Federal Court of Appeal  Cour d'appel fédérale

Date: 20170314

Docket: A-508-15

Citation: 2017 FCA 50

CORAM: **GAUTHIER J.A.**
DE MONTIGNY J.A.
GLEASON J.A.

BETWEEN:

TEVA CANADA LIMITED

Appellant

And

LEO PHARMA INC. and LEO PHARMA A/S

Respondents

and

THE MINISTER OF HEALTH

Respondent

Heard at Montréal, Quebec, on February 2, 2017.

Judgment delivered at Ottawa, Ontario, on March 14, 2017.

REASONS FOR JUDGMENT BY: GAUTHIER J.A.

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

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REASONS FOR JUDGMENT

GAUTHIER J.A.

[1] Teva Canada Limited (Teva) appeals a decision of Locke J. of the Federal Court (2015 FC 1237) allowing Leo Pharma Inc. and Leo Pharma A/S's (Leo) application under the *Patented Medicines (Notice of Compliance) Regulations*, S.O.R./93-133 (Regulations) for an order

prohibiting the Minister of Health from issuing a notice of compliance (NOC) to Teva in respect of 50 mcg/g calcipotriol and 0.5 mg/g betamethasone dipropionate ointment until the expiry of Canadian Patent No. 2,370,565 (the 565 Patent).

[2] This patented non-aqueous ointment is for use in the treatment of psoriasis. It is prepared using three components referred to in the claims in the 565 Patent as Component A (vitamin D or a vitamin D analogue), Component B (a corticosteroid) and Component C (a solvent of the type described in the claims). Components A and B are described as two pharmacologically active compounds in the composition. In Claim 17, Component C is limited to polyoxypropylene-15-stearylether, a solvent referred to as POP-15.

[3] The findings of the Federal Court in respect of the common general knowledge and the characteristics of the person skilled in the art are not disputed (Federal Court's Reasons (Reasons) at paras. 104, 107-112). Among other things, at the relevant time, the person skilled in the art to whom the 565 Patent is addressed knew that Components A and B were active pharmaceutical compounds useful in the treatment of psoriasis. It was also known that treatment by sequential application of both calcipotriol (a vitamin D analogue) and a corticosteroid provided better results than either compound alone in treating this condition. That said, it was also known that calcipotriol (Component A) could not be combined with a corticosteroid (Component B), given their pH incompatibility; calcipotriol requires a pH above 8 for maximum stability, whereas corticosteroids require pH values in the range of 4-6 for maximum stability (Reasons at paras. 108-109).

[4] In its notice of allegation (NOA) and before the Federal Court, Teva contested the validity of the 565 Patent on the basis of obviousness, lack of utility and insufficiency. In this appeal, the debate is more limited. First, Teva contests the Federal Court's finding that the utility of the compositions covered in Claim 17 of the 565 Patent could be soundly predicted, mainly because Leo could not explain exactly why these combinations worked and because the line of reasoning relied upon by the Federal Court was not set out in the disclosure. Second, Teva submits that the Federal Court did not properly address two of the issues raised in respect of insufficiency. Hence, for the purpose of this appeal, it is undisputed that the invention claimed was new and not obvious.

[5] For the reasons below, I am of the view that this appeal should be dismissed.

I. The Federal Court's Decision

[6] I will limit my brief review to the most relevant findings of the Federal Court in respect of the issues properly raised before us (see paragraphs 39-40 below). Thus findings made in respect of arguments not raised in the appeal, even in relation to utility and insufficiency, are not discussed below (for example see para. 167(1) of the Reasons).

[7] At paragraphs 187 to 192 of its Reasons, the Federal Court dealt with Teva's only argument to support the allegation of insufficiency; Teva claimed it had set out this argument in its NOA. More particularly, Teva argued that the 565 Patent is silent as to which, if either, of the Components A and B has to be dissolved in the solvent (Component C). It also submitted that the fact that the 565 Patent does not mention that calcipotriol (Component A) must be dissolved in

the solvent (Component C) leaves the skilled person with insufficient information to put the invention into practice (Reasons at para. 188). This argument arose from a portion of the cross-examination of Dr. Hansen discussed at paragraph 187 of the Reasons. However, the Federal Court made no finding based on this evidence that one should conclude, as argued before us, that if calcipotriol is not first, or the first component, dissolved in the solvent, the composition will not be effective.

[8] Instead, the Federal Court rejected Teva's argument on two bases. First, it found that the allegations in the NOA in respect of insufficiency could not be understood as encompassing this argument (Reasons at paras. 189-190). Second, and in any event, on the evidentiary record before it, the Federal Court found that the argument had no merit (Reasons at para. 191).

[9] The Federal Court noted that even Teva's own expert, Dr. Cooper, testified that dissolving or dispersing an active ingredient in a solvent is a common and helpful practice particularly when the active ingredient is a powder (Reasons at para. 191). In the Federal Court's view, there was no need to explicitly tell the person skilled in the art that the calcipotriol (Component A) had to be dissolved in the solvent (Component C) since a skilled person would be able to make the claimed formulation based on his or her own knowledge. It added that even if some non-inventive trial and error testing could "possibly" be required, this would permit and would not prevent the description from meeting the requirements of subsection 27(3) of the *Patent Act*, R.S.C., 1985, c. P-4 (*Act*).

[10] With respect to Teva's allegations of lack of utility, the relevant findings of the Federal Court are limited to Claim 17 as the Federal Court found that its analysis could be simplified by focusing on this claim which was in play in this proceeding (Reasons at para. 176). In the Reasons, the Federal Court first summarized at paragraphs 156 to 164 the general principles applicable to determine whether the subject matter claimed is useful.

[11] Considering that Leo did not test all the combinations claimed, the Federal Court found that the issue to be determined was whether the utility of the subject matter of Claim 17 had been soundly predicted at the date of the Canadian filing. The Federal Court relied on the test as enunciated at paragraph 70 in *Apotex Inc. v. Wellcome Foundation Ltd.*, 2002 SCC 77, [2002] 4 S.C.R. 153 [*AZT*] (Reasons at para. 159). It is not disputed that the Federal Court correctly described the three components of the test to be applied. Briefly stated, these are whether the inventor had (i) a factual basis, ii) a sound line of reasoning from which the desired result could be inferred from the factual basis, and iii) proper disclosure.

[12] The Federal Court also noted that although the focus is on the inventor's point of view under the second component of the test (sound line of reasoning), this does not exclude taking into consideration the perspective of the skilled person. For the Federal Court, this was especially so considering the teachings of this Court stated at paragraph 154 of *Bell Helicopter Textron Canada Limitée v. Eurocopter, société par actions simplifiée*, 2013 FCA 219, 449 N.R. 219 [*Bell Helicopter*]. In that decision, our Court found that the elements of the sound prediction doctrine need not be explicitly disclosed in the specification if they would be self-evident to the person

skilled in the art to whom the patent is addressed in view of the common general knowledge possessed by such person.

[13] Teva's sound prediction argument is dealt with at paragraphs 177 to 183 of the Reasons. As is usually the case in NOC proceedings where time is often of the essence, the Federal Court's 65 page decision analyzes each of Teva's arguments briefly. Despite this, it is clear that the Federal Court was alert and alive to all the points raised in Teva's memorandum on appeal (for example, that EB 1089 could have been tested). It acknowledged that nobody at Leo understood exactly why the combinations covered in Claim 17 worked while a combination using another common solvent did not (see example 2 table 2 in the 565 Patent).

[14] Still, on the evidentiary record before it, the Federal Court found as a fact that as of January 27, 2000 (the date of the Canadian filing of the application for the 565 Patent), Leo had a factual basis and a sound line of reasoning to predict the utility of the subject matter covered by Claim 17. The Federal Court also found that a person skilled in the art would have understood from a review of the specification read as a whole, that the inventors' line of reasoning was that the alternatives for Components A and B share a chemical scaffold, that they would therefore behave similarly and that there was no need for an express mention of this fact in the disclosure of the 565 Patent. The Federal Court held that this line of reasoning was sound.

II. Issues

[15] Teva characterized the issues that it relies upon in this appeal as errors of law. It describes the issues in its memorandum as follows:

> 1. Did the [Federal Court] err in law by reformulating the test of sound prediction to permit reliance on a line of reasoning advanced by Leo's expert, rather than by the inventors or Leo, to establish the factual basis and line of reasoning to support Leo's sound prediction of utility, even if that line of reasoning was not held by the inventors or Leo at the time the 565 Patent was filed? If so, are Teva's allegations of inutility justified?
>
> 2. Did the [Federal Court] err in law by failing to allow Teva to advance its allegations of insufficiency and by failing to find that the 565 Patent fails to correctly and fully disclose the invention as contemplated by the inventors? If so, are Teva's allegations of insufficiency justified?
>
> Teva's memorandum at paragraph 25

[16] The standards of review are those set out in *Housen v. Nikolaisen*, 2002 SCC 33, [2002] 2 S.C.R. 235. Questions of fact (including factual inferences) are reviewed only for palpable and overriding errors. The same standard applies to questions of mixed fact and law unless there is an extricable question of law. When such a question of law is identified, it is reviewed on the correctness standard like any other question of law.

[17] In *Sattva Capital Corp. v. Creston Moly Corp.*, 2014 SCC 53, [2014] 2 S.C.R. 633, at paragraph 54, Rothstein J. expressly warned that courts should be cautious in identifying an extricable question of law so as to not unduly limit the level of deference that should normally apply to findings of mixed fact and law. This will be discussed further when reviewing the merits of Teva's arguments for I do not agree with Teva's characterization of the two questions before us.

[18] This is particularly important here considering that Teva acknowledged at the hearing before us that if the applicable standard was palpable and overriding error, it was unlikely that it could meet its burden in respect of the Federal Court's findings of utility and sufficiency.

III. Sound Prediction

[19] In my view, the somewhat convoluted question framed by Teva in its memorandum rests on the following two premises:

a) The Federal Court had no evidence of the factual basis on which the inventors relied to claim the compositions covered by Claim 17; and

b) The Federal Court had no evidence to determine the actual logic or reasoning of the inventors.

Thus, Teva says that this Court should infer that the Federal Court necessarily failed to apply the test it set out in the Reasons (which it claims would be an extricable error of law).

[20] On the record before us, Teva has not persuaded me that the Federal Court erred in law. Considering that applying the *AZT* test is normally a question of fact, Teva has not established that the Federal Court made a palpable and overriding error (see *Zero Spill Systems (Int'l) Inc. v. Heide*, 2015 FCA 115 at para. 49, 472 N.R. 127) [*Zero Spill*]. Thus, there is no basis for this Court to substitute its assessment of the evidence to determine whether the allegations made by Teva in its NOA were justified.

[21] Teva argues that one cannot make a sound prediction when one does not know exactly why a particular combination works. This may well apply in many cases, or even to other claims

in the 565 Patent, but the Federal Court rejected the argument in this case in respect of Claim 17 because it found that in the particular circumstances in the matter and on this evidentiary record, it simply was not so (Reasons at para. 179).

[22] It is important to recall that the invention covered in Claim 17 may be quite important in practical terms for patients suffering from psoriasis. But, it remains that, as found by the Federal Court, the invention covered in Claim 17 is quite simple (Reasons at para. 127). As mentioned by Teva in first instance, there were ointments on the market using only Component A or only Component B to treat psoriasis. The active pharmaceutical components involved have been well-known for years, and the use of the invention did not involve any new process. Simply put, the application of the doctrine of sound prediction turns on the nature of the invention, the particularities of each discipline to which it relates and on the particular facts of each case.

[23] There was expert evidence supporting the finding of the Federal Court that on the factual basis available to the inventors (and disclosed in the patent), the inventors could make a prediction that was reasonable and sound. Based on what was known about Component A and B at the time of filing, and the test data disclosed in the 565 Patent, Dr. Goldberg testified that there was a high probability that if the particular solvent (POP 15) worked for the combination of the Component A and Component B tested, it would work for the other combinations claimed in Claim 17 (see Cross-Examination of Dr. Goldberg, Appeal Book, Vol. 14, Tab 310 at pp. 3807-3808). Dr. Walters' evidence, expressly referred to by the Federal Court, also supports the finding of the Federal Court.

[24] During the hearing, Teva took us through various extracts of evidence on the basis of which it argued that one should conclude to the contrary (see Teva's Compendium). This exercise was insufficient to make the tree fall down, to evoke the imagery of my colleague Justice Stratas in *Zero Spill* above. Teva therefore did not establish a palpable and overriding error.

[25] Turning to the evidence on which the Federal Court relied to make its finding in respect of the inventors' factual basis and line of reasoning, it is important to note that the inventors could not participate in the proceedings.

[26] Indeed, on the basis of Leo's explanations, the Federal Court was satisfied that Leo could not present the two inventors as witnesses. It accepted as necessary and reliable the testimony of Dr. Hansen, a supervisor of the inventors at Leo as of 1998, a significant period when the invention was being developed. The Federal Court also found that most of Dr. Hansen's evidence was based on reports, notebooks and records that constituted business records, a recognized exception to the rule against hearsay.

[27] Although Teva originally objected to this evidence, it did not contest the aforementioned Federal Court findings in this appeal. In fact, Teva relied heavily on such evidence to support its arguments on both insufficiency and lack of utility.

[28] In my view, it was open to the Federal Court to infer that the inventors' logic and line of reasoning was, as a matter of fact, the one conveyed to the person skilled in the art in the 565

Patent. There was a legitimate basis to make that inference. Teva tries to elevate this issue of fact to a legal principle. It argues that the Federal Court failed to follow a "subjective approach" and submits that one must produce evidence emanating directly from the inventors either as witnesses or through express words in the disclosure of the patent. In Teva's view, expert evidence cannot be used to determine facts such as the line of reasoning of the inventors.

[29] Nowhere in *AZT* does the Supreme Court of Canada limit how the facts necessary to apply the doctrine of sound prediction can be established. How one proves a fact depends on the particular circumstances of each case.

[30] It is only when asked why this Court should deny a patentee the right to rely on the doctrine of sound prediction when an inventor dies before the validity of the patent is challenged, that Teva acknowledged that the Court could probably infer the inventor's line of reasoning from an express sentence in the disclosure of the patent. It further acknowledged that in this case, it might have been open to the Federal Court to make the factual finding that it made if the 565 Patent had included a sentence to the effect that the logic followed to claim the subject matter covered by Claim 17 was that the chemical scaffold of all Components A and B were the same as those tested in Example 1 of the Patent (second requirement of the test). Obviously in such a case, this would mean that the third requirement of the *AZT* test (disclosure) would also have been met. But this should not detract from the fact that in a particular case the same evidence can be used to establish two distinct elements of the test.

[31] From the perspective of a person skilled in the art, I see no difference in this case between an express sentence to this effect and conveying the same logic through technical information disclosed in the specification read as a whole. In both instances, the inventor conveys his or her logic to the person to whom the patent is addressed, thereby fulfilling its part of the patent bargain if this line of reasoning is held to be reasonable and sound at the relevant times. In short, in both instances, the person to whom the patent is addressed, namely, the person skilled in the art, understands the sound line of reasoning of the inventors premised on what is said in the patent.

[32] Similarly, this Court held in *Bell Helicopter* that there is no need to spell out in a patent that which is self-evident and would be generally known to the person skilled in the art.

[33] It bears repetition that in all cases, the application of the doctrine of sound prediction is a matter of fact. Technical facts, such as whether all vitamin D analogues covered in Claim 17 have the same chemical scaffold, can be established by way of expert evidence.

[34] What logic or reasoning, if any, is conveyed in a patent, even when the logic is expressly set out, will also usually require consideration of expert evidence to explain its significance unless the field to which the invention relates can easily be understood by a court without the assistance of an expert. Finally, expert evidence will be required to determine the soundness of this logic.

[35] On a fair reading of the Reasons, the Federal Court did apply the proper test — the one it expressly set out in the Reasons. It had evidence of the factual basis actually available to the inventors before the Canadian filing date. It essentially consisted of the tests and other data referred to in the disclosure of the 565 Patent, including matters that were part of the common general knowledge at the time, as well as confirmation that calcipotriol was one of the most unstable Vitamin D analogues (half-life testing of vitamin D analogues done in 2000 prior to the filing date).

[36] There was also evidence before the Federal Court from Dr. Walters that as a matter of fact, all claimed alternatives of Vitamin D analogues have the same chemical scaffold as calcipotriol, and that all corticosteroids claimed have a sterone structure (see Affidavit of Dr. Walters, Appeal Book, Vol. 6, Tab 104, at para. 210). These were not disputed facts.

[37] There was also expert evidence before the Federal Court that the person skilled in the art would understand the logic of the inventor from reading the 565 Patent as a whole, namely, that as all claimed alternatives for Components A and B have the same chemical scaffold as the ones tested in combination with POP-15, they would all be expected to be useful.

[38] The Federal Court was entitled to use this expert evidence together with the evidence of the actual factual basis available to the inventors to reach the conclusion that it did. As mentioned, the evidentiary record also supports the finding that the line of reasoning was sound. Thus, Teva's first argument on appeal fails.

IV. Insufficiency of the Disclosure

[39] I will now turn to the sufficiency of the description of the invention in the disclosure and start with two preliminary comments. First, Teva raises an argument (that particular combinations would not work according to prior art) that it acknowledged was not raised before the Federal Court (see paragraphs 74 to 81 of Teva's memorandum). Hence, the Federal Court could not and did not make any finding in this respect. After this was clarified at the hearing, Teva advised that it would not pursue this argument. I will therefore not consider it.

[40] Second, as indicated in the question put forth by Teva in respect of its allegation of insufficiency, this Court should normally deal with the Federal Court's finding that the NOA did not include the argument that the inventors failed to disclose an essential element of the invention to the effect that the active pharmaceutical ingredients (especially Component A and more particularly calcipotriol) had to first be dissolved in the solvent (Component C) for the non-aqueous ointment to be effective. Teva argues that there is no need to deal with this alleged error regarding the contents of its NOA if this Court agrees that, in any event, its argument has no merit. Thus, I will simply say that in my view, the Federal Court did not err in finding that this argument was not properly raised in the NOA. There is no need to say anything further on this issue for I agree that, in any event, the argument has no merit.

[41] Teva argued that based on a brief portion of the cross-examination of Dr. Hansen it had established that the order in which the components of the patented compositions must be added to the other ingredients that make a non-aqueous ointment (such as a petrolatum-based ointment)

is an essential element of the invention that should have been disclosed in the 565 Patent. Teva added that the Federal Court erred in law by referring to the possibility of having to do some trial and error experiments to determine that in fact calcipotriol must be dissolved or dispersed in the solvent before completing the ointment using a petrolatum-base.

[42] Again, the question to be determined is presented as a pure question of law. However, I believe that Teva's theory rests on a fact or facts in respect of which the Federal Court did not make an actual finding other than stating that some trial and error may perhaps be a possibility.

[43] The Federal Court properly instructed itself that the description mandated by subsection 27(3) of the Act must enable the person skilled in the art to produce the invention using only the instructions contained in the disclosure. Obviously, this also means that the person skilled in the art comes equipped with his or her common general knowledge.

[44] Whether or not a particular disclosure is sufficient to meet the requirements of subsection 27(3) of the *Act* depends on what the skilled person would consider sufficient to enable it to work the invention (*Teva Canada Ltd. v. Pfizer Canada Inc.*, 2012 SCC 60 at para. 79, [2012] 3 S.C.R. 625 [*Sildenafil*] . This is a question of fact (*Pfizer Canada Inc v Apotex Inc.*, 2014 FCA 250 at para.60, 465 N.R. 306, leave to appeal to SCC denied, 36227 (December 23, 2014).

[45] Thus, a key issue is whether or not the Federal Court was required to conclude that the order in which the three components listed in the claims were mixed was an essential element of the invention that had to be disclosed.

[46] As discussed at the hearing, the passage of the cross-examination Teva relies on is far from conclusive.

[47] The Federal Court described the relevant excerpt at paragraph 187 of the confidential version of the Reasons. Simply put, in an experiment done without a solvent "to see if oil and petrolatum were needed", Leo could not obtain an equally-distributed amount of the Component A it used (see cross-examination of Dr. Hansen, Appeal Book, Vol. 18, Tab 351, at p. 4984).

[48] Teva acknowledged that there was no other evidence, expert or otherwise, that would help this Court conclude that, as Teva's counsel suggested, this passage necessarily meant that the Component A that was tested had to be dissolved in solvent C in order for the claimed composition to be effective. Particularly, Teva did not test its theory during the cross-examination of any of the affiants, including Dr. Hansen. This is important because the composition that was referred to in the cross-examination excerpt that Teva relies on did not include one of the essential elements of the patented invention — Component C.

[49] The issue here is not whether the Federal Court could have made the inference suggested by Teva. Rather, it is whether the Federal Court made a palpable and overriding error in not doing so. This Court cannot simply assume that if Component C had been added to the tested composition, the result would have been the same. Nor can it assume that the problem with respect to the dispersion did not simply make the formulation less effective rather than not effective. Leo also alluded to the fact that there may have been an issue with the dry milling

process used in making the composition referred to in the cross-examination excerpt Teva relies on.

[50] Moreover, it appears that the issue raised in this portion of Dr. Hansen's evidence relates to the dispersion of the active ingredient in a non-aqueous base. This has little to do with the nature of the invention, which is directed to a combination of three components that will allow the active ingredients to "co-exist without degradation, despite their different pH/stability profiles" (the 565 Patent at page 12 lines 1 to 5).

[51] One must always consider the nature of the invention to determine what needs to be included in the description. As mentioned earlier, the invention is not about the process of making a non-aqueous ointment. This was well-known. It is instead directed to the combination of three particular sets of components to be included in a non-aqueous ointment recipe. At page 13 of the 565 Patent, the inventors specify that the invention "may be prepared in accordance with methods well known to the person skilled in the field of pharmacy… As an example, preparation of a composition according to the invention is typically performed by melting white soft paraffin, adding a solution (typically at a concentration in the range of 0.0005-2.5% w/w) of the vitamin D analog in the required amount of solvent component C … followed by addition of a dispersion of the corticosteroid component B in paraffin oil…" (lines 1-12).

[52] In example 1 of the specification, the calcipotriol (Component A) is dissolved in the solvent (Component C). This appears to be the best embodiment for the inventor. Although I agree with Teva that this does not limit how the claimed compositions could be prepared, this is

not, in and of itself, evidence that dissolving Component B in Component C before adding Component A to the solvent mixture would not work. As a solvent, Component C would normally be used to dissolve the active ingredients.

[53] As a matter of fact, Teva's own expert evidence supports the conclusion that no information about how to mix or process Components A, B and C to complete the patented aqueous ointment was required. Indeed, Dr. Cooper's evidence indicates that it was commonly known that dissolving or dispersing active ingredients in a small amount of solvent prior to adding them to a petrolatum base helped to ensure that the active ingredients are evenly dispersed in the ointment. The same expert added that it was especially useful when an ointment is made on a commercial scale to add the active ingredient to the petrolatum as a liquid as opposed to adding them in powder form (Affidavit of Dr. Cooper, Appeal Book, Vol. 13, Tab 293 at paras. 93-94).

[54] In the circumstances, the Federal Court did not make a palpable and overriding error in weighing the evidence and in refusing to conclude that the order in which the components are mixed together before being incorporated into whatever base was used to make the ointment was an essential element of the invention that had to be disclosed.

[55] This brings me to the comment of the Federal Court to which Teva also objects. At paragraph 191 of the Reasons, the Federal Court stated that "a skilled person would be able to make the claimed formulation based on his or her own knowledge, possibly through some non-inventive trial and error (which is permitted per *Valence Technology Inc v Phostech Lithium Inc*,

2011 FC 174 at para 224), without having to be explicitly told that the calcipotriol must be dissolved in the solvent C".

[56] In adding the last portion of this sentence, the Federal Court appears to be dealing with Teva's theory that calcipotriol is somewhat special. First, this is only viewed as a possibility, not a probability, and second, the Federal Court simply followed in this respect a decision (Valence) which has been confirmed by our Court in Phostech Lithium Inc. v. Valence Technology Inc., 2011 FCA 237, 422 N.R. 162 [Valence, FCA]. I moreover note that this comment is in line with the law in the U.K. and in Europe (see *Synthon BV v. Smithkline Beecham plc*, [2005] UKHL 59 at paras. 27, 30). It is also how the Supreme Court of Canada defined an enabling description or disclosure in *Apotex Inc. v. Sanofi-Synthelabo Canada Inc.*, 2008 SCC 61 at para. 43, [2008] 3 S.C.R. 265 [Sanofi-Synthelabo], albeit in a different context (anticipation). The wording of subsection 27(3) of the Act is essentially the same as the provisions applicable in England and in Europe. There is no reason to exclude the limited type of testing that is usually referred to when one uses the expression used by the Federal Court. As Justice Rothstein noted in *Sanofi-Synthelabo*, in a field such as the one involved before us where trial and error experiments are generally carried out, such limited testing is permitted, and does not involve an undue burden.

[57] Teva argues that the Supreme Court of Canada changed the law since *Valence* FCA in *Sildenafil*, where Justice LeBel wrote at paragraph 74:

> [74] The disclosure in the specification would not have enabled the public "to make the same successful use of the invention as the inventor could at the time of his application", because even if a skilled reader could have narrowed the effective compound down to the ones in Claim 6 and Claim 7, further testing

> would have been required to determine which of those two compounds was actually effective in treating ED. As the trial judge stated, at para. 146, "[a] skilled reader would then conduct tests on those two compounds and determine which of those compounds worked". And as he also stated, at para. 135, "the skilled reader must undertake a minor research project to determine which claim is the true invention". [Emphasis added]

[58] The case before us is very different from the one that was before the Supreme Court of Canada in *Sildenafil*, where the patentee had deliberately omitted essential information, thereby obscuring the fact that only one of the compounds claimed actually worked (*Sildenafil* at paras 72, 73 and 76) . Thus, the invention itself was not even properly disclosed.

[59] Furthermore, the Supreme Court refers to the factual findings of the Federal Court in *Sildenafil* which found that in that case, one would require a minor research project to determine the true invention. This statement of Justice Lebel is, as mentioned, perfectly in line with the law as I understand it, not only in Canada but elsewhere, such as the U.K. and Europe, which recognizes that some non-inventive trial and error may be required to put a properly disclosed invention into practice. Had the Supreme Court wished to change the law on this point in *Sildenafil*, one would have expected a much more fulsome analysis of the issue and discussion of the relevant authorities. In the absence of such a discussion, I do not believe that the Supreme Court changed the law in *Sildenafil* in the manner Teva argues.

[60] In any event, what the Federal Court was referring to in the present case was in no way a minor research project within the meaning of *Sildenafil*. Rather, I would compare it to the trial and error required to determine the most effective way to make a good pancake mix with no lumps, i.e., whether one should put the eggs before or after the flour and sugar are dissolved in

milk. The possible need for this sort of trial and error to enable the skilled person to use the invention does not render the disclosure in a patent insufficient.

V. Conclusion

[61] In view of the foregoing, I conclude that this appeal should be dismissed with costs.

"Johanne Gauthier"
J.A.

“I agree
Yves de Montigny J.A.”

“I agree
Mary J.L. Gleason J.A.”

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKET:	A-508-15
APPEAL FROM A JUDGMENT OF THE HONOURABLE JUSTICE LOCKE DATED OCTOBER 30, 2015, DOCKET NO. T-1791-13 (2015 FC 1237)	
STYLE OF CAUSE:	TEVA CANADA LIMITED v. LEO PHARMA INC. AND LEO PHARMA A/S AND THE MINISTER OF HEALTH
PLACE OF HEARING:	MONTRÉAL, QUEBEC
DATE OF HEARING:	FEBRUARY 2, 2017
REASONS FOR JUDGMENT BY:	GAUTHIER J.A.
CONCURRED IN BY:	DE MONTIGNY J.A. GLEASON J.A.
DATED:	MARCH 14, 2017

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