circumstances was part of a move away from rigid rules that had limited the obviousness inquiry, towards a more flexible, expansive, and fact driven inquiry (*Sanofi* at paragraphs 61-63). The Court only wanted to bring more structure, clarity, and objectivity to the analysis (*Sanofi* at paragraph 67).
>
> (See also, in a pharmaceutical context, *Teva Canada Ltd. v. Novartis Pharmaceuticals Canada Inc.*, 2013 FCA 244, 451 N.R. 246 at para. 7.)

[61] While the Supreme Court accepted the "obvious to try" test as a way of addressing the issue of obviousness, other inquiries remain possible, including the *Beloit* test, subject to the Court's warnings about a rigid "acontextual" application of that test, or of any other for that matter. The Court has made it clear that it favours "an expansive and flexible approach that would include 'any secondary considerations that [will] prove instructive'": *Plavix 1* at para. 63.

[62] As a result, I am of the view that a categorical approach to obviousness, such as that advocated by BMS, is inappropriate. The elaboration of a hard and fast rule that obviousness cannot be shown unless all the elements of the inventive concept can be predicted with a high degree of certainty is the antithesis of the approach to obviousness that the Supreme Court favoured in *Plavix 1*. Not every case requires recourse to the "obvious to try" test and not every recourse to the "obvious to try" test must follow in the furrow of the preceding application of that test.

[63] The caution with which the Supreme Court approached the "obvious to try" test might be contrasted with the manner in which it adopted the *Windsurfing/Pozzoli* framework. There was no discussion of the reasons why the Supreme Court felt that it would be useful to adopt that framework beyond its conclusory statement that it "should bring better structure to the obviousness inquiry and more objectivity and clarity to the analysis": *Plavix 1* at para. 67. Nor did the Supreme Court refer to the cautionary note struck in *Pozzoli* with respect to the inventive concept:

> In some cases the parties cannot agree on what the concept is. If one is not careful such a disagreement can develop into an unnecessary satellite debate. In the end what matters is/are the difference(s) between what is claimed and the prior art. It is those differences which form the "step" to be considered at stage (4). So if a disagreement about the inventive concept of a claim starts getting too involved, the sensible way to proceed is to forget it and simply to work on the features of the claim.
>
> *Pozzoli* at para. 19 (my emphasis).

[64] It is true that the *Windsurfing/Pozzoli* framework does provide structure but it is not obvious that it has been useful. In *Allergan Inc. v. Canada (Minister of Health)*, 2012 FC 767, 103 C.P.R. (4th) 155 at paras. 135-141, Hughes J. quickly surveyed some of the varying

interpretations of the inventive concept which have emerged since 2008. A more comprehensive survey is found in Joshua Sealy-Harrington, "The Inventive Concept in Patent Law: Not So Obvious" (2015) 27 I.P.J. 385 at 394-409.

[65] It may be helpful to keep in mind that the obviousness analysis asks whether the distance between two points in the development of the art can be bridged by the Skilled Person using only the common general knowledge available to such a person. If so, it is obvious. The first of those points is the state of the prior art at the relevant date. References in the jurisprudence to "the inventive concept", "the solution taught by the patent", "what is claimed" or simply "the invention" are attempts to define the second point.

[66] Prior to *Plavix 1*, the jurisprudence followed *Beloit* and treated the second point as "the solution taught by the patent" which was often treated as synonymous with "what is claimed in the patent" or "the invention": *Proctor & Gamble Pharmaceuticals Canada Inc. v. Canada (Minister of Health)*, 2004 FCA 393, [2005] 2 F.C.R. 269 at para. 47, *Pfizer Canada Inc. v. Canada (Health)*, 2007 FCA 209, 366 N.R. 347 at para. 133, *Novopharm Limited v. Janssen-Ortho Inc.*, 2007 FCA 217, 366 N.R. 290 at para. 25. The question is whether the "inventive concept" was intended to redefine the second point as it was understood to be prior to *Plavix 1*. I note that in the passage from *Pozzoli* quoted above, the English Court of Appeal did not consider the "inventive concept" to have changed anything of substance. If the parties could not agree on it, it could be forgotten. It went on to say at paragraph 19 of its reasons: "In the end what matters is/are the difference(s) between what is claimed and the prior art." This is essentially the state of Canadian law prior to *Plavix 1*.

[67] Is it the case that changing one of the two points I referred to earlier amounts to changing the definition of obviousness? Given that obviousness is concerned with whether bridging the difference between the prior art and a second point requires inventiveness, changing the second point will affect the difficulty of bridging that difference, therefore making inventiveness more or less likely. If that is so, is it reasonable to conclude that the Supreme Court intended to change the definition of the obviousness analysis when it adopted, without commentary, the *Windsurfing/Pozzoli* framework? Is it likely that the Supreme Court, having taken great care in modifying the test for obviousness, would, without saying so, change the definition of obviousness?

[68] My inclination is to believe that the Supreme Court does not change substantive law by implication, particularly when it has shown a cautious approach to change in the same context: see *Apotex Inc. v. Eli Lilly Canada Inc.*, 2016 FCA 267, 142 C.P.R. (4th) 171 at para. 37.

[69] As an aside, it seems to me that the use of "inventive concept" begs the question which the *Windsurfing/Pozzoli* framework seeks to answer. The question in an obviousness inquiry is whether there has been inventiveness or not. Requiring the Court to identify the inventive concept assumes inventiveness. It is illogical to ask the Court to identify the inventive concept of the claimed invention and then to ask it to determine if the claimed invention is in fact inventive.

[70] In my view, this is the conundrum which the Federal Court faced in this case. Having identified the inventive step as comprising three elements, the Federal Court was forced to say at the conclusion of its analysis that two of those elements were not inventive at all. It is this conclusion which feeds the present appeal. I would say, in light of the Federal Court's reasoning, that its error was not in its application of the "obvious to try" test but in its identification of the inventive concept.

[71] All of this brings me to the merits of this appeal.

[72] The first steps of the *Windsurfing/Pozzoli* framework are not contentious. The Federal Court's correctly identified the person skilled in the art and the common general knowledge. In particular, I note the conclusion at paragraph 412 of the Federal Court's reasons that the Skilled Person would have expected that a salt screen would likely identify at least one salt that would have improved pharmaceutical properties compared to the free base of atazanavir.

[73] The relevant prior art is the teaching of the '840 patent which teaches atazanavir and claims it and its pharmaceutically acceptable salts.

[74] The key issue was the identification of the inventive concept. In my view, the Federal Court erred in its identification of the inventive concept. The source of its error was its failure to articulate the meaning of the inventive concept. On the basis of the arguments made to it by the parties, the Federal Court implicitly adopted a definition of the inventive concept which

focussed on the properties of atazanavir bisulfate. This was, in my view, an extricable error of law that justifies our intervention.

[75] For the reasons set out above, I find that the "inventive concept" is not materially different from "the solution taught by the patent". Had the Federal Court applied that definition to the facts, it would have found that the inventive concept in this case is atazanavir bisulfate, a salt of atazanavir which is pharmaceutically acceptable because it has equal or better bioavailability than the atazanavir free base. Atazanavir's limited bioavailability was the source of the motivation to pursue the solution. The fact that claim 2 of the '736 patent claims a pharmaceutical dosage form of Type-I atazanavir bisulfate confirms its acceptability for pharmaceutical purposes.

[76] Had the Federal Court correctly defined the inventive concept, it would have found, at step 3 of the *Windsurfer/Pozzoli* framework, that there is no difference between the prior art and the inventive concept or the solution taught by the patent. This is to say that there is no difference between (i) atazanavir and its pharmaceutically acceptable salts and (ii) atazanavir bisulfate, a salt of atazanavir which is pharmaceutically acceptable because of its bioavailability. In any event, such difference as there was between the two could be bridged, at step 4 of the *Windsurfing/Pozzoli* framework, without inventiveness using only the common general knowledge of the person skilled in the art. The Skilled Person would have expected that a salt screen would likely identify at least one salt that would have improved pharmaceutical properties, specifically bioavailability, compared to the free base of

atazanavir: Reasons at paras. 412, 495. Furthermore, it was only a matter of routine work to characterize the properties of such a salt: Reasons at paras. 400, 504.

[77] On that basis, if the Federal Court had correctly defined the inventive concept, it would not have found it necessary to apply the "obvious to try" test. However, if it were necessary to apply that test, its consideration of the second *Lundbeck* factor, at paras. 501-504 of its reasons was a sufficient ground upon which to find that Teva's allegation of obviousness was justified.

[78] It will be recalled that the second *Lundbeck* factor is the extent, nature and amount of effort required to achieve the invention. In essence, this inquiry is very similar to the *Beloit* inquiry as to whether, having regard to the prior art and the common general knowledge, the Skilled Person would come directly and without difficulty to the claimed invention. The Federal Court found that the extent, nature and amount of effort required to get to Type-I atazanavir bisulfate showed that its discovery was obvious: Reasons at paras. 502-503.

[79] It will be recalled that the '840 patent claimed atazanavir and its pharmaceutically acceptable salts: Reasons at para. 381. It will also be recalled that the experts were agreed that conducting salt screens were routinely used when attempting to increase the solubility of a compound. Increasing a compound's solubility will generally increase its bioavailability: Reasons at para. 496. In addition, the '840 patent identified sulfuric acid as one of the acids which might be used to make an atazanavir salt: Reasons para. 408.

[80] The Federal Court reviewed the course of BMS' development work resulting in the isolation of Type-I atazanavir bisulfate as a candidate for patentability. BMS scientists succeeded in making Type-I atazanavir bisulfate salts, among others, on the first day of their drug development process. It took approximately six weeks to characterize Type-I and Type-II salts insofar as their various properties were concerned, but this work was routine and not arduous: Reasons at paras.399-400, 504. There was no suggestion that BMS scientists were working at a higher level than would have been persons skilled in the art: Reasons at para. 503. On this evidence, the Federal Court was entitled to conclude that a skilled person "would quickly, easily, directly and relatively inexpensively, in light of the prior art and common general knowledge" come to Type-I atazanavir bisulfate salt. In the Federal Court's view, the discovery of Type-I atazanavir bisulfate was obvious: Reasons at paras. 509-10. I agree.

[81] In addition, the Federal Court concluded that there was motivation to find a pharmaceutically acceptable salt of atazanavir with superior bioavailability than the free base of atazanavir, the third *Lundbeck* factor: Reasons at paras. 481-84. Though not necessarily a sufficient ground for finding that the development of atazanavir bisulfate was obvious, this factor confirms the conclusion to which the Federal Court came in considering the second *Lundbeck* factor.

[82] On the facts of this case, it seems to me that the facts which support the conclusion that the distance between the prior art and the inventive concept (defined as the solution taught by the patent) could be bridged without recourse to inventiveness would also satisfy the first *Lundbeck* factor in that it was more or less self-evident that what was being tried ought to

work. It seems to me that when this factor is taken it was articulated by the Supreme Court, the conclusion that the Skilled Person would have regarded a salt screen as a more or less self-evident way of getting to a form of atazanavir with greater bioavailability is inescapable.

[83] In the result, I would dismiss the appeal because, having regard to the prior art and the common general knowledge of the Skilled Person, the development of atazanavir was obvious.

V. CONCLUSION

[84] I would therefore dismiss the appeal with costs.

"J.D. Denis Pelletier"
J.A.

“I agree
D.G. Near J.A.”

“I agree
Donald J. Rennie J.A.”

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

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