Federal Court of Appeal | Cour d'appel fédérale

Date: 20190125

Docket: A-283-17

Citation: 2019 FCA 15

CORAM: **WEBB J.A.**
BOIVIN J.A.
DE MONTIGNY J.A.

BETWEEN:

TEVA CANADA LIMITED

Appellant

and

PFIZER CANADA INC., WYETH LLC
and THE MINISTER OF HEALTH

Respondents

Heard at Ottawa, Ontario, on November 19, 2018.

Judgment delivered at Ottawa, Ontario, on January 25, 2019.

PUBLIC REASONS FOR JUDGMENT BY: BOIVIN J.A.

CONCURRED IN BY: WEBB J.A.
DE MONTIGNY J.A.

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PUBLIC REASONS FOR JUDGMENT

BOIVIN J.A.

I. Introduction

[1] On August 22, 2017, following proceedings under the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133, Brown J. of the Federal Court (the Federal Court Judge) issued an order as part of his judgment (2017 FC 777) prohibiting the Minister of Health from

issuing a Notice of Compliance (NOC) to Teva Canada Limited (Teva) in respect of a Notice of Allegation dated July 10, 2015 sent by Teva to Pfizer Canada Inc., previously Wyeth LLC, (Pfizer or Wyeth) until the expiry of Canadian Patent No. 2,436,668 ('668 Patent). The '668 Patent concerns a drug called O-desmethyl-venlafaxine (ODV). It is used for the treatment of depression. This appeal relates to Form I ODV succinate which is a particular crystal form of a particular salt of ODV, namely ODV succinate.

[2] Teva appeals the Federal Court Judge's decision. This appeal, along with the companion appeal in *Apotex Inc. v. Pfizer Canada Inc. et al*. (2019 FCA 16), concern issues related to the Federal Court Judge's obviousness analysis in respect of the '668 Patent. These appeals did not proceed jointly and the hearings took place separately. A number of arguments advanced by Teva and Apotex against Pfizer nonetheless overlap as do, to some extent, these reasons and those forming part of the companion appeal decision.

[3] In essence, Teva argues that the Federal Court Judge misconstrued and misapplied the test for obviousness as set out in *Apotex Inc. v. Sanofi-Synthelabo Canada Inc*., 2008 SCC 61, [2008] 3 S.C.R. 265 [*Sanofi*] and that his obviousness analysis is directly contrary to two judgments rendered by our Court: *Bristol-Myers Squibb Canada Co. v. Teva Canada Limited*, 2017 FCA 76, 146 C.P.R. (4th) 216 [*Atazanavir*]; and *Pfizer Limited v. Ratiopharm Inc.*, 2010 FCA 204, 87 C.P.R. (4th) 185 [*Amlodipine*]. Teva also argues that the Federal Court Judge made palpable and overriding errors in considering the properties in his reasons because they are not part of the inventive concept and that he further erred in accepting hearsay evidence and misunderstanding the evidence particularly as it relates to the work conducted by Wyeth.

[4] For the reasons below, I would dismiss the appeal with costs.

II. Federal Court Judge's decision

[5] The Federal Court Judge issued a decision spanning over 350 paragraphs. For the purposes of this appeal, the following account of this decision is required.

[6] It is noted from the outset that the Federal Court Judge provided a thorough and comprehensive review of the facts and evidence submitted by the parties. This includes the invention story; the experimentation with ODV fumarate; the failed attempt to form a new drug of ODV; the attempt to form an acceptable salt of ODV; the screening of polymorphs and crystals; the evaluation of solubility of drug candidates; the preparation of ODV succinate; the permeability and bioavailability testing of the most promising ODV salt forms, including *in vitro* human cell-based Caco-2 assay and the *in vivo* rat perfusion test; the Beagle dog testing; and the Human testing and its subcontracting to SSCI, Inc. (SSCI).

[7] Against this background, the Federal Court Judge found that, on a balance of probabilities, Teva's allegations of invalidity due to obviousness and inutility were not justified. In reaching that conclusion, the Federal Court Judge discussed obviousness at length, as this was the primary issue at first instance and essentially remains the main issue in this appeal. The Federal Court Judge thoroughly reviewed the test for obviousness, reiterating and relying first and foremost on the Supreme Court's decision in *Sanofi*. In particular, the Federal Court Judge noted that *Sanofi* introduced the "obvious to try" test, but that in doing so, the Supreme Court

directed that the "obvious to try" analysis should be approached cautiously (Reasons at paras. 167-169).

[8] The Federal Court Judge also recalled this Court's jurisprudence on obviousness rendered post *Sanofi*. He expressly referred to the recent decision of our Court in *Atazanavir* which not only reiterated that the innovative element of *Sanofi* was the introduction of the "obvious to try" test but also that the obviousness to try analysis is not meant to replace all previous inquiries and that other inquiries remain possible (Reasons at paras. 177-182).

[9] Having addressed the applicable principles of law, the Federal Court Judge undertook "step 1" of the obviousness analysis in accordance with the *Sanofi* framework. More particularly, after first identifying the notional skilled person in the art (skilled person), the Federal Court Judge discussed the common general knowledge of the skilled person. He noted that the common general knowledge would include the methods and techniques for salt and crystal formation, as well as knowledge of ODV as the active metabolite of venlafaxine and ODV as a free base and a fumarate salt (Reasons at paras. 189-190). He further noted that, while the prior art disclosed ODV succinate as a potential salt, neither Form I ODV succinate nor any other crystal form of ODV succinate had ever been disclosed, made or characterized (Reasons at para. 191). As a result, the Federal Court Judge found the skilled person could not predict whether or not a particular salt formation experiment would result in stable crystals. Hence, the skilled person would not have known in advance whether ODV succinate generally, or Form I ODV succinate specifically, "would work" (Reasons at paras. 192-193). The Federal Court Judge also found that polymorph screening was not mechanical and repetitious work and that the skilled person would

not be able to further predict before a polymorph screen "how many solid forms would [be] identified, what they would be, or what solid forms would result from any particular method or set of conditions." (Reasons at para. 194).

[10] The Federal Court Judge then turned to "step 2" in the obviousness analysis for purposes of defining the "inventive concept". He determined that the inventive concept of the relevant claims of the '668 Patent was the novel crystal form *i.e.*, Form I ODV succinate (Reasons at para. 211). This led to "step 3" of the obviousness analysis, whereby the Federal Court Judge concluded that the difference between the state of the art and the inventive concept of the relevant claims was "the invention of a new composition of matter namely Form I ODV succinate." (Reasons at para. 229).

[11] The Federal Court Judge's obviousness analysis subsequently turned to "step 4" *i.e.*, whether the differences between the state of the art and the inventive concept "constitute steps which would have been obvious to the person skilled in the art" or whether they require any degree of invention. The Federal Court Judge first undertook this step by applying the pre-*Sanofi* definition of obviousness set out in *Beloit Canada Ltd. v. Valmet Oy*, (1986), 64 N.R. 287, 8 C.P.R. (3d) 289 (F.C.A.) [*Beloit*], namely whether the skilled person would have come directly and without difficulty to the solution taught by the '668 Patent (Reasons at paras. 242-243 and 248). The Federal Court Judge determined, in the present case, that the skilled person would not have come directly and without difficulty to the novel crystalline Form I ODV succinate. Relying on the evidence provided by the experts, he found that it would have been impossible at the relevant time to predict "whether the ODV succinate salt would form as a solid, whether that

solid would be crystalline, or what the properties of a hypothetical crystalline solid would be." (Reasons at para. 247). The Federal Court Judge added that the skilled person would foresee a difficult and indirect road ahead that was in effect equivalent to a research program (Reasons at paras. 248-249).

[12] The Federal Court Judge then considered the "obvious to try" test and deemed it applicable in the circumstances as the matter is one pertaining to the "pharmaceutical industry". In doing so, he recalled that the "obvious to try" test must be approached cautiously and that it is meant to be only one factor to assist in the obviousness inquiry (Reasons at para. 253). The Federal Court Judge proceeded to review the matter against the "obvious to try" test by considering the factors discussed by the Supreme Court in *Sanofi* with the understanding that they are not meant to be exhaustive.

[13] First, the Federal Court Judge determined that it was not "more or less self-evident that what is being tried ought to work". He acknowledged the cases cited by the parties in this regard but concluded that none of these cases confirm that all salt screens and all polymorph or crystal screens are obvious to try or are routine; rather, he observed that each case turns on its particular facts (Reasons at para. 257). In the present case, based on his review of the evidence of Pfizer's witnesses, Dr. Myerson and Dr. Park, as well as the evidence of Teva's expert, Dr. Fiese, the Federal Court Judge concluded that the skilled person could not predict that Form I ODV succinate existed, what properties it would have, or how it could be prepared, if at all (Reasons at para. 258).

[14] The Federal Court Judge also determined that, in the present case, there were not "a finite number of "identified predictable solutions" known to persons skilled in the art". Rather, the number of potential experiments "was in fact extremely large" (Reasons at para. 264). He explained that the knowledge of salt screens and polymorph tests merely provided avenues of research. The evidence demonstrated only "mere possibilities of identifying the ODV succinate salt, or perhaps no salt at all, in a salt screen in first instance, and a possibility of finding Form I ODV succinate crystalline, or perhaps no crystalline form at all, in crystallization and polymorph screening" and that "mere possibilities are not sufficient" (Reasons at paras. 267 and 274).

[15] In addition, the Federal Court Judge concluded that "the extent, nature and amount of effort required to achieve the invention" was considerable (Reasons at para. 276). There was no evidence that the skilled person would know which salt or crystalline form would achieve the invention. On the contrary, there was reason to believe that ODV succinate would not work because past experimentation with ODV fumarate had proved unsuccessful. ODV in its disassociated state (separated from the ODV fumarate salt once dissolved) did not work when introduced into the body. The evidence therefore demonstrated that it was logical to expect that succinate salt also would not work "because the ODV dissociated from the succinate salt would be the same as the ODV dissociated from the fumarate salt." (Reasons at para. 277). In the words of the Federal Court Judge, the nature of the work was "uphill" (*ibid*).

[16] The Federal Court Judge also determined that while the salt screening alone may not be characterized as prolonged and arduous work, the invention story considered as a whole,

including the pro-drug experiments and the SSCI polymorph and crystallization work, was "anything but trivial" (Reasons at para. 279).

[17] As for the motive provided in the prior art, the Federal Court Judge affirmed the following:

> [282] There is no evidence of motivation in the prior art that points in the direction of the succinate salt of ODV, nor to any particular solid state form of ODV succinate, let alone the Form I monohydrate. This is not unexpected given the [s]killed [p]erson would have had no knowledge or predictability of what forms existed nor how they could be formed.

[18] The Federal Court Judge explained that while there may have been a motive to find a form of ODV that could be formulated, there was no evidence of motivation that suggested succinate salt as the solution (Reasons at para. 283).

[19] Finally, the Federal Court Judge examined the course of conduct which culminated in Form I ODV succinate. He concluded that this course of conduct in the context of the invention story which led to the making of Form I ODV succinate was not routine. Salt forms were seen as counter-intuitive and viewed with skepticism based on the past experience with ODV fumarate. More particularly, the Federal Court Judge indicated that five of the seven salts screened by Wyeth in the summer of 2000 could not be formed or were not crystalline. Moreover, work was performed prior to the salt screen, including the work with ODV fumarate and pro-drugs. Also, the considerable work conducted by Wyeth after the detailed salt and specialized crystal polymorph screening could not be ignored (Reasons at paras. 294-297). Although some steps may not have been independently arduous, the Federal Court Judge was of the view that the

course of conduct overall entailed a research program, and that the skilled person would have viewed it as such (Reasons at paras. 301-302).

[20] On the basis of the above, the Federal Court Judge concluded that Form I ODV succinate was not obvious or "obvious to try". Teva's allegations were accordingly dismissed.

[21] Additionally, in response to Teva's contention, the Federal Court Judge determined that the '668 Patent was not a selection patent. If other patents (*i.e.*, US 186 and WO 851) refer to ODV succinate and other possible salts, they do not disclose the crystalline form of ODV – Form I ODV succinate – which is the subject matter of the relevant claims of the '668 Patent (Reasons at para. 290). The Federal Court Judge therefore found that "[w]hile the salt was disclosed, the crystal form was not" and concluded that Form I ODV succinate is "a new composition of matter" (Reasons at paras. 290-291).

III. Issues in this appeal

[22] The issues in this appeal are as follows:

- Did the Federal Court Judge err in applying the test for obviousness?
- Did the Federal Court Judge err in his finding regarding fumarate and in relying on the skepticism at Wyeth?

IV. Standard of review

[23] Obviousness is a factual inquiry which involves questions of mixed fact and law. Hence, each case will turn on its own facts, and it is ultimately the role of the judge to apply the law to

these facts. Absent an extricable legal error, the Federal Court Judge's application of the law to the facts is subject to the deferential standard of palpable and overriding error (*Housen v. Nikolaisen*, 2002 SCC 33; [2002] 2 S.C.R. 235 [*Housen*]; and *Alcon Canada Inc. v. Actavis Pharma Company*, 2015 FCA 191, [2015] F.C.J. No. 1083 (QL) [*Alcon*]).

V. Analysis

A. *The applicable legal framework for obviousness*

[24] In this appeal, Teva essentially contends that the Federal Court Judge made extricable errors of law in applying the test for obviousness and that he also made palpable and overriding errors in his application of the test. Prior to addressing Teva's contentions, it is apposite to recall the law on obviousness as it currently stands.

[25] The well-established framework for the obviousness inquiry remains the one set out by the Supreme Court in *Sanofi*. In that case, the Supreme Court established four steps (at para. 67):

1- Identify the notional "person skilled in the art" and the relevant common general knowledge of that person;

2- Identify the inventive concept of the claim or the claims in question;

3- Identify what differences exist between the "state of the art" and the inventive concept; and

4- Determine whether, viewed without knowledge of the alleged invention as claimed, those differences constitute steps which would have been obvious to the person skilled in the art or whether they require any degree of invention. In other words: Is the inventive concept obvious?

[26] In *Sanofi*, the Supreme Court also introduced at the fourth step the "obvious to try" test which lists a number of non-exhaustive factors to consider in determining whether the invention was "obvious to try" (*Sanofi* at para. 69). Although not every case will require an application of the "obvious to try" test, it can be appropriate in instances where the art in question encompasses advances made as a result of experimentation.

[27] Following *Sanofi*, our Court in *Atazanavir* echoed the Supreme Court's consideration of obviousness by reiterating that the "obvious to try" test must be approached with caution as it remains one factor amongst many that may assist in the obviousness inquiry (*Atazanavir* at para. 38; *Sanofi* at paras. 64-65). Our Court in *Atazanavir* explained that the "obvious to try" test introduced by *Sanofi* had in no way displaced other tests, including the test set out in *Beloit*. Our Court also expressly recalled that while the Supreme Court in *Sanofi* introduced the "obvious to try" test, it favours "an expansive and flexible approach that would include 'any secondary considerations that [will] prove instructive'" (*Atazanavir* at para. 61, referring to *Sanofi* at para. 63). As a result, a categorical approach to the obviousness inquiry and the elaboration of a "hard and fast rule" was specifically deemed inappropriate and rejected by our Court (*Atazanavir* at para. 62).

[28] With this in mind, I will now address the arguments put forward by Teva as part of the present appeal.

B. *Did the Federal Court Judge err in applying the test for obviousness?*

(1) The application of the obviousness test by the Federal Court Judge

[29] Teva contends that the Federal Court Judge made an error in his application of the obviousness test. As can be seen by the above-detailed account of the Federal Court Judge's decision, this contention is unfounded.

[30] Indeed, it is clear on the face of the Federal Court Judge's decision that he proceeded with his analysis of obviousness by using the four-step inquiry set out in *Sanofi*. Moreover, a review of the Federal Court Judge's decision shows that he fully considered the teachings of this Court in *Atazanavir* and properly applied *Beloit*. He also methodically considered whether or not the invention was "obvious to try". Specifically, the Federal Court Judge recognized that the "obvious to try" factors enumerated by the Supreme Court in *Sanofi* are not exhaustive and that the "obvious to try" test is not a "panacea for alleged infringers" (Reasons at paras. 252-253; and *Sanofi* at para. 64). The Federal Court Judge's application of the obviousness analytical framework was conducted in a thorough and considered manner and Teva's parsing of the Federal Court Judge's analysis fails in showing any error on his part.

[31] In reality, Teva is seeking to bring this Court to apply a correctness standard to the Federal Court Judge's analysis on obviousness. Yet, absent an extricable question of law, it is well established that the standard of review to be applied for findings of fact or mixed fact and law is palpable and overriding error (*Housen*; *Alcon*). Furthermore, the Federal Court Judge is entitled to deference on his appreciation of the evidence, including the weight given to

competing evidentiary submissions. It is not the role of this Court to reweigh the evidence put to him and to second-guess the Judge's assessment of filed evidence (*Nova Chemicals Corporation v. Dow Chemical Company*, 2016 FCA 216, [2016] F.C.J. No. 995 (QL) at para. 14). In short, absent any palpable and overriding error by the Federal Court Judge, this Court ought not to interfere with his findings of fact or mixed fact and law.

(2) The Federal Court Judge's consideration of properties in relation to the inventive concept

[32] Teva agrees in its memorandum that the inventive concept of the relevant claims is Form I ODV succinate (Teva's Memorandum of Fact and Law at para. 52) and there is no dispute between the parties that the inventive concept does not include properties: the inventive concept or the solution taught by the '668 Patent is the novel crystal Form I ODV succinate.

[33] However, Teva argues that the Federal Court Judge erred when he made reference to the properties of ODV succinate – and specifically Form I – in his reasons as they are not part of the inventive concept. Teva also faults the Federal Court Judge for considering the skilled person's inability to predict the properties of ODV succinate, the salt, as a basis for concluding that the relevant claims were not obvious.

[34] In considering Teva's argument, I am mindful that our Court cautioned in *Atazanavir* to not implicitly adopt a definition of the inventive concept that focuses on properties if the properties are not part of the inventive concept (*Atazanavir* at para. 74). However, in this case, the Federal Court Judge did not find non-obviousness on the basis that the properties were not

predictable in the manner seemingly suggested by Teva. Indeed, although the Federal Court Judge discusses properties in various parts of his reasons, his conclusion that Form I ODV succinate is not obvious does not rest solely on the unpredictability of the properties of a salt form. Rather, the Federal Court Judge relied on evidence that demonstrated that a skilled person could not have known or predicted that the Form I ODV succinate – *i.e.*, the crystal form itself – could be made or even existed. I cannot agree with Teva's contention that the Federal Court Judge's conclusion was based on a general proposition that it is impossible to predict any property in advance of testing given his assessment of the common general knowledge and the state of the art which made reference to what was known about the properties:

> [191] However, Pfizer is correct in stating that while the prior art explicitly disclosed ODV as a free base and a fumarate salt, and ODV succinate as a potential salt, no crystal form of that salt let alone the crystalline Form I ODV succinate had ever been expressly disclosed, made or characterized. Also, none of the prior art teaches the successful preparation of a succinate salt of ODV nor does it teach, more importantly for this case, the successful preparation of Form I ODV succinate, and nothing in the prior art discloses any of the properties or [sic] either ODV succinate or Form I ODV succinate.
>
> [192] In my view, the number of experiments required to move from the acceptable pharmaceutical salts to the Form I ODV succinate was "extremely large", as Dr. Myerson deposes at para 81 of his affidavit, and in the nature of a research program, not routine experimentation. Even though a [s]killed [p]erson may have had some general expectations about which salts may form, these expectations were theoretical and the common evidence is that empirical testing was required to determine if a salt could be made and only then could its properties be assessed. It was impossible to predict in advance which of the many possible salts, if any, would have the most appropriate properties for formulation as a drug in terms of stability, solubility, permeability and bioavailability. Much the same was known in the prior art of crystals: the [s]killed [p]erson would know (sic) and could not predict which salt would crystallize, nor what properties the crystalline form, if any, would have. One would not know in advance that the succinate salt, or the crystalline Form I ODV succinate, in the language of the *Sanofi* test, "would work."

[35] Moreover, *Sanofi* and *Atazanavir* teach that the obviousness analysis must not be performed in a rigid way. On the contrary, it must proceed as part of a flexible, contextual, expansive and fact driven inquiry. Applying this principle to the present case, it was open to the Federal Court Judge to take the properties of the invention into consideration the way he did as part of his analysis. But more specifically, a fair reading of the Federal Court Judge's decision shows that his analysis is grounded in the fact that Form I ODV succinate itself is not obvious (Reasons at para. 274). As such, the references to properties in the Federal Court Judge's reasons provide relevant context in the present case as to whether the invention was obvious or obvious to try. Such references cannot sustain Teva's contentions of error on the part of the Federal Court Judge.

[36] Teva further submitted on several occasions during its oral argument that the Federal Court Judge erred in relying on experts to find that "it would have been impossible at the relevant time for the [s]killed [p]erson to predict whether the ODV succinate salt would form as a solid, whether that solid would be crystalline, or what the properties of a hypothetical crystalline solid would be" because in doing so, the Federal Court Judge foreclosed any experimentation (Reasons at paras. 196 no. 84; 244 and 247). As such, argues Teva, one would have to be able to predict results "from the office" prior to experimentation in order for a new salt or crystal to be obvious. However, I am of the view that the Federal Court Judge concluded on the basis of the evidence that the amount of experimentation required and the unpredictability of the outcome of this experimentation was too high, in a way that would render the solution taught by the patent not obvious to try. His conclusion that there were no finite number of predictable outcomes and that "the number of potential experiments that can be conducted is

extremely large" *i.e.*, there was too much unpredictability – support his finding of not obvious to try (Reasons at paras. 191-194). Accordingly, this ground of appeal is dismissed.

(3) The Federal Court Judge's application of *Atazanavir* and *Amlodipine*

[37] Along the same lines, at hearing before our Court, Teva argued that the Federal Court Judge also erred by failing to follow *Atazanavir* and *Amlodipine* because the fundamental facts in the present case are allegedly "indistinguishable" from those two cases. Had the Federal Court Judge followed *Atazanavir* and *Amlodipine*, says Teva, he would have found its allegations of obviousness to be justified.

[38] Teva's argument is misplaced. Indeed, prior to undertaking his detailed analysis of obviousness, the Federal Court Judge carefully considered a number of cases addressing the "obvious to try" test, namely *Atazanavir* but also *Apotex Inc. v. Pfizer Canada Inc.*, 2009 FCA 8, [2009] 4 F.C.R. 223; *Novartis Pharmaceuticals Canada Inc. v. Cobalt Pharmaceuticals Company*, 2013 FC 985, 440 F.T.R. 1; and *Eli Lilly Canada Inc. v. Mylan Pharmaceuticals ULC*, 2015 FCA 286, 2015 F.C.J. No. 1463 (QL) (Reasons at paras. 172-183).

[39] There is no question that this jurisprudence as well as other past cases can provide helpful illustrations of the obviousness inquiry; however, contrary to what Teva appears to urge, past cases cannot be used to force a given conclusion on obviousness based on broad factual similarities to the detriment of otherwise significant differences in a given case. However trite, each case is decided on the basis of the specific evidentiary record put before a judge.

[40] In the present case, the Federal Court Judge considered cases cited by the parties with the understanding that this jurisprudence does not establish any "hard and fast rules" on obviousness when it comes to evaluating whether or not a salt screen or any other form of experimentation is obvious or not:

> [257] … Both parties cited cases where, on the accepted evidence in a particular case, courts came to conclusions on obvious to try one way or the other. While of relevance, each case in this connection has been decided on facts particular to it, and having regard to the submissions of the experts and counsel. None of the cases say that all salt screens are obvious to try, or are only matters of routine experimentation. Nor do any say that all polymorph or crystal screen research is obvious to try or merely entails routine experimentation. None do and of course none could. Ultimately this is a question of applying the law of obvious to try to the evidence before the Court.

[41] There are specific factual and evidentiary differences between both *Atazanavir* and *Amlodipine* and the present case which support the Federal Court Judge's finding on obviousness. These include the fact that in *Amlodipine* and *Atazanavir* the inventive concepts properly construed were salts whereby the inventive concept in the present case is a novel crystal form (Form I ODV succinate). Furthermore, in *Amlodipine*, the obviousness finding was based on the fact that a "person skilled in the art would be motivated to test sulphonic acid salts in general and would have every reason to test the besylate salt as this had already been shown to offer advantages over other salts in terms of stability." (*Amlodipine* at para. 28). Also, in *Atazanavir*, it was uncontested that "the [s]killed [p]erson would have expected a salt screen to identify at least one salt with improved pharmaceutical properties over the free base: …" (*Atazanavir* at para. 7).

[42] In the present case, the Federal Court Judge determined that it was not predictable whether Form I ODV succinate could be prepared at all (Reasons at para. 258). He also noted that there was no motivation pointing toward ODV succinate, and that, in fact, there was reason to believe that ODV succinate would not work, or for that matter, any other salt as observed by the Federal Court Judge at paragraph 277 of his Reasons:

> Again with reference to *Sanofi* at para 86, there is no evidence that at the relevant time a [s]killed [p]erson would know which salt, or which crystalline form, would work to achieve the invention *i.e.*, the crystalline Form I ODV succinate. In fact, in this case the evidence is stronger than that in *Sanofi* against obviousness to try, because here there is evidence which I accept on a balance of probabilities that the salt ODV succinate in fact would *not* work. This evidence was based on the fact that ODV fumarate, another salt of ODV, had not worked. Because ODV in its dissociated state, *i.e.*, separated from the ODV fumarate salt once dissolved, did not work when introduced into the body, it was logical to expect that a different salt, namely ODV succinate, also would not work, because the ODV dissociated from the succinate salt would be the same as the ODV dissociated from the fumarate salt. If one did not work it was logical the other would now (sic) work… The nature of the work seen in this context was uphill.

[43] The above further demonstrates that the Federal Court Judge properly applied the analytical framework of obviousness set out in *Sanofi* as considered by our Court in *Atazanavir*. Teva has failed to establish any reviewable error which would warrant our intervention.

C. *Did the Federal Court Judge err in his finding regarding fumarate and in relying on the skepticism at Wyeth?*

[44] Teva raises two further arguments regarding certain evidentiary findings made by the Federal Court Judge.

[45] First, Teva submits that the Federal Court Judge erred in relying on Pfizer's evidence regarding ODV fumarate as this information was not in the public domain and the skilled person would not be imbued with this knowledge. Yet, the Federal Court Judge considered the difficulties experienced with fumarate as part of his analysis of the amount of effort required to obtain the invention and his analysis of the actions of Pfizer in this regard (Reasons at paras. 277 and 295). The *Sanofi* analytical framework is a flexible one and it expressly permits consideration of the course of conduct of those involved in the claimed invention including the inventor and his or her team (*Sanofi* at para. 71).

[46] Second, Teva contends that Dr. Shah's evidence to the effect that others at Wyeth were skeptical that a novel salt could overcome the issues with fumarate is hearsay, the "alleged skeptics" having not provided any evidence of their skepticism. In response, Pfizer counters that the Federal Court Judge found this evidence to be reliable as it was corroborated by other evidence, and that, in any event, the skepticism was but one factor in the Federal Court Judge's analysis.

[47] Assuming without deciding that the evidence of skepticism is hearsay, it was clearly but one factor in the Federal Court Judge's detailed analysis. Even if this evidence were to be excluded, the remainder of the Federal Court Judge's findings, on a balance of probabilities, support a conclusion of non-obviousness, particularly: (i) the lack of predictability of Form I ODV succinate itself; (ii) the inability to predict how it could be made; (iii) the Federal Court Judge's findings regarding the expert evidence; and (iv) the course of conduct of Pfizer before turning to the invention, including the experimentation with other salts and pro-drugs. These

findings also include the problems experienced with fumarate and the later comparative success of succinate (Reasons at paras. 50 & seq. and 87 & seq.). The potential hearsay evidence was therefore neither determinative nor decisive. On the basis of the record, the conclusion on obviousness would remain the same, whether or not this evidence should have been considered.

D. *Is the '668 Patent a selection patent?*

[48] At the hearing, Teva conceded that on appeal "nothing turned" on the argument as to whether the '668 Patent was a selection patent and that this argument would not be pursued. Accordingly, it need not be considered.

VI. Conclusion

[49] In summary, the Federal Court Judge properly weighed the evidence before him in this case. In putting forward arguments based on a number of alleged reviewable errors, Teva essentially attempted to convince this Court to reweigh and reassess the evidence. The Federal Court Judge was alive to the conflicting views of experts, preferred some over others and he provided fulsome reasons for doing so. His findings are deeply rooted in the evidence and the facts and ought not to be disturbed.

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

[51] These reasons may contain information subject to a Protective Order and are therefore being released on a confidential basis. Teva and Pfizer shall have four days to jointly provide the

Court with submissions as to the portions of the reasons that in their view must be redacted, failing which these reasons will become the public reasons and will be placed on the public file.

"Richard Boivin"
J.A.

"I agree
Wyman W. Webb J.A."

"I agree
Yves de Montigny J.A."

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKET:	A-283-17
STYLE OF CAUSE:	TEVA CANADA LIMITED v. PFIZER CANADA INC., WYETH LLC, and THE MINISTER OF HEALTH
PLACE OF HEARING:	OTTAWA, ONTARIO
DATE OF HEARING:	NOVEMBER 19, 2018
PUBLIC REASONS FOR JUDGMENT BY:	BOIVIN J.A.
CONCURRED IN BY:	WEBB J.A. DE MONTIGNY J.A.
DATED:	JANUARY 25, 2019

APPEARANCES:

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