



NON-INVENTIVE TRIAL AND ERROR: CANADA’S FEDERAL COURT OF APPEAL CLARIFIES SOUND PREDICTION DOCTRINE AND BURDEN REGARDING SUFFICIENCY OF DISCLOSURE

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On March 14th 2017, the Canadian Federal Court of Appeal dismissed an appeal by TEVA CANADA LIMITED (“TEVA”) of a decision under Canada’s PMNOC regulations prohibiting the Minister of Health from granting TEVA market approval for an ointment containing calcipotriol and betamethasone dipropionate, until the expiry of Canadian Patent No 2, 370, 565 (565 Patent), owned by LEO PHARMA INC (“LEO”). [*TEVA CANADA LIMITED v LEO PHARMA INC, 2017 FCA 50*].

The Invention

The patented non-aqueous ointment is used for the treatment of psoriasis and is prepared using 3 components: Component A (Vitamin D or a Vitamin D analogue), Component B (a corticosteroid) and Component C (a solvent).

It was known that Components A and B were active pharmaceutical compounds and that these compounds were useful for the treatment of psoriasis. It was also known that the sequential application of calcipotriol (component A) and a corticosteroid (component B) provided better results than the use of either component alone. However, it was also known that component A could not simply be combined with component B to make one product because of their pH incompatibility. The art needed to find a way to solubilize these components so that they could be present together in the same formulation without affecting their efficacy.

TRIAL DECISION

Teva’s attack on the validity of the 565 Patent focused mainly on the lack of utility of the invention, and on the insufficiency of the patent’s disclosure.

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On the issue of sufficiency, Teva argued that the 565 Patent is silent as to which of the components need to be dissolved in the solvent (component C), and in which order. Teva alleged that since the 565 Patent makes no mention of the fact that it is in fact calcipotriol (Component A) that needs to be dissolved in the solvent, there is not enough information in the disclosure to enable a person skilled in the art to practice the invention. First, the Court found that there is no evidence to support that the order in which each component is dissolved has an impact on the overall effectiveness. Furthermore, Teva's own expert had testified that dissolving or dispersing an active ingredient in a solvent, such as calcipotriol, is common practice. Therefore, there was no need to specifically tell a person skilled in the art that Component A had to be dissolved in the solvent of Component C. Trial and error testing could possibly be required to determine the order that the components would need to be added and according to the Court, this would not prevent the description from meeting the requirements under the Patent Act. *Patent Act*, R.S.C., 1985, c. P-4 (*Act*).

Concerning Teva's allegations of lack of utility, since Leo did not test all combinations of the components found in the relevant claims of the 565 Patent. Therefore, Court had to consider if the utility of the subject matter had been soundly predicted.

Sound Prediction

Briefly, the doctrine of sound predictions allows for utility to be determined on the basis of a three pronged test: whether the inventor had i) a factual basis, ii) a sound line of reasoning from which the desired result can be inferred from the factual basis, and iii) proper disclosure.

LEO did not test all the combinations it claimed. However, the Court noted that while the test of sound prediction focuses on the inventor's point of view (ie: did the inventor have a sound line of reasoning to infer the intended result), this does not inherently exclude taking into account the perspective of the skilled person, someone outside of the invention. In other words, the facts relied on to put into practice the sound prediction test do not need to be disclosed explicitly in the specification, nor be factually attached to the inventor. If these facts would be self evident to a person skilled in the art, in view of the common general knowledge, they can be applied to the test.

As such, the Court found that, while no one at Leo understood why the combinations covered by the relevant claims worked, it nevertheless had a factual basis and a sound line of reasoning to predict the utility of the subject matter covered by the claim. The Court found that a skilled person in the art would have understood from a review of the disclosure that Components A and B share a "chemical scaffold" and that they therefore behave similarly. No express mention of this in the disclosure was necessary to make this reasoning sound and the inventors did not need to relay their factual awareness of this common general knowledge either.

Appeal

On appeal, Teva contested the Federal Court's decision and alleged:

- that it erred in law in its findings that the utility of the compositions of the 565 Patent (claim 17 specifically) could be soundly predicted. Leo couldn't explain why the combinations worked and the line of reasoning the Court relied on was based on expert evidence and was not specifically set out in the disclosure.
- That it erred in law by failing to allow Teva to advance its allegation that the patent's disclosure was insufficient and that the 565 Patent fails to fully disclose the invention as contemplated.

On appeal, the novelty and non-obviousness of the patent was not in dispute. The Federal Court of Appeal reiterated that questions of fact are reviewed only for palpable and overriding errors and that errors in law are reviewed under the correctness standard.

On the question of sound prediction, Teva argued that the Court had no evidence of the factual basis that was relied on by the inventors. Without this factual basis, the Court could not determine the inventor's actual line of reasoning and could not have applied the test correctly. The Federal Court of Appeal did not agree.

Since applying the sound prediction test is a question of fact, the standard is that of palpable and overriding error. The Federal Court of Appeal found that Teva did not establish a palpable and overriding error in this regard. TEVA's argument that "one cannot make a sound prediction when one does not know exactly why a particular combination works" was rejected since the application of the doctrine of sound prediction depends on the nature of the invention, and any particularities of its field of use, or discipline. There is no requirement that the inventors know exactly why their invention works. If that were the case, the utility would not need to be soundly predicted.

Use of Components A or B in ointments for the treatment of psoriasis was known. There was expert evidence that established that there was a high probability that if a solvent was used with the specific combination of components A and B that was tested by LEO, that the results would likely be reproducible for other combinations of the same categories.

Teva argued that this expert evidence cannot be used to determine facts that are normally intimate to the inventors in order to establish their line of reasoning. However, the Federal Court of Appeal found that this limitation does not exist. The caselaw in support of the sound prediction doctrine does not limit how the facts necessary to apply this doctrine can be established. In other words, how someone proves a fact that leads to this line of reasoning depends on each case. TEVA also

argued that, at the very least, the line of reasoning should be inferred from a statement found in the disclosure of the patent. The Federal Court of Appeal held that there is no such criteria and that there is no need to spell out what is self-evident or what is generally known to a person skilled in the art. Therefore, since the application of the doctrine of sound prediction is a matter of fact, facts can be established in many ways, such as by way of expert evidence. With this in mind, the Federal Court of Appeal found that the Court applied to proper test. All claimed alternatives for Components A and B have the same chemical scaffold as the ones tested for the 565 Patent and therefore, these alternatives would be expected to be as useful. The Court was entitled to use this expert evidence in its application of the sound prediction doctrine.

On the matter regarding insufficiency of the disclosure, TEVA's first hurdle was convincing the Federal Court of Appeal to hear its arguments since this allegation was not properly raised at trial. TEVA argued that in portions of the cross examination of LEO's expert, it had been established, and that it was of record, that the order in which a component is added to the non-aqueous ointment is an essential element to the invention that should have been disclosed. TEVA alleged that consequently, the Court erred in law by not considering this limitation and despite this, acknowledged that one may have to do some trial and error experiments to establish how a component must be dissolved or dispersed in solvent, and in which order, before making the petroleum based ointment.

Considering the excerpt of the cross examination of Leo's expert at trial, was the Court required to conclude that the order in which the components are mixed was an essential element of the invention that had to be disclosed? The Federal Court of Appeal found that the Court made no error in this regard and 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". Or put another way, the "trial and error required to determine the most effective way to make a good pancake mix with no lumps". The need for this type of trial and error to enable a skilled person to use the invention does not make the disclosure automatically insufficient. TEVA's argument was therefore dismissed.

Conclusion

While it may be surprising on the onset to see that the Federal Court of Appeal accepted the Court's decision that external elements as factual evidence to establish the inventor's desired result where the inventor's themselves did not know why their invention worked, this decision is in line with Canadian caselaw on the issue of sound prediction. Furthermore, it was interesting to see the Federal Court of Appeal also clarify that certain non-inventive trial and error could be required to put in practice an invention (like finding a good pancake mix) and it needs to be kept in mind that these findings are very much fact based and depend on the field of the invention. As such,

not all trial and error is enabling, and not all general knowledge is useful to establish an inventor's sound line of reasoning.

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