Federal Court  Cour fédérale

**Date: 20141218**

**Docket: T-1791-13**

**Citation: 2014 FC 1241**

**Ottawa, Ontario, December 18, 2014**

**PRESENT: The Honourable Mr. Justice Harrington**

**BETWEEN:**

**LEO PHARMA INC.**

**Applicant**

**and**

**TEVA CANADA LIMITED AND THE MINISTER OF HEALTH**

**Respondents**

## ORDER AND REASONS

[1] Leo Pharma Inc. has appealed from a decision of Prothonotary Tabib in which she dismissed its motion for leave to file reply evidence in an Application under the *Patented Medicines (Notice of Compliance) Regulations*. Before analysing her decision the context in which it was issued should be considered.

[2] In its underlying application Leo Pharma seeks an order prohibiting the Minister of Health from issuing a Notice of Compliance to Teva that would allow it to market its version of a Calcipotriol and Betamethasone Dipropionate ointment for the topical treatment of psoriasis. Teva has compared its product to Leo Pharma's, which is covered by Canadian Patent No. 2,370,565 and which has been listed on Health Canada's Patent Register. The patent is titled *Dermally Applicable Vitamin D–Containing Pharmaceutical Compositions* and is due to expire 27 January 2020.

[3] In accordance with the fiercely litigated *PM (NOC) Regulations*, Teva served Leo Pharma with a Notice of Allegation the relevant portion of which claims that the patent is not valid because the invention was obvious.

[4] Leo Pharma in turn filed a Notice of Application in this Court on 31 October 2013, which serves to prohibit the Minister from issuing a Notice of Compliance for two years or until a decision is rendered, whichever comes first. The application is scheduled to be heard 14 September 2015. Although the aim of these proceedings is to determine whether the Minister is free to issue the requested NOC, this Court must consider the allegation of obviousness that is at issue in this appeal, although its tentative finding on that point will not bind the Court in the underlying action on the validity or infringement of the patent. The Patentee is in no way deprived of all the recourses normally available to enable it to enforce its rights by commencing an action for infringement should its Application be dismissed. Likewise, Teva, if unsuccessful, may by action seek a declaration of patent invalidity.

[5] The proceedings are somewhat counterintuitive in that Leo Pharma is to prove a negative, that is to say that Teva's allegation is not justified. The normal procedure was followed in this case, which meant that Leo Pharma filed its evidence first.

[6] According to the affidavit of Dr. Kenneth Andrew Walters, filed on behalf of Leo Pharma:

> The 565 Patent relates to a pharmaceutical composition for dermal use that comprises a first pharmacologically active component (A), which consists of at least one vitamin D or vitamin D analogue, and a second pharmacologically active agent (B), which consists of at least one steroid. More specifically, the invention relates to pharmaceutical compositions containing two or more pharmacologically active compounds that have low compatibility with respect to the pH value of optimum stability. The Patent teaches that if these incompatible active ingredients are put in a non-aqueous topical formulation with a solvent component C, the formulation is stable and efficacious.

[7] The current appeal relates to two other paragraphs in Dr. Walters' affidavit (paragraphs 55 and 60), to which Dr. Eugene R. Cooper, retained by Teva, replied.

[8] In paragraph 55 of his affidavit Dr. Walters stated:

> While the majority of pharmaceutical topical products containing single active entities, and the combination products used in acne are cream and gel formulations, the 565 Patent distances itself from this norm. The preferred embodiment is a non-aqueous ointment composition comprising the two active ingredients and a solvent (component C). The selection of a non-aqueous formulation is, in itself, surprising because of the patient and physician preference for aqueous-based formulations. Although the vitamin D derivative was available in an ointment formulation, the formulation contained added water. The 565 Patent further teaches that in the presence of the solvent (Component C) "the active components can co-exist without degradation, despite their different pH/stability profiles." The 565 Patent describes several

> suitable candidates that can act as the solvent (Component C). These include polyoxypropylene-[15]-stearyl ether, 2-octyldodecanol, isostearyl benzoate, isopropyl palmitate, isopropyl myristate, and several other solvents.

[9] Dr. Cooper replied at paragraph 140 of his affidavit:

> I note that at paragraph 55 of the [Walters] Affidavit, Dr. [Walters] indicates that the combination products used in acne were cream and gel formulations. Dr. [Walters] is ignoring a number of approved combination ointment formulations used to treat other conditions including:
>
> a. Diprogen® was sold as both an ointment and a cream. The ointment contained betamethasone diproprionate (active ingredient), gentamicin (active ingredient) and white petrolatum. It was indicated for use in the topical treatment of corticosteroid responsive dermatoses when complicated by secondary infection caused by organisms sensitive to gentamicin or when the possibility of such infection is suspected.
>
> b. Valisone-G® was sold as both an ointment and a cream. The ointment contained betamethasone valerate (active ingredient), gentamicin (active ingredient) and petrolatum. It was indicated for use in the topical management of secondarily infected allergic or inflammatory dermatoses responsive to corticosteroid therapy (e.g., contact dermatitis, seborrheic dermatotitis, neurodermatitis, intertrigo, exfoliative dermatitis, stasis dermatitis and psoriasis.
>
> c. Locacorten Vioform® was sold as both an ointment and a cream. The ointment contained flumethasone (active ingredient), clioquinol (active ingredient) and a petrolatum base. It was indicated for the treatment of skin disorders complicated by bacterial and/or fungal infections. It was also indicated for treating atopic dermatitis, seborrheic dermatitis, neurodermatitis, eczematoid dermatitis, psoriasis, anogenital pruritus, lichen simplex, lichen planus, chronic neurodermatitis, stasis dermatitis, and intertrigo.
>
> d. Diprosalic® was sold as a lotion and an ointment. The ointment contained betamethasone dipropionate (active ingredient), salicylic acid (active ingredient), white petrolatum and mineral oil. It was indicated for the topical management of

> subacute and chronic hyperkeratotic and dry dermatoses responsive to corticosteroid therapy.
>
> e. Cortisporin® was sold as a cream and an ointment. The ointment contained polymyxin B sulfate (active ingredient), bacitracin zinc (active ingredient) neomycin sulfate (active ingredient), hydrocortisone (active ingredient) and special white petrolatum. It was indicated for use in the treatment of corticosteroid-responsive dermatoses with secondary infection.
>
> These formulations are all simple ointment formulations containing a petrolatum base. Accordingly, the skilled person would be well aware that simple ointment formulations can be used to formulate two active ingredients together.
>
> (Footnotes omitted.)

[10] Leo wishes to file reply evidence to the effect that the five combination formulations referred to by Dr. Cooper cannot not be compared to the patented formulations because there is no known incompatibility in the optimum pH stability of the active ingredients. The ingredients are thus easier to combine.

[11] The other bone of contention is paragraph 60 of Dr. Walters' affidavit, where he said:

> Overall, the 565 Patent teaches the skilled person how to make a pharmaceutical product containing two previously incompatible active ingredients that, when applied to the skin of a patient, will have a therapeutic effect that is greater than the effect of the individual active ingredients when applied separately, as described on p13 of the Patent

[12] Dr. Cooper commented as follows at paragraph 203 of his affidavit:

> With respect to paragraph 60, I note that the 565 Patent does not actually mix a calcipotriol formulation with a betamethasone formulation and show that it was in fact incompatible. I note that Diprosone ointment contained only betamethasone dipropionate and white petrolatum. The Disprosone [*sic*] ointment was not

> stabilized with an acid. There is no information in Leo's affidavits or the 565 Patent to show that adding this formulation to the calcipotriol ointment will cause any degradation to either active ingredient. Likewise there is no data to show that betamethasone dipropionate could not have been added to the calcipotriol ointment. As well, none of the formulations tested in Patel contained betamethasone dipropionate. As such, there is no data showing that they are not stable when mixed together.
>
> (Footnote omitted)

[13] Leo Pharma wishes in reply to produce a report showing that a combination of Diprosone and Calcipotriol was tested (post-patent) and found to be unstable.

## I. The Prothonotary's Decision

[14] Prothonotary Tabib:

a. was satisfied that Leo could not have anticipated the specific content of the evidence adduced by Dr. Cooper;

b. was not convinced that allowing Leo to file a proposed reply would cause substantial or serious prejudice, provided that Teva were allowed to file sur reply evidence; and

c. was of the view that Leo was not splitting its case;

d. Nevertheless, she was not satisfied that the proposed reply:

i would assist the Court in making its final determination; and

ii would serve the interests of justice.

[15] She was of the view that if the reply evidence were to be permitted, Teva should be given a right of sur reply, which would give rise to further controversy and potential motions, with a significant risk that the proceedings would be delayed and the controversy would distract us from the real issues in dispute. She was further of the opinion that all that Dr. Cooper said in paragraph 203 was that there were no data in the patent or in Leo's evidence that demonstrates that two ointments would not be stable if mixed together.

[16] Leo wishes to adduce in reply evidence post-patent tests that allegedly demonstrate that normally such mixtures are unstable. However, did Dr. Cooper opine that the two ointments would or might be stable when mixed? Consequently, is Leo's proposed reply to an argument that has not in fact been made, but rather to diffuse an innuendo or to guard against a possibility?

## II. Analysis

[17] A decision under Rule 312 of the *Federal Courts Rules* to allow reply evidence by way of affidavit is discretionary in nature. Any decision of a prothonotary, whether interlocutory or final, whether discretionary or not, may be appealed to a judge of the Federal Court in accordance with Rule 51 of the *Federal Courts Rules*. In turn, the decision of that judge, whether interlocutory or final, whether discretionary or not, may be appealed to the Federal Court of Appeal (*Federal Courts Act*, s. 27). This can lead to a very tight timetable in PM (NOC) applications in which each side files extensive affidavit evidence and schedules weeks upon weeks of cross-examination. Cross-examinations are currently to be completed by 17 April 2015.

[18] The Federal Court judge sitting in appeal of a discretionary order of a prothonotary should not exercise his or her discretion anew unless the questions raised in the motion are vital to the final issue in the case, or the order is clearly wrong in the sense that the exercise of discretion was based upon a wrong principle or upon a misapprehension of the facts (*Merck & Co v Apotex Inc*, 2003 FCA 488, [2004] 2 FCR 459, 30 CPR (4th) 40).

[19] It is well established, and conceded by Leo, that a decision under Rule 312 is not vital to the outcome of the case (*Solway Pharma Inc v Apotex Inc*, 2007 FC 913, 62 CPR (4th) 54).

[20] Therefore, this appeal turns on whether the decision was clearly wrong as being based upon a wrong principle or upon a misapprehension of the facts.

[21] Even more caution must be exercised when the prothonotary is acting as case manager. She has a detailed grasp of the issues and is called upon to render a great number of decisions, many in an informal setting (*Constant v Canada*, 2012 FCA 87, [2012] FCJ No 354 (QL); and *Taseko Mines Limited v Minister of the Environment* (17 April 2014), Ottawa, FC, T-1977-13 (interlocutory order)).

[22] The appeal turns on Prothonotary Tabib's view that reply evidence would not assist the Court in reaching its final decision or that the interests of justice would be served.

[23] Although not to be read *au pied de la lettre*, Mr. Justice O'Keefe in *Merck Frost Canada and Co v Canada (Minister of Health)*, 2003 FCT 287 at para 12, 25 CPR (4th) 56, set out five

factors normally considered by the Court in determining whether or not reply evidence should be allowed:

> (a) the respondent's evidence could not have been anticipated by the applicant;
>
> (b) it may assist the Court in making its final determination;
>
> (c) to refuse to do so would cause substantial prejudice to the applicant;
>
> (d) it will serve the interests of justice;
>
> (e) it will not cause unreasonable delay.

[24] Although Teva agrees in the result, it takes issue with the prothonotary's opinion that Leo Pharma could not have anticipated the evidence of Dr. Cooper. For its part, Leo Pharma maintains that Dr. Cooper did not simply reply to Dr. Walters but actually stepped outside the four corners of the Notice of Allegation, which is not permitted (*AB Hassle v Canada (Minister of National Health and Welfare)*, [2000] FCJ No 855 (QL), 7 CPR (4th) 272). On that basis it would have been open to Leo Pharma to move to have the paragraphs in question struck. However, its chance of success would be slight. As Mr. Justice Evans held in *Apotex Inc. v Lundbeck Canada Inc.*, 2008 FCA 265 at para 6, [2008] FCJ No 1275 (QL):

> The fact that the *Federal Courts Act*, R.S.C. 1985, c. F-7, provides for appeals as of right in interlocutory matters from a Prothonotary to a Judge of the Federal Court, and then to the Federal Court of Appeal, is not an open invitation to subject discretionary decisions at first instance to close scrutiny. The interests of justice are normally best served in summary and, indeed, in other proceedings, by minimising delays in the determination of the substantive matter. Whenever possible, the resolution of ongoing evidential wrangles (and some procedural issues) should be left to be decided by the judge hearing the application, or conducting the trial.

[25] It is important to keep in mind that the issue in *Lundbeck* was whether an affidavit should be struck. The issue here is whether additional evidence should be allowed. While the judge hearing the application on the merits can deal with evidence which is in the record, he or she obviously cannot deal with evidence which is not in the record.

[26] I see no reason to interfere with the prothonotary's decision with respect to paragraph 203 of Dr. Cooper's affidavit. Stability or instability is at the heart of the case. Leo Pharma did not produce a study when it could have easily done so. Furthermore, I would not have exercised my discretion in favour Leo Pharma, which should have anticipated the issue. It is too late to bring forth that evidence now.

[27] However, I have come to the conclusion that the learned prothonotary erred with respect to paragraph 140 of Dr. Cooper's affidavit. Having found, as she did, that Leo Pharma could not have anticipated that evidence, that she was not convinced that a proposed reply would cause substantial or serious prejudice, and that Leo Pharma was not splitting its case, in my view she erred in law in concluding that proposed reply would not assist the Court in making its final determination and that the evidence would not serve the interests of justice.

[28] The principle *audi alteram partem* applies. In light of the conclusion that Leo Pharma was taken by surprise, it is only fair and just that it be given an opportunity to reply.

[29] It falls upon the judge who hears the case on the evidence to construe the patent. Claims are to be read in the light of expert evidence provided to the Court as to the technical meaning of

the terms and concepts (*Free World Trust v Électro Santé Inc*, 2000 SCC 66, [2000] 2 SCR 1024; and *Whirlpool Corp v Camco Inc*, 2000 SCC 67, [2000] 2 SCR 1067). Cross-examinations have yet to be completed.

[30] It seems to me that the prothonotary was interpreting the patent before all the evidence was in. Leo Pharma is right in asserting that the applications judge may have a different point of view.

[31] In *NV Bocimar SA v Century Insurance Co*, [1987] 1 SCR 1247, 39 DLR (4th) 465 (cited to SCR), the Supreme Court disagreed with the Court of Appeal, which had interpreted expert evidence based on affidavits in a way contrary to the trial judge. In speaking for the Court, Mr. Justice Le Dain said (at 1250):

> The Court of Appeal appears to have taken the position that it could assess the weight of the evidence in support of the facts on which the expert witnesses expressed an opinion because the evidence of those facts was before the trial Court in a documentary form. The findings of the trial Judge were similar to the assumed facts and the opinions in the affidavits of the expert witnesses. In coming to a different conclusion, on a balance of probabilities, from that of the trial Judge with respect to some of those facts, the Court of Appeal in effect rejected the expert testimony which was based in part on those facts. It did so without having heard the expert witnesses and without being in a position to determine what their testimony would have been had the factual basis for their testimony been qualified to the extent considered necessary by the Court of Appeal. In doing so, the Court of Appeal, in my respectful opinion, erred.

[32] In my opinion, the same principle applies to forming an opinion before the expert testimony is complete.

[33] For these reasons, I shall allow the appeal in part. Leo Pharma shall be given leave to reply to paragraph 140 of Dr. Cooper's affidavit. That reply evidence has already been sketched out, which is sufficient for present purposes (*Lundbeck*, above).

[34] It is more appropriate that the prothonotary set out the delays for the filing of this reply evidence, and then to determine whether or not sur reply evidence is required.

[35] Costs shall be in the cause.

**ORDER**

**FOR REASONS GIVEN;**

**THIS COURT ORDERS that:**

1. The appeal of Leo Pharma Inc. is granted in part. Leo Pharma is given leave to file affidavit evidence in reply to paragraph 140 of Dr. Cooper's affidavit.

2. Scheduling of the serving and filing of that evidence, and consideration as to whether it would be appropriate to permit Teva Canada Limited to file sur reply evidence, are referred back to the case management judge.

3. Costs are in the cause.

"Sean Harrington"

Judge

**FEDERAL COURT**

**SOLICITORS OF RECORD**

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| **DOCKET:** | T-1791-13 |
| **STYLE OF CAUSE:** | LEO PHARMA INC. v TEVA CANADA LIMITED AND THE MINISTER OF HEALTH |
| **PLACE OF HEARING:** | OTTAWA, ONTARIO |
| **DATE OF HEARING:** | NOVEMBER 26, 2014 |
| **ORDER AND REASONS:** | HARRINGTON J. |
| **DATED:** | DECEMBER 18, 2014 |

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