Federal Court  Cour fédérale

Date: 20151118

Docket: T-1791-13

Citation: 2015 FC 1237

Toronto, Ontario, November 18, 2015

PRESENT: The Honourable Mr. Justice Locke

BETWEEN:

LEO PHARMA INC.

Applicant

and

TEVA CANADA LIMITED AND THE MINISTER OF HEALTH

Respondents

and

LEO PHARMA A/S

Respondent/Patentee

PUBLIC JUDGMENT AND REASONS
(Confidential Judgement and Reasons issued October 30, 2015)

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I. Overview

[1] This is an application by Leo Pharma Inc. (Leo) under the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 [the Regulations], for an Order prohibiting the Minister of Health (the Minister) from issuing a notice of compliance (NOC) to Teva Canada Limited (Teva) in respect of 50 mcg/g calcipotriol and 0.5 mg/g betamethasone (as dipropionate) ointment until after the expiry of Canadian Patent No. 2,370,565 (the 565 Patent).

[2] The patented ointment is for use in the treatment of psoriasis, a chronic skin disease.

[3] Teva filed an Abbreviated New Drug Submission with the Minister seeking an NOC for approval to sell its version of the patented ointment. Because the 565 Patent is registered against the patented ointment on the patent register maintained by the Minister under sections 3 and 4 of the Regulations, Teva had to address the 565 Patent under section 5 of the Regulations before it could obtain its NOC.

[4] By letter dated September 18, 2013 to Leo, Teva served a notice of allegation (NOA) making a number of allegations that the 565 Patent is invalid and that it will not be infringed by its version of the patented ointment.

[5] In response to Teva's NOA, Leo commenced the present application on October 31, 2013, by filing a notice of application asserting that Teva's allegations are not justified. By virtue of paragraph 7(1)(e) of the Regulations, the commencement of this application began a 24-month period during which the Minister is prohibited from issuing the NOC that Teva has requested. The impending expiry of that 24-month period has created an urgency for the release of this decision.

[6] By the time of the hearing of this application, the issues in dispute raised in the NOA and the notice of application had been narrowed substantially. The infringement issues had been resolved such that the parties no longer dispute that claims 1 to 8, 10, 11, 15 to 18, 20 and 21 of the 565 Patent would be infringed by Teva's version of the patented ointment, and claims 9, 12, 13 and 19 would not be infringed. Claim 14 no longer exists by virtue of a disclaimer that was submitted to the Patent Office in 2012 and recorded on November 4, 2013.

[7] Three invalidity allegations remain in dispute: obviousness, lack of utility, and insufficiency. Each of these issues is discussed in turn later in this decision. For the reasons provided, I have concluded that each of Teva's remaining invalidity allegations is not justified.

II. Background

[8] As indicated above, psoriasis is a chronic skin disease. It is not normally deadly, but it is incurable and can cause great discomfort and/or embarrassment. It typically involves repeated recurrences of scaly and inflamed skin. The severity of an occurrence of psoriasis may vary greatly. It may be mild, moderate or severe. Severity is often estimated by the Psoriasis Area and

Severity Index (PASI) which takes into account the size of the affected area, redness, thickness and scaling.

[9] Just as occurrences of psoriasis are intermittent, treatment is normally likewise intermittent, being directed to reducing the symptoms. During the 1990s, the most popular treatments were corticosteroids (of which betamethasone dipropionate is one) and vitamin D analogues, more specifically calcipotriol (which is also known as calcipotriene). Leo held a patent on calcipotriol in a number of countries which expired around 2009.

[10] Corticosteroids and calcipotriol could be applied individually. Each had advantages and disadvantages. In the early 1990s, it was found that there were advantages to a treatment regimen that involved both compounds. A sequential therapy, whereby each of the corticosteroid and the calcipotriol was applied at different times of the day or the week, became a well-known treatment. The sequential therapy resulted in fewer side effects, less irritation and more rapid onset of healing.

[11] However, there were problems of patient compliance with the sequential therapy, e.g. due to patients erring as to which compound should be applied at a particular time, or simply not having the patience to apply the treatment twice every day. A combined formulation of calcipotriol and a corticosteroid was sought.

[12] Unfortunately, it was not a simple matter to develop a combined formulation because the two products are pH incompatible. That is, their respective optimum stabilities are at

significantly different pH values. Calcipotriol requires a pH value above 8 (an alkaline environment) for maximum stability, while corticosteroids require pH values in the 4-6 range (an acidic environment) for maximum stability. This pH incompatibility would make a combined formulation of a corticosteroid and calcipotriol alone unstable in that one or both of the compounds would be liable to degrade prior to application.

[13] The parties disagree as to the extent to which dermatologists and/or patients, prior to the development of the patented formulation, mixed calcipotriol and corticosteroids despite their incompatibility. Teva alleges that some dermatologists routinely instructed patients to apply the two compounds simultaneously on the skin. Leo does not accept that this method of treatment was common. The expert evidence likewise differs on this point. In any case, it is common ground that there was a motivation to create a combined formulation for treatment of psoriasis that would be stable for a reasonable period of time so that patients would not have to deal with two separate compounds and mix the compounds themselves.

III. The 565 Patent

[14] The 565 Patent has a filing date of January 27, 2000, and is based on a priority application that was filed in Denmark on April 23, 1999. It was published on November 2, 2000, and is to expire on January 27, 2020. It names two inventors: Erik Didriksen and Gert Høy. At the time of its issuance on November 25, 2008, the 565 Patent had 21 claims, of which the only independent claim was claim 1. As indicated above, Leo submitted a disclaimer in 2012 against the 565 Patent. That disclaimer disclaimed claim 14 entirely and reduced the scope of claim 1. Neither the validity nor the effect of this disclaimer is in issue in the present application.

[15] The 565 Patent describes and claims a combined formulation of the two psoriasis drugs discussed above, with the addition of a solvent, which resolves the instability problem that had impeded combining the two previously. The patented formulation is in the form of a pharmaceutical non-aqueous ointment composition for dermal use comprising pharmacologically active components A and B, wherein the difference between their respective optimum stability pH values is at least 1, and at least one solvent component C. The broadest claim (independent claim 1) defines components A, B and C as follows:

Component A: at least one vitamin D or vitamin D analogue

Component B: at least one corticosteroid

Solvent C: at least one selected from

(i) a compound of the general formula $R^3(OCH_2C(R^1)H)x\ OR^2$ (I)

wherein x is in the range of 2-60, R^1 in each of the x units independently is H or CH_3, R^2 is straight chain or branched C_{1-20}alkyl or benzoyl, and R^3 is H;

(ii) a straight or branched C_{12-18}-alkyl benzoate;

(iii) a straight or branched C_{2-4}-alkyl ester of straight or branched C_{10-18}-alkanoic or -alkenoic acid;

(iv) a propylenglycol diester with C_{8-14}-alkanoic acid; or

(v) a branched primary C_{18-24} alkanol.

[16] Further claims in the 565 Patent define the various components more narrowly. Claims 2 to 5 reduce the scope of component A with claim 5 focusing on calcipotriol or its hydrate. Claims 6 to 9 reduce the scope of component B. Claims 15 to 17 reduce the scope of solvent component C. Claim 17 specifies that solvent component C is polyoxypropylene-15-stearyl ether

(POP-15). It should be noted that claim 10 specifies that the claimed composition is non-aqueous, and claim 11 specifies that it is an ointment. Since the disclaimer, which narrowed claim 1 to a non-aqueous ointment, claims 10 and 11 are essentially redundant. As indicated above, claim 14 was disclaimed entirely.

[17] The 565 Patent provides data concerning the results of a four-week clinical trial. The trial measured the efficacy in patients (in terms of percentage change in PASI score) of a composition combining calcipotriol (as component A) and betamethasone dipropionate, a corticosteroid (as component B), and compared those results to results for patients treated either with calcipotriol alone, with betamethasone dipropionate alone, or with a composition containing neither active ingredient. The combination composition produced the best results.

[18] The 565 Patent describes an Example 1 in which an ointment was tested for stability. It comprised calcipotriol as component A, betamethasone dipropionate as component B, and POP-15 as solvent component C. This ointment also included α-Tocopherol, the nature and purpose of which is discussed below in relation to the allegation of lack of utility. The test of the Example 1 ointment showed adequate stability of both the calcipotriol and the betamethasone dipropionate.

[19] A similar test was conducted on another ointment, this one using propylene glycol as solvent component C in place of POP-15, and also containing lanolin as an emulsifier. This ointment did not contain α-Tocopherol. This time the calcipotriol degraded badly.

IV. The Witnesses

[20] The record in this application includes the evidence of 13 witnesses. Leo had nine witnesses (five experts and four fact witnesses) and Teva had four witnesses (three experts and one fact witness). The witnesses are each discussed briefly below.

[21] Each party devoted considerable efforts to arguing that I should discount the evidence of certain of the other party's experts because of a lack of expertise and/or a tendency to advocate on behalf of the party that retained them. Having now considered the parties' arguments on these points, I have concluded the same for all: As regards expertise, I am satisfied that all of the expert witnesses have adequate expertise to provide relevant opinions in this case. As regards the concerns about witnesses' bias, I recognize that, despite intentions to be neutral, there is a natural tendency to emphasize the points that favour one's client and downplay points that work against the client. I have read the experts' evidence with this in mind. However, I have not been convinced that any of the experts' evidence is so flawed in this respect or demonstrates bias to such an extent that I should give it little or no weight.

A. *Leo's Expert Witnesses*

(1) Arthur H. Goldberg

[22] Dr. Goldberg is an expert in formulation. He obtained a PhD in Pharmaceutical Chemistry from the University of Michigan, and taught for four years at the College of Pharmaceutical Sciences, Colombia University, before entering the pharmaceutical industry as a

formulator. In his positions at various pharmaceutical companies, he was involved in the development of several topical formulations, including one unsuccessful coal tar preparation for psoriasis. He has written a book chapter on dispersion techniques in relation to topical ointments.

[23] In his affidavit, Dr. Goldberg presented his interpretation of the 565 Patent as well as his assessment of issues of infringement and validity of the 565 Patent. He devoted the majority of his affidavit the issue of obviousness.

(2) Kenneth Andrew Walters

[24] Dr. Walters is another expert in formulation. He is the director of An-eX Analytical Services Ltd, an independent contract research and development laboratory that focuses on the dermatological and transdermal field and regularly performs *in vitro* human skin permeation studies. Dr. Walters obtained his PhD from the University of Strathclyde, Glasgow, following the submission of a thesis entitled The Effects of Nonionic Surface-Active Agents on Epithelial Membranes. He has worked in a variety of positions involving research and development (R&D) on systems designed to deliver drugs into and through the skin, and has over 30 years of experience in the design and formulation of transdermal drug delivery systems. Since the 1980s, he has both participated in and organized many academic conferences on percutaneous absorption and formulation science.

[25] Like Dr. Goldberg, Dr. Walters' affidavit reviewed the 565 Patent and then addressed issues of infringement and validity thereof. In relation to obviousness, Dr. Walters opined that it would not have been more or less self-evident for a person skilled in the art to arrive to the

invention of the 565 Patent, based on his or her common general knowledge and/or the prior art. Dr. Walters also considered utility and over-breadth, concluding that Teva's arguments in this regard were unfounded. Finally, in relation to sufficiency, Dr. Walters concluded that the 565 Patent discloses everything that is essential for the invention to function properly and for the skilled formulator to reproduce it.

[26] Dr. Walters also provided a reply affidavit that was responsive to a comment by Teva's expert witness Eugene Cooper concerning known combination formulations.

(3) Paul Contard

[27] Dr. Contard is an Associate Clinical Professor of Dermatology at Mount Sinai School of Medicine and a practising dermatologist who regularly treats patients with psoriasis. He has an MD from The Mount Sinai School of Medicine and a PhD in Biology from the City University of New York.

[28] In his affidavit, he provided a primer on psoriasis and its treatment prior to the invention of the 565 Patent, focusing particularly on vitamin D analogue and corticosteroid treatments. He stated that these products require different pH values in their environment to be stable and so, prior to the patented invention, had to be applied sequentially, leading to problems of patient compliance. He opined that, by combining these two products into a single stable, efficacious formulation, the patented product solves this problem, as well as providing a number of additional benefits. Finally, Dr. Contard addressed Teva's claims regarding the broad range of dosages covered by the patent, opining that the doses claimed and described in the 565 Patent are

appropriate, useful, and sufficiently clear given the knowledge of the skilled person at the relevant time.

(4) Neil Shear

[29] Dr. Shear is a professor at the University of Toronto and a practising dermatologist who regularly treats patients with psoriasis. He earned his MD from McMaster University and is currently Head of Dermatology at the Sunnybrook Health Science Centre.

[30] In his affidavit, Dr. Shear summarized the teachings of the 565 Patent and discussed his medical experience with the use of Dovobet, which is the name of Leo's patented formulation in Canada and which he prescribes frequently and finds to be very effective.

(5) Fritz Blatter

[31] Dr. Blatter is a Project Manager in the Department for Solid-State Development at Solvias AG, a privately held company which supports the research and development of drug substances and the optimization of manufacturing processes for pharmaceutical, biotechnology, and life sciences companies.

[32] Dr. Blatter was asked to reproduce an experiment from the prior art and investigate whether calcipotriol in ointment mixtures containing another active pharmaceutical ingredient would be stable over at least three months. The results of this study confirmed the finding in the

prior art, that significant degradation occurs when the testing is extended to fifteen days and beyond.

B. *Leo's Fact Witnesses*

(1) Jens Hansen

[33] Dr. Hansen was Vice-President, Analysis and Pharmaceutical Development at Leo, and the direct supervisor of the two inventors around the time the subject-matter of the 565 Patent was being developed. His testimony was introduced in large part based on the unavailability of both inventors. According to Dr. Hansen, one of the inventors (Erik Didriksen) retired in 2004 and was adamant that he did not want to participate in this litigation. [redacted]

[34] Dr. Hansen joined Leo on January 1, 1998. At that time, Leo was already developing a topical formulation for the treatment of psoriasis. Dr. Hansen managed the development team, participating in discussions about formulations as a result of his interest in the topic. Relying on development reports, lab notebooks, meeting minutes, memos, and other documents from the relevant time period, Dr. Hansen recounted in his affidavit the history of the research and

development that led to the patented formulation. He concluded that the development of this product was the result of a series of experience, coincidence, and luck.

[35] Teva argues that most of the evidence provided by Dr. Hansen on the subject of the development of the patented formulation is hearsay, and as such should be given little, if any, weight. In support of this assertion, the respondent cites *R v Khelawon*, 2006 SCC 57, for a definition of hearsay (paras 35-36), a reiteration of the importance of the hearsay rule in relation to a fair trial (paras 48-49), and a review of the principled approach to addressing hearsay issues, which is directed to assessing the reliability and necessity of the hearsay evidence (paras 42, 61).

[36] Hearsay evidence is presumptively inadmissible unless it falls under an exception to the hearsay rule. The traditional exceptions to the hearsay rule remain presumptively in place: *R v Mapara*, 2005 SCC 23, at para 15. One of these exceptions concerns business records, which exception is discussed in *Distrimedic Inc v Dispill Inc*, 2013 FC 1043 at para 83:

> The main requirements for admission of hearsay evidence under the common law business records exception are that the person who created the record did so contemporaneously, based on personal knowledge and under a duty to do so: *Ares v Venner*, [1970] SCR 608.

[37] The reports, notebooks, minutes, memos, and other documents relied upon by Dr. Hansen in his affidavit appear to meet these criteria. Teva does not argue the contrary. Accordingly, I conclude that these documents satisfy the business records exception to the hearsay rule.

[38] The focus of Teva's hearsay challenge is more on statements made by Dr. Hansen based on meetings and conversations with the inventors and others involved in the development of the

patented formulation prior to Dr. Hansen's arrival at Leo. Here, Leo must rely on the principled approach which assesses the reliability and the necessity of the hearsay statements. Reliability is to be assessed functionally, by focusing on the particular dangers raised by the hearsay evidence sought to be introduced and on those attributes or circumstances relied upon by the proponent to overcome those dangers: *Clayson-Martin v Martin*, 2015 ONCA 596 at para 29 [*Clayson-Martin*]. Necessity is to be interpreted flexibly, and is not restricted to the absolute unavailability of a witness: *Clayson-Martin* at para 28.

[39] As regards the reliability of Dr. Hansen's statements, Teva argues that he was unsure what he himself had done (quite aside what others had told him), and that he volunteered information that was not asked of him during cross-examination. Teva argues that Dr. Hansen's testimony is not reliable. Having considered Teva's assertions in this regard, I am not satisfied that Dr. Hansen's testimony impairs the reliability of his evidence. I am not satisfied that his memory was poor or that his testimony demonstrated any sort of bias.

[40] With regard to the issue of necessity, Teva argues that the evidence concerning the unavailability of the inventors to testify is inadequate. I do not agree. With regard to Dr. Høy, I am fully satisfied that Leo has established that there was a good reason not to have him testify. I have no reason to doubt the evidence submitted by Leo in this regard. The reason for omitting Erik Didriksen as a witness is less compelling. It is simply a matter of his having been retired for a long time and not wishing to participate. However, based on the flexible approach taken to the necessity requirement, I am satisfied that Dr. Hansen's testimony satisfies this requirement for both inventors.

[41] Overall, I am satisfied that it is not unfair to Teva to admit Dr. Hansen's hearsay evidence. Accordingly, I conclude that his testimony is admissible.

(2) Jacob Anker Rasmussen

[42] Mr. Rasmussen has been employed by Leo since 1997, most recently as Vice-President, Global Patient Solutions Dermatology. In his affidavit, Mr. Rasmussen provided a history of Leo, as well as details on the commercial success of the patented ointment. This information includes sales data from 11 countries, including Canada, for the time period between 2001, when the product was launched, and 2013. Mr. Rasmussen also provided charts on the comparative sales of major topical psoriasis treatments across America, Europe, and Asia from 2011 to 2013.

(3) Karen Gow

[43] Ms. Gow is currently the Vice-President, Market Access and Business Intelligence at Leo, and has been employed there since 2009. In her affidavit, she provided some background information regarding the current litigation.

(4) Kang Lee

[44] Mr. Lee is a lawyer with Leo's counsel Fasken Martineau DuMoulin. He reproduced documents and information concerning certain patent documents discussed in the parties' arguments.

C. *Teva's Expert Witnesses*

(1) Eugene R. Cooper

[45] Dr. Cooper obtained his PhD in Chemistry from Iowa State University, and has spent his professional career researching and developing nanoparticle technology in relation to drug delivery. He has experience in formulation development, and has developed a theory for predicting skin transport from molecular properties and for designing penetration enhancers. Though Leo vigorously challenged Dr. Cooper's expertise, I am satisfied that his testimony is admissible and should not be discounted.

[46] In his affidavit, Dr. Cooper construed the patent, and then considered whether the patented invention was obvious. He concluded that that the skilled person would have been led directly and without difficulty to making the non-aqueous ointment described and claimed in the 565 Patent. Dr. Cooper also opined that the 565 Patent lacks utility as the skilled person could not have predicted, based on the information provided in the 565 Patent, that all of the claimed non-aqueous ointments would be stable and effective. In relation to insufficiency, Dr. Cooper indicated in the alternative that the 565 Patent fails to provide sufficient information to allow the skilled person to make ointments across the entire range of components claimed. Dr. Cooper concluded his affidavit by commenting on the affidavits of Dr. Hansen, Dr. Walters, and Dr. Goldberg.

[47] Dr. Cooper also provided a sur-reply affidavit that responded to Dr. Walters' reply affidavit.

(2) Gerald G. Krueger

[48] Dr. Krueger is a Professor of Dermatology at the University of Utah Health Sciences Center, where his research focus is the diagnosis and treatment of psoriasis. He has held several specialized positions in relation to the study and treatment of psoriasis, including Chairman of the National Institute of Health's Committee to Evaluate Psoriasis Research.

[49] In his affidavit, Dr. Krueger described his experience in treating psoriasis prior to 1999, when he would generally prescribe simultaneous once-a-day application of calcipotriol and a topical corticosteroid. He continues to prescribe this treatment today. Though he has also prescribed the patented formulation, it is not his preferred formulation due to factors of efficacy and cost. Dr. Krueger also responded to the affidavits of Dr. Shear and Dr. Contard.

(3) Steven R. Feldman

[50] Dr. Feldman is a Professor of Dermatology at Wake Forest Baptist Health, where he directs the Center for Dermatology Research and the Psoriasis Treatment Center. He received his MD and PhD from Duke University, and his chief clinical expertise relates to treatment of psoriasis. He has published numerous articles and book chapters in the field of dermatology. In his affidavit, he provided background information on psoriasis and its treatment, and explained his understanding of the 565 Patent as a dermatologist.

[51] Dr. Feldman opined that, from an efficacy and side effects standpoint, the patented formulation is not better than the calcipotriol and topical corticosteroid combination regimens that were being prescribed by dermatologists as of January 1999. Dr. Feldman also responded to the applicant's experts, Dr. Shear, Dr. Contard, and Mr. Rasmussen.

[52] Further, Dr. Feldman provided a sur-reply affidavit that responded to Dr. Walters' reply affidavit.

D. *Teva's Fact Witness*

(1) Anna Hucman

[53] Ms. Hucman is a law clerk employed with Teva's counsel Aitken Klee LLP. In her affidavits, she reproduced the NOA as well as a number of publications related to the issues in dispute.

V. Agreed Facts

[54] The parties are agreed on a number of the relevant facts. There is no disagreement that vitamin D and vitamin D analogues, specifically calcipotriol, were known for treatment of psoriasis prior to the 565 Patent. Likewise, corticosteroids were known for treatment of psoriasis. The parties do not dispute that Leo held a patent on calcipotriol which expired around 2009.

[55] As of 1994 at the latest, it was well-known that sequential therapy of calcipotriol and a corticosteroid was advantageous over either treatment alone. The parties are agreed that, because

of this synergy, there was motivation to create a formulation that combined calcipotriol and a corticosteroid. However, these two drugs could not simply be mixed because of the instability of calcipotriol in any environment in which the pH value was favourable to the stability of a corticosteroid, and vice versa.

[56] The parties agree on the qualities of the person skilled in the art from whose point of view the 565 Patent is to be construed and the allegations of invalidity are to be assessed. The skilled person is a developer of topical formulations. The 565 Patent is also directed to clinicians (dermatologists).

[57] Finally, and as indicated above, the parties acknowledge that Teva's version of the patented ointment would infringe claims 1 to 8, 10, 11, 15 to 18, 20 and 21 of the 565 Patent, but would not infringe claims 9, 12, 13 and 19.

VI. The Issues

[58] As indicated above, the allegations of invalidity of the 565 Patent which remain in issue are obviousness, lack of utility, and insufficiency. In light of the acknowledged infringement of certain claims by Teva's version of the patented ointment, it follows that Leo will be entitled to the Order it seeks in this application if it is able to establish that, for at least one of the claims in issue, all of Teva's allegations of invalidity are not justified.

[59] The parties have made many arguments in relation to these issues. Because of my findings on some of the arguments, it is not necessary for me to decide others. Accordingly, I have not reached conclusions with regard to some of these other arguments.

A. *Preliminary Issues*

[60] Before discussing the invalidity issues in dispute, there are a few preliminary issues that require discussion.

(1) Burden of Proof

[61] The parties do not appear to disagree on the burden of proof in the present application in respect of Teva's allegations of invalidity of the 565 Patent. However, because the burden of proof is complicated and somewhat counterintuitive in the context of an application under the Regulations, it warrants some discussion.

[62] The general principle in an application is that the applicant bears the onus of proof. This applies in the present application, even on issues of patent validity.

[63] Because subsection 43(2) of the *Patent Act*, RSC 1985, c P-4 [the *Patent Act*], creates a presumption that a patent is valid, the jurisprudence has held that, once the existence of the patent has been established, the onus shifts to the respondent (Teva, here) who then has the burden of putting its allegations of invalidity "into play": *Pharmascience Inc v Canada (Health)*, 2014 FCA 133 at para 32 [*Pharmascience*]. This can be done by adducing evidence which is

"not clearly incapable of establishing its allegations of invalidity": *Pfizer Canada Inc v Canada (Health)*, 2007 FCA 209 at para 109. The respondent's burden in this respect has also been characterized as the requirement to "lead sufficient evidence to give its allegations 'an air of reality'." The standard of proof here is lower than a balance of probabilities: *Pharmascience* at para 33; *Pfizer Canada Inc v Apotex Inc*, 2007 FC 971 at para 51, aff'd 2009 FCA 8 [*Pfizer*]. However, the respondent's onus cannot be satisfied by the mere fact of detailing its allegations in its NOA: *Pharmascience* at para 36.

[64] Once the respondent has properly put its invalidity allegations into play, the onus shifts back to the applicant (Leo, here) to establish, on a balance of probabilities, that those allegations are not justified.

[65] Leo argues that Teva's invalidity allegations have not been put into play, and that the onus of proof has therefore not shifted back to Leo. For the purposes of this application, I have assumed, without deciding, that those of Teva's invalidity allegations that were properly raised in its NOA have indeed been put into play and that the onus of proof has indeed shifted back to Leo.

(2) Notice of Allegation

[66] Leo also argues that Teva has improperly raised new arguments not contemplated in its NOA. Leo argues that Teva is not entitled to raise any new arguments, allegations, facts, or prior art that were not set out in the NOA: *Alcon Canada Inc v Apotex Inc*, 2014 FC 791 at para 75 [*Alcon*]; *Bayer Inc v Cobalt Pharmaceuticals Company*, 2013 FC 1061 at paras 34-36. This is

because it would be unfair for Leo, who decided to commence the present application, and who prepared its notice of application and its evidence, on the basis of Teva's NOA, to face shifting allegations and facts.

[67] For its part, Teva argues that there is a recognized exception to this general rule which permits it to defend itself against Leo's arguments and to respond to Leo's evidence: *AstraZeneca Canada Inc v Teva Canada Limited*, 2013 FC 245 at para 54 [*AstraZeneca*].

[68] For the most part, it is not necessary for me to decide whether there is any merit to Leo's objections on this issue. In many cases, I have not refused to consider Teva's arguments simply on the basis that they were not raised in the NOA. Cases in which I have refused to consider Teva's argument are discussed in my analysis of the relevant issues.

(3) Scope of Oral Representations

[69] Each party also argues that the other made oral representations at the hearing of this application that were not included in their respective memoranda of fact and law, and which should therefore be ignored. In my view, little turns on this issue. Most such arguments were made by Leo against Teva. However, I have not excluded any of Teva's arguments simply on the basis that they were not mentioned in its memorandum of fact and law.

(4) The Rule in *Browne v Dunn*

[70] This issue was raised at the hearing by Teva concerning an argument made by Leo. Leo argues that I should give less weight to the testimony of Teva's witnesses Dr. Feldman and Dr. Krueger because some of the opinions expressed in their affidavits are inconsistent with opinions they expressed in earlier publications. Teva objects to this argument on the basis of the Rule in *Browne v Dunn* (1893), 6 R 67 (HL) [*Browne v Dunn*]. This Rule is discussed in *Green v Canada (Treasury Board)* (2000), 254 NR 48 (FCA) at para 25:

> *Browne v. Dunn* stands for a rule of evidence that where the credibility of a witness is to be impeached by evidence that contradicts his testimony, the witness must be given a fair opportunity to explain the discrepancy. This is a rule grounded in fairness and reason. Its application depends upon the circumstances of the case. The trier of fact is always entitled to disbelieve or reject any evidence that is presented (J. Sopinka, S.N. Lederman and A.W. Bryant, The Law of Evidence in Canada, 2nd ed., (Toronto: Butterworths, 1999) at 954-957).

[71] With regard to Dr. Feldman, I see no inconsistency in his testimony. In his affidavit, Dr. Feldman stated that the patented combination ointment is not his first choice in treating psoriasis because it is greasy and expensive. In an earlier publication, he had discussed several advantages of the patented combination ointment. However, these advantages do not contradict the assertions of greasiness and expense. Accordingly, I need not consider the Rule in *Browne v Dunn* as it relates to Dr. Feldman.

[72] The situation with Dr. Krueger is different. He made several statements in his affidavit that, before the claim date of the 565 Patent, he had prescribed and discussed publicly the

simultaneous application of calcipotriol and a corticosteroid in the treatment of psoriasis. A publication of which he is a co-author, dating from the period after the claim date of the 565 Patent but before the commencement of the present application, discussed recommended treatments for psoriasis. Though the publication mentions sequential application of calcipotriol and a corticosteroid (*e.g.* corticosteroids applied twice a day for two weeks, followed by calcipotriol twice a day for one week, followed by alternating weeks of each), it is conspicuously silent on the subject of simultaneous treatment. Leo argues that this is inconsistent with Dr. Krueger's affidavit.

[73] With regard to the Rule in *Browne v Dunn*, Leo argues that it showed this publication to Dr. Krueger during his cross-examination, and read him certain portions of it. However, I note that Leo did not go to the portions of the publication that discuss recommended treatment regimens for psoriasis. The cross-examination focused instead on a statement in the publication that calcipotriol "is a relatively unstable molecule and is inactivated by an acid pH. It is therefore not compatible in combination with some therapies." Leo did not put the allegedly inconsistent statement to Dr. Krueger.

[74] Leo also argues that its reference to these earlier publications by these witnesses is not in order to impeach their credibility. Leo draws my attention to *R v Quansah*, 2015 ONCA 237, which states at para 81 that

> Compliance with the rule in *Browne v. Dunn* does not require that every scrap of evidence on which a party desires to contradict the witness for the opposite party be put to that witness in cross-examination. The cross-examination should confront the witness with matters of *substance* on which the party seeks to impeach the witness's credibility and on which the witness has not had an

> opportunity of giving an explanation because there has been no suggestion whatever that the witness's story is not accepted.
>
> [Emphasis in original]

[75] As regards the failure of the publication co-authored by Dr. Krueger to acknowledge the use of simultaneous application of calcipotriol and a corticosteroid in the treatment of psoriasis, I sustain Teva's objection on the basis of the Rule in *Browne v Dunn*. In my view, the passages in question were clearly relied upon by Leo in order to challenge Dr. Krueger's credibility, and he was entitled to have those passages (or at least their subject) brought to his attention during cross-examination so that he would have an opportunity to explain the omission of reference to simultaneous application of calcipotriol and a corticosteroid.

B. *Claim Construction*

[76] The interpretation of the claims in issue is preliminary to determination of the invalidity issues in dispute discussed below. This is because the meaning of those claims must be understood before their validity can be assessed.

[77] The issue of claim construction is also important in determining the inventive concept of the 565 Patent. Leo argues that it concerns the stability of the patented ointment, while Teva notes that the claims do not mention stability and simply define a pharmaceutical non-aqueous ointment composition for dermal use comprising certain defined components.

(1) Applicable Law

[78] Claims construction is antecedent to consideration of both validity and infringement issues: *Whirlpool Corp v Camco Inc*, 2000 SCC 67 at para 43 [*Whirlpool*].

[79] A patent is not addressed to an ordinary member of the public, but to a worker skilled in the art described as:

> [A] hypothetical person possessing the ordinary skill and knowledge of the particular art to which the invention relates, and a mind willing to understand a specification that is addressed to him. This hypothetical person has sometimes been equated with the "reasonable man" used as a standard in negligence cases. He is assumed to be a man who is going to try to achieve success and not one who is looking for difficulties or seeking failure.
>
> [*Free World Trust v Électro Santé Inc*, 2000 SCC 66 at para 44, quoting Fox, Harold G. *The Canadian Law and Practice Relating to Letters Patent for Inventions*, 4th ed., Toronto: Carswell, 1969 at 184]

[80] As stated in *Catnic Components Ltd v Hill & Smith Ltd*, [1982] RPC 183 at 242-243, and quoted in *Whirlpool* at para 44:

> A patent specification should be given a purposive construction rather than a purely literal one derived from applying to it the kind of meticulous verbal analysis in which lawyers are too often tempted by their training to indulge. The question in each case is: whether persons with practical knowledge and experience of the kind of work in which the invention was intended to be used, would understand that strict compliance with a particular descriptive word or phrase appearing in a claim was intended by the patentee to be an essential requirement of the invention so that *any* variant would fall outside the monopoly claimed, even though it could have no material effect upon the way the invention worked.

[Emphasis in original]

[81] As stated in *Consolboard Inc v MacMillan Bloedel (Saskatchewan) Ltd*, [1981] 1 SCR 504 at 520:

> We must look to the whole of the disclosure and the claims to ascertain the nature of the invention and methods of its performance, (*Noranda Mines Limited v. Minerals Separation North American Corporation* [[1950] S.C.R. 36]), being neither benevolent nor harsh, but rather seeking a construction which is reasonable and fair to both patentee and public. There is no occasion for being too astute or technical in the matter of objections to either title or specification for, as Duff C.J.C. said, giving the judgment of the Court in *Western Electric Company, Incorporated, and Northern Electric Company v. Baldwin International Radio of Canada* [[1934] S.C.R. 570], at p. 574, "where the language of the specification, upon a reasonable view of it, can be so read as to afford the inventor protection for that which he has actually in good faith invented, the court, as a rule, will endeavour to give effect to that construction". Sir George Jessel spoke to like effect at a much earlier date in *Hinks & Son v. Safety Lighting Company* [(1876), 4 Ch. D. 607]. He said the patent should be approached "with a judicial anxiety to support a really useful invention".

[82] In construing the claims of a patent, recourse to the disclosure portion of the specification is (1) permissible to assist in understanding the terms used in the claims, (2) unnecessary where the words are plain and unambiguous, and (3) improper to vary the scope or ambit of the claims: *Monsanto Canada Inc v Schmeiser*, 2002 FCA 309 at para 37, var'd on other points 2004 SCC 34.

[83] Terms used in the claims must be read in context, and it is therefore unsafe in many instances to conclude that a term is plain and unambiguous without a careful review of the specification: *Whirlpool* at para 52, quoting from W.L. Hayhurst, "The Art of Claiming and

Reading a Claim", in G.F. Henderson, ed, *Patent Law of Canada* (Toronto: Carswell, 1994) at 190.

(2) Person Skilled in the Art

[84] As discussed above, the person skilled in the art for the purposes of construing the claims is a developer of dermatological formulations and a dermatologist.

(3) Analysis

[85] As indicated above, Teva argues that the claims of the 565 Patent should not be understood to include any element of stability since the words of the claims do not refer to stability. Because the claims do not explicitly limit themselves to stable compositions, Teva argues that they could encompass compositions that are not stable.

[86] Teva asserts that Leo's own experts agreed that the stability of the patented composition is not the inventive concept. Teva refers to para 181 of Dr. Walters' Affidavit, which reads as follows:

> The Patent does not state that component C is a stabiliser. The Patent says that a non-aqueous ointment of a therapeutically active agent A and a therapeutically active agent B together with a solvent C is stable and efficacious. In the comparison formulation of Example 2 of the Patent, propylene glycol was used as a solvent (not a solvent C) and it was not stable. The 565 Patent has nothing to do with the discovery of stabilizing properties of certain solvents contrarily to what is alleged by Teva.
>
> [Emphasis added]

[87] Teva also refers to para 54 of Dr. Goldberg's Affidavit:

> Teva alleges that the solvent Compound C is a stabilizing agent or a stabilizer. I read the Patent many times and I did not see anywhere, nor did I understand, that component C "is what operates to stabilize a combination". The Patent simply states that it has been observed that in combination [with] compositions containing solvent C, the active components can co-exist without degradation despite their different pH/stability profiles. The tendencies of the active compounds to affect one another with regard to pH is minimised or eliminated.
>
> [Emphasis added]

[88] In my view, Teva misinterprets the statements of Dr. Walters and Dr. Goldberg. By their statements, these witnesses were not concluding that stability was not the inventive concept. Rather, they were stating that (i) the invention of the 565 Patent concerns the discovery that the combination of components A, B, and C is stable, and (ii) it is incorrect to conclude from this that component C operates as the stabilizer. In other words, the combination is stable but nothing is suggested as to the individual roles of each of the components in giving rise to that stability. This is an important nuance. It should also be noted that both Dr. Walters and Dr. Goldberg stated explicitly in their affidavits that stability is part of the inventive concept: see paras 41 and 120, respectively.

[89] Teva also notes that the wording of the claims is non-exhaustive (using the word "comprising" rather than the term "consisting of") meaning that other components could be added to the composition without falling outside the scope of the claims. Teva argues that there is nothing in the preamble to the claims ("[a] pharmaceutical non-aqueous ointment composition for dermal use") that suggests that they are limited to compositions that are useful in treating psoriasis. Teva further argues that claim 1 therefore encompasses compositions that include a

second solvent in addition to solvent component C. Such a second solvent could be propylene glycol.

[90] I also do not agree with this argument. Firstly, as Leo points out, this argument that the claims of the 565 Patent should be read to permit the inclusion of additional ingredients (which could render the composition non-functional and therefore invalid) was never raised in Teva's NOA. Leo does not bear the burden of establishing that such an allegation of invalidity, not raised in the NOA, is not justified.

[91] In addition, with regard to propylene glycol, reading the 565 Patent as a whole, the skilled person would note that a composition using propylene glycol as the solvent was not stable. Bearing in mind that the skilled person is trying to achieve success and not looking for difficulties or seeking failure, s/he would be inclined to avoid using a compound that had been shown not to work. The skilled person would likewise avoid using other compounds that were known to interfere with the purpose of the patented ointment (to treat psoriasis), even though the claims do not explicitly exclude such interfering compounds.

[92] Teva further argues that, if the claims of the 565 Patent are somehow limited to compositions that will work in the treatment of psoriasis, then they are invalid because they claim a result rather than a specific composition: *Sanofi-Aventis Canada Inc v Ratiopharm Inc*, 2010 FC 230 at paras 62-67. Once again, I do not agree with Teva. The compositions claimed in the 565 Patent are limited to a finite set of combinations of possible components A, B, and C and

they are defined so that a skilled person knows what those possible combinations are. This is not a case of the patentee attempting to claim anything that achieves the desired result.

[93] To conclude on the issue of claim construction, the claims should be construed as including stability as one of the characteristics of the claimed pharmaceutical compositions. There is no need to address any argument that the claims encompass formulations that are not stable since no such allegation was made in the NOA.

C. *Obviousness*

(1) Applicable Law

[94] The issue of obviousness begins with section 28.3 of the *Patent Act*:

Invention must not be obvious	*Objet non évident*
28.3 The subject-matter defined by a claim in an application for a patent in Canada must be subject-matter that would not have been obvious on the claim date to a person skilled in the art or science to which it pertains, having regard to	**28.3** L'objet que définit la revendication d'une demande de brevet ne doit pas, à la date de la revendication, être évident pour une personne versée dans l'art ou la science dont relève l'objet, eu égard à toute communication :
(*a*) information disclosed more than one year before the filing date by the applicant, or by a person who obtained knowledge, directly or indirectly, from the applicant in such a manner that the information became available to the public in Canada or elsewhere; and	*a*) qui a été faite, plus d'un an avant la date de dépôt de la demande, par le demandeur ou un tiers ayant obtenu de lui l'information à cet égard de façon directe ou autrement, de manière telle qu'elle est devenue accessible au public au Canada ou ailleurs;

(*b*) information disclosed before the claim date by a person not mentioned in paragraph (*a*) in such a manner that the information became available to the public in Canada or elsewhere.	*b*) qui a été faite par toute autre personne avant la date de la revendication de manière telle qu'elle est devenue accessible au public au Canada ou ailleurs.

[95] Pursuant to paragraph 28.3(b), a patent claim will be invalid if, based on information that was available to the public before the claim date (April 23, 1999, here), its subject-matter would have been obvious to a person skilled in the art or science to which it pertains (the skilled person).

[96] The threshold for inventiveness (non-obviousness) has long been understood to be low. As stated in *Beloit Canada Ltd v Valmet Oy* (1986), 8 CPR (3d) 289 at 294 (FCA) [*Beloit*]:

> The test for obviousness is not to ask what competent inventors did or would have done to solve the problem. Inventors are by definition inventive. The classical touchstone for obviousness is the technician skilled in the art but having no scintilla of inventiveness or imagination; a paragon of deduction and dexterity, wholly devoid of intuition; a triumph of the left hemisphere over the right. The question to be asked is whether this mythical creature (the man in the Clapham omnibus of patent law) would, in the light of the state of the art and of common general knowledge as at the claimed date of invention, have come directly and without difficulty to the solution taught by the patent. It is a very difficult test to satisfy.
>
> […]
>
> Every invention is obvious after it has been made, and to no one more so than an expert in the field. Where the expert has been hired for the purpose of testifying, his infallible hindsight is even more suspect. It is so easy, once the teaching of a patent is known, to say, "I could have done that"; before the assertion can be given any weight, one must have a satisfactory answer to the question, "Why didn't you?"

[97] Obviousness was discussed by the Supreme Court of Canada (SCC) in *Apotex Inc v Sanofi-Synthelabo Canada Inc*, 2008 SCC 61 [*Sanofi-Synthelabo*]. At para 67 of that decision, the SCC borrowed the following approach to assessing obviousness from *Pozzoli SPA v BDMO SA*, [2007] FSR 37 (p 872), [2007] EWCA Civ 588, at para. 23:

> (1) (a) Identify the notional "person skilled in the art";
>
> (b) Identify the relevant common general knowledge of that person;
>
> (2) Identify the inventive concept of the claim in question or if that cannot readily be done, construe it;
>
> (3) Identify what, if any, differences exist between the matter cited as forming part of the "state of the art" and the inventive concept of the claim or the claim as construed;
>
> (4) Viewed without any knowledge of the alleged invention as claimed, do those differences constitute steps which would have been obvious to the person skilled in the art or do they require any degree of invention?

[98] The SCC then noted that the fourth step in this approach may give rise to the issue of whether the invention was "obvious to try". The Court indicated that the "obvious to try" test might be appropriate in areas of endeavour where advances are often won by experimentation, where there may be numerous interrelated variables with which to experiment. The parties do not dispute that the "obvious to try" test is appropriate in the present case.

[99] At para 69 of its decision, the SCC provided the following non-exhaustive list of factors applicable in assessing obviousness to try:

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

> 2. What is the extent, nature and amount of effort required to achieve the invention? Are routine trials carried out or is the experimentation prolonged and arduous, such that the trials would not be considered routine?
>
> 3. Is there a motive provided in the prior art to find the solution the patent addresses?

[100] The SCC also noted that, though obviousness is largely concerned with how a skilled worker would have acted in the light of the prior art, there is no reason to exclude evidence of the history of the invention in question, particularly where the knowledge of those involved in finding the invention is no lower than what would be expected of the skilled person.

[101] The first of the listed factors applicable to the "obvious to try" test (whether it is more or less self-evident that what is being tried ought to work) has sometimes been translated as "whether it was self-evident or plain that there was a fair expectation of success": *Eli Lilly Canada Inc v Mylan Pharmaceuticals ULC*, 2015 FC 178 at para 150 [*Eli Lilly*]; *AstraZeneca* at para 41; *Pfizer Canada Inc v Ratiopharm Inc*, 2010 FC 612 at para 171.

(2) Person Skilled in the Art

[102] The first of the steps set out in *Sanofi-Synthelabo* for assessing obviousness is to identify the notional person skilled in the art. It is generally understood that this person is sufficiently skilled to understand the nature and description of the invention, and reasonably diligent in keeping up with advances in the field, but unimaginative. I will repeat here a portion of the extract from *Beloit* reproduced above as it relates to the skilled person:

> The classical touchstone for obviousness is the technician skilled in the art but having no scintilla of inventiveness or imagination; a

> paragon of deduction and dexterity, wholly devoid of intuition; a triumph of the left hemisphere over the right.

[103] In general, the qualities and capabilities of the person skilled in the art for the purposes of assessing obviousness are the same as those for the purpose of construing the patent: D.H. MacOdrum, *Fox on the Canadian Law of Patents*, 5th ed (Toronto: Carswell, 2013) at 4:13(b) (MacOdrum), quoting *Ratiopharm Inc v Pfizer Limited*, 2009 FC 711 at para 30.

[104] Accordingly, and as indicated above, the person skilled in the art from whose point of view the patent should be read and understood is a developer of dermatological formulations and a dermatologist.

[105] Leo asserts that the person skilled in the art also does not take risks. However, it has not been able to produce any authority in support of this assertion. While I accept that the skilled person has some conservative qualities, I am unaware of any authority indicating that risk aversion is one of them. I do not accept that the skilled person avoids risk.

[106] I note that two of Leo's experts were under the impression in their affidavits that the skilled person does not like to take risks: Dr. Goldberg at para 171, Dr. Walters at para 33. While this impression was erroneous, I find that it did not impair the relevance of their opinions. I have not relied on aspects of their opinions that depend on the idea that the skilled person is not a risk-taker.

(3) Common General Knowledge

[107] Common general knowledge means knowledge that is generally known by persons skilled in the relevant art at the relevant time: *Sanofi-Synthelabo* at para 37. However, not all information available to the skilled person is necessarily common general knowledge. As stated in *Eli Lilly and Company v Apotex Inc*, 2009 FC 991, at para. 97, quoting from *General Tire & Rubber Co v Firestone Tyre & Rubber Co Ltd*, [1972] RPC 457 at pp 482-483, itself quoting from *British Acoustic Films* (53 RPC 221 at 250):

> A piece of particular knowledge as disclosed in a scientific paper does not become common general knowledge merely because it is widely read, and still less because it is widely circulated. Such a piece of knowledge only becomes general knowledge when it is generally known and accepted without question by the bulk of those who are engaged in the particular art; in other words, when it becomes part of their common stock of knowledge relating to the art.

[108] As discussed above in the Agreed Facts section of this decision, the parties agree on several elements of common general knowledge before the claim date:

a. vitamin D and vitamin D analogues, specifically calcipotriol, were a known treatment for psoriasis;
b. corticosteroids were a known treatment for psoriasis;
c. treatment of psoriasis by sequential application of both calcipotriol and a corticosteroid was known to provide better results than either compound alone, and was commonly prescribed;

d. calcipotriol cannot be combined with a corticosteroid without regard to their pH incompatibility: calcipotriol requires a pH above 8 for maximum stability, whereas corticosteroids require pH values in the 4-6 range for maximum stability.

[109] In addition, the parties do not dispute that all of the vitamin D analogues and corticosteroids identified and claimed in the 565 Patent were known for treatment of psoriasis.

[110] Since psoriasis causes dry lesions, a dry composition (an oil-based composition such as an ointment) was generally preferred to treat it. Petrolatum was the most common base for ointments.

[111] Both calcipotriol and betamethasone dipropionate were sold individually as ointments.

[112] This issue of pH relates to water and aqueous environments. In the absence of water, pH incompatibility problems do not arise.

(4) State of the Art

[113] In addition to the common general knowledge of which the skilled person would have been aware, section 28.3 of the *Patent Act* provides that it is also relevant to consider "information disclosed before the claim date […] in such a manner that the information became available to the public". Jurisprudence indicates that prior art relevant for the purpose of assessing obviousness is that which would have been revealed in a diligent search by a skilled person: *Eurocopter v Bell Helicopter Textron Canada Ltée*, 2012 FC 113 at para 80; *Pfizer* at

para 108; *Illinois Tool Works Inc v Cobra Fixations*, 2002 FCT 829 at para 100, var'd on costs 2003 FCA 358.

[114] Doubt has been expressed as to whether it is correct to limit the scope of relevant prior art to the results of a diligent search since the wording of section 28.3 is not so limited: MacOdrum at 4:11(i); R.H. Barrigar, *Canadian Patent Law Annotated*, 2d ed (Aurora: Canada Law Book, 1994) at PA-341. However, this point was rejected in *Novartis Pharmaceuticals Canada Inc v Teva Canada Limited*, 2015 FC 770 at para 53. Moreover, the Federal Court of Appeal recently declined an opportunity to revisit the question: *E Mishan & Sons, Inc v Supertek Canada Inc*, 2015 FCA 163 at para 21.

[115] Teva relies heavily on an argument that a skilled person would have been aware, or become aware, of POP-15, and specifically certain prior art using POP-15 that I will call Turi, after the principal author and inventor of the paper and patent identified below. Teva argues not only that Turi would have been found in a diligent search by a skilled person, but also that Turi was part of the common general knowledge. Turi comprises:

1. a paper entitled "Effects of Polyoxypropylene 15 Stearyl Ether and Propylene Glycol on Percutaneous Penetration Rate of Diflorasone Diacetate", published in the Journal of Pharmaceutical Sciences, vol. 68, no. 3, March 1979; and
2. US Patent No. 4,083,974, issued April 11, 1978.

[116] The Turi paper used an animal model (which, by the claim date of the 565 Patent, was no longer accepted as reliable) to investigate the effects of different amounts of POP-15 or

propylene glycol on the skin penetration rate of diflorasone diacetate, which is one of the corticosteroids contemplated in the 565 Patent. The Turi patent claims compositions developed during the same research, noting their non-irritating and lubricating properties, as well as surprising anti-bacterial and anti-fungal properties.

[117] Teva notes that POP-15 was used in a number of pharmaceutical products on the market prior to the claim date, including Florone, Maxiflor and Psorcon E. These three products appear to be related and appear to have anti-inflammatory properties by virtue of diflorasone diacetate dissolved in propylene glycol. Teva also notes that Leo itself indicated to the Food and Drug Administration in the US that POP-15 was contained in 41 cosmetic products in 1998.

[118] In my view, Turi would not have been part of the common general knowledge of the skilled person. It was not generally known to the skilled person treating psoriasis, and POP-15 was not listed in the usual sources of information as a solvent or as a treatment for psoriasis.

[119] However, Turi was clearly available to the public and there were a number of ways by which a skilled person could have found Turi in a diligent search. For example, a search of PubMed (a database of medical publications) conducted during the cross-examination of Dr. Walters using the keywords “corticosteroid”, “solvent” and “topical” found the Turi paper among 186 hits. Given the generality of these keywords, it appears that a diligent search by a skilled person might indeed have found reference to Turi. On the other hand, there is nothing in the record to indicate that Turi would have been found by any other specific combination of general search terms that a skilled person might have used in attempting to solve the problem of

pH incompatibility when combining calcipotriol and a corticosteroid. I note that Teva's own expert Dr. Cooper suggested initially that the skilled person would have searched for "articles relating to formulations containing calcipotriol (also known as calcipotriene) and betamethasone dipropionate, as well as information about the stability of the two active ingredients." It appears unlikely that Turi would have been found using these search criteria. In any case, and as explained below, it is not necessary that I decide whether Turi would have been found in a diligent search. I have proceeded on the assumption that Turi would have been available to the skilled person.

[120] Leo notes that Turi concerned a product for cosmetic use, not for psoriasis. Leo also notes that Turi dates from the late 1970s, many years prior to the development of the patented product, and does not address the combining of different active ingredients, or issues of stability. Leo argues that any search that found Turi would also have found many other prior art references and that, even if Turi would have been found in a diligent search, the skilled person would not have been led by that prior art to the invention of the 565 Patent. These issues are considered below in assessing whether the claimed invention would have been obvious to try.

[121] Teva argues that the simultaneous (not merely sequential) topical application of calcipotriol and a corticosteroid in the treatment of psoriasis was also part of the common general knowledge at the claim date. Leo disputes this. In my view, the evidence favours Leo on this point. Dr. Krueger stated that he has been prescribing simultaneous application of calcipotriol and a corticosteroid since 1995 and continues to do so. He also testified that he gave

numerous talks and presentations about this treatment regimen before the claim date. However, he did not indicate that any other dermatologists had adopted this method of treatment.

[122] Dr. Feldman stated that, before the claim date, he and other dermatologists were prescribing a once-a-day simultaneous application of calcipotriol and corticosteroid. However, the only publications cited by Dr. Feldman on the subject emphasized the difficulties of combining calcipotriol and corticosteroids. For example, the first paragraph of a paper by Patel ("Compatibility of calcipotriene with other medications", J Amer. Acad. of Dermatology, June 1998 at 1010), immediately after acknowledging that patients occasionally combine calcipotriol and other treatments on the skin, refers to cases in which "pharmacists or patients combine these in a single container without regard for the compatibility of the agents." [Emphasis added.]

[123] For Leo, both Dr. Contard and Dr. Shear indicated that, prior to the claim date, they had never heard of any patient being instructed to apply calcipotriol and a corticosteroid simultaneously to treat psoriasis.

[124] Though there were clearly understood advantages of a psoriasis treatment regimen that combined calcipotriol and a corticosteroid, it does not appear that the simultaneous use of these two drugs was common among dermatologists.

(5) Inventive Concept

[125] Further to my discussion above in the Claim Construction section, I find that the inventive concept of the 565 Patent is the development of a pharmaceutical composition for

dermal use (in the form of a non-aqueous ointment) comprising three components (A, B, and C) that is stable enough to be practical as a pharmaceutical composition. Stability is clearly the main object discussed in the 565 Patent, and it would be unreasonable, in my view, to reach a conclusion concerning the inventive concept without having regard to the disclosure and its consistent concern with stability.

[126] Both parties acknowledge that it was not clear, either at the time that the application for the 565 Patent was filed or later, how or why the composition of components described and claimed therein works. None of the expert witnesses was able to offer a reasonable hypothesis as to why the compound described in Example 1 in the 565 Patent was stable, while a similar ointment using propylene glycol as a solvent in place of POP-15, and also containing lanolin as an emulsifier, was not stable.

(6) Differences between Prior Art and the Inventive Concept

[127] The difference between the inventive concept and the state of the art prior to the claim date is quite simple: it is the leap from (i) a composition of two active pharmaceutical compounds (A and B) which, due to pH incompatibility of the compounds, begin degrading upon combining and cannot therefore be a practical pharmaceutical product, to (ii) a composition including those same two compounds, and with the addition of a solvent C, which remains stable enough to be practical as a pharmaceutical product.

[128] There are no other advances on the state of the art described in the 565 Patent.

(7) Obvious to Try Analysis

[129] As stated above, the following non-exhaustive factors should be considered in assessing whether an invention was obvious to try:

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

[130] These factors are more conveniently discussed in reverse order.

(a) *Motive to Find the Solution*

[131] With regard to motivation, it is clear that, at the claim date, there was a desire for a composition that would combine two well-known topical psoriasis treatments (a vitamin D analogue and a corticosteroid) to simplify treatment and be stable enough to be practical.

[132] Of course, this motivation cuts both ways as regards obviousness. On the one hand, the skilled person was motivated to devote substantial resources to finding a solution to the instability problem. Arguably, this might have made it easier for an unimaginative person to have made the invention. On the other hand, the failure of skilled persons, given such motivation, and

over a substantial period of time, to have found the solution could suggest inventiveness: *AstraZeneca Canada Inc v Ranbaxy Pharmaceuticals Canada Inc*, 2013 FC 232 at para 82.

[133] Leo makes an argument based on the classic question quoted above from *Beloit* at 294:

> It is so easy, once the teaching of a patent is known, to say, "I could have done that"; before the assertion can be given any weight, one must have a satisfactory answer to the question, "*Why didn't you*?"
>
> [Emphasis added]

[134] Leo argues that there had been a clear motivation to combine calcipotriol and a corticosteroid in a stable formulation since at least 1994. If the invention were obvious, Leo argues, someone would have found the solution earlier.

[135] Teva notes that Leo had a patent on calcipotriol which did not expire in Canada and the US until around 2009. Teva argues that, because of this patent, a pharmaceutical company other than Leo would have been dissuaded, before the claim date (April 1999), from conducting research on a combined formulation including calcipotriol. Even if its research were successful, it would not be able to exploit the combined formulation without permission from Leo. Dr. Cooper testified that "pharmaceutical companies do not develop formulations containing a patented active ingredient until close to the time the compound patent expires." In my view, this is a good answer to the question of why Teva or another pharmaceutical company did not make the invention before Leo did.

[136] Leo disputes the theory that a pharmaceutical company would not conduct research on a compound that was under patent. In support of this argument, Leo refers (with considerable vigour) to Teva's own Canadian patent application (no. 2,670,425) which, much like the 565 Patent at issue here, discussed compositions combining vitamin D analogues, including calcipotriol, and corticosteroids. Leo argues that it is "surprising" that Teva would argue that a pharmaceutical company would not do research on a compound that is covered by a patent when that is precisely what Teva itself did on the very compound that is in issue here.

[137] Unfortunately for Leo, there is a significant flaw in its argument on this point. Teva's patent application was filed in August 2007 on the basis of a priority application that was filed in August 2006. At that time, Leo's patent on calcipotriol was set to expire soon. In light of that and in view of Dr. Cooper's statement that pharmaceutical companies' reticence to conduct research on a patented compound would end "close to the time the compound patent expires", I see no reason to conclude that Teva's research discussed in its patent application negates in any way the argument that pharmaceutical companies other than Leo had a disincentive to develop a formulation combining calcipotriol and a corticosteroid.

[138] Teva also argues that Leo itself was likewise disinclined to develop any formulation combining calcipotriol and a corticosteroid, which could explain why it did not make the invention earlier. Teva argues that Leo saw itself as "*the* company that provided patients with a psoriasis product that had similar efficacy to corticosteroids, without the side effects", [redacted]

[redacted]

[139] [redacted] I do not draw the inference that Teva urges from Dr. Hansen's cross-examination. In my view, the Business Assessment document in question does not suggest that Leo was disinclined to develop a combined formulation of calcipotriol and a corticosteroid. It would have been apparent to Leo that success on such a project would likely increase its market share considerably.

[140] In summary, there was motivation in the prior art to find a way to combine calcipotriol and a corticosteroid in the same formulation. Leo had reason to act on this motivation. Because of Leo's patent, other companies were dissuaded from acting on this motivation. However, that dissuasion does not indicate obviousness.

(b) *Extent, Nature and Amount of Effort Required*

[141] The second of the factors to be considered in assessing whether an invention was obvious to try is the extent, nature and amount of effort required to achieve the invention. There are two

points worthy of note in relation to this factor. Firstly, the experimentation to be carried out to confirm whether a particular combination of compounds is stable in the current context is quite straightforward and routine. Essentially, one need only create the necessary testing conditions and then wait. The second point is that, if we accept a scenario in which the skilled person conducting a diligent search would find the Turi prior art, we must also accept that the skilled person would also find many hundreds (possibly, thousands) of other prior art references, all pointing to different possible solutions.

[142] Even if stability testing is relatively simple, the extent of effort required to achieve the invention will be very high unless the number of combinations can be reduced. Accordingly, the main challenge in conceiving the invention would be in narrowing the scope of possible compositions for testing to a practical number.

(c) *More or Less Self-Evident that What is Being Tried Ought to Work*

[143] Teva's argument on this point is that, having found the Turi prior art, the skilled person would have been led to the claimed combination and would have concluded that it was more or less self-evident that this combination ought to work. In other words, it was plain that there was a fair expectation of success.

[144] Teva points out that Turi discloses an ointment comprising a corticosteroid (diflorasone diacetate) with POP-15. Teva also notes that both calcipotriol and betamethasone dipropionate were sold individually as ointments.

[145] Teva argues that it would be obvious for a skilled person, faced with a problem of pH incompatibility of two compounds to be combined in a single formulation, to use a non-aqueous base, so that pH is not an issue. Leo acknowledges that using a non-aqueous base would indeed reduce the amount of water, and hence the extent of the problem of pH compatibility, but Leo asserts that small amounts of water exist in the ingredients of the composition such that the problem could not be eliminated entirely. This may be true, but there is no evidence as to whether the amount of water that might remain with a non-aqueous base comprising a vitamin D analogue and a corticosteroid would be sufficient to affect the stability of either. Without more, I am not prepared to accept that Leo's argument in this respect "holds water".

[146] However, Teva's argument concerning the obviousness of using a non-aqueous base to resolve the pH incompatibility problem is not enough to establish that the invention of the 565 Patent was obvious. To establish obviousness, it would be necessary to show that this was all that was needed to achieve a stable composition when combining calcipotriol with a corticosteroid, *e.g.* a simple combination of calcipotriol and a corticosteroid (and without POP-15) in a non-aqueous base would be stable. The evidence does not support this. The unsuccessful example described in the 565 Patent, in which calcipotriol and betamethasone dipropionate were combined in a non-aqueous ointment using propylene glycol as the solvent and lanolin as an emulsifier suggests otherwise. As indicated above, it was not clear why that composition was unstable, while the composition using POP-15 was stable.

[147] Teva responds to this point by noting that, as of the claim date, it was not publicly known that the composition with propylene glycol as the solvent would not work, and therefore there

was no reason for the skilled person not to have a fair expectation of success even with a composition including propylene glycol.

[148] For its part, Leo replies that propylene glycol was a common solvent in pharmaceuticals, whereas POP-15 was not part of the common general knowledge of the skilled person. Moreover, propylene glycol has a lower acid and water content than POP-15. Therefore, the skilled person would have tried propylene glycol (as acknowledged by Dr. Cooper during his cross-examination), and would have done so before trying POP-15. The unsuccessful result of that attempt, together with the commonly-known information about propylene glycol's more promising acid and water content properties, would have removed any fair expectation of success that the skilled person might otherwise have had in trying POP-15. I agree with Leo's position.

[149] Leo argues that much of the prior art taught away from combining a vitamin D analogue and a corticosteroid in the same composition. In my view, this mischaracterizes the prior art. It is true that there were clear indications of challenges to be overcome in combining these drugs. However, nothing in the prior art would have led the skilled person to believe that a combined composition including POP-15 would not resolve the stability problem. Nothing urged the skilled person away from investigating this solution. In this sense, the prior art did not teach away from the solution taught in the 565 Patent.

[150] As indicated earlier, for the purposes of this analysis, I assume without deciding that a diligent search by a skilled person would have revealed the Turi prior art. Even if the skilled person had been aware of Turi, it is my view that s/he would not have been led to the solution

taught in the 565 Patent. There would have been many other prior art references to consider; so many in fact that it would seem impractical to expect the skilled person to have tested them all. Accordingly, for the skilled person to have focused on Turi over other possibilities there would have to have been something promising in it. I do not see such promise. The value of POP-15 would not have been apparent until after the invention had been found.

[151] Moreover, even if the skilled person had been led to combine a vitamin D analogue, a corticosteroid and POP-15, it would have been without a fair expectation of success. Nothing in Turi suggested any solution to the problem of pH incompatibility between vitamin D analogues and corticosteroids, or between any other compounds. Moreover, nothing in Turi was concerned with the stability of any formulation. A skilled person faced with the problem discussed in the 565 Patent would not have been led to focus on Turi for the solution.

(d) *Actual Course of Conduct in Making the Invention*

[152] This fourth factor is mentioned in para 70 of the SCC's decision in *Sanofi-Synthelabo*. Teva notes that Leo tested a composition including POP-15 because it had already worked with it. Teva argues that there was therefore nothing unusual or surprising in considering POP-15. Teva notes that POP-15 would have been attractive as a candidate for testing since it was already used in a marketed product and therefore was presumably safe and not irritating. Teva also notes that Leo found success quickly and easily in developing a stable composition comprising calcipotriol and a corticosteroid.

[153] However, the fact that Leo had POP-15 and decided to use it in its testing does not change my view that the skilled person would not have had much expectation of success in doing so. Dr. Hansen's testimony confirmed this. Though nothing suggested that POP-15 was not worth investigating, nothing suggested that it was the solution. Moreover, the fact that the solution to a problem was found quickly by luck does not negate inventiveness.

(8) Conclusion on Obviousness

[154] For the foregoing reasons, and principally because the patented combination was not obvious to try in light of the many other possible combinations that might also be tried, I conclude that the claims in issue of the 565 Patent are not obvious.

[155] I have not found it necessary to address the parties' arguments on the secondary consideration of commercial success.

D. *Lack of Utility*

(1) Applicable Law

[156] Pursuant to section 2 (Definitions) of the *Patent Act*, an invention must be useful. Accordingly, all valid patents must limit the scope of their claims to embodiments that have utility.

[157] The Federal Court of Appeal provided a useful discussion of the requirements of utility in *Apotex Inc v Pfizer Canada Inc*, 2014 FCA 250 at para 64:

> The courts, however, have long held that the minimum requirements for utility under the *Act* are fairly forgiving. First, the inventor need not expressly set out the utility of the invention in the patent. It is merely required that, where the inventor is called upon to prove the utility of the invention, utility can be shown to be demonstrated or soundly predicted as of the patent's filing date. Second, the threshold that must be proven to establish utility is generally quite low, described as being no more than a "scintilla of utility".
>
> [References omitted.]

[158] Therefore, as of the filing date of the 565 Patent (January 27, 2000), the utility of the claims thereof must have been either demonstrated or soundly predicted.

[159] As stated by the SCC in *Apotex Inc v Wellcome Foundation Ltd*, 2002 SCC 77 at para 70, the doctrine of sound prediction has three components:

1. there must be a factual basis for the prediction;
2. the inventor must have at the date of the patent application an articulable and "sound" line of reasoning from which the desired result can be inferred from the factual basis; and
3. there must be proper disclosure.

[160] To be sound, a prediction does not need to amount to certainty, as it does not exclude the risk that some compounds within the area claimed may, at some later time, prove to be devoid of utility: *Merck & Co Inc v Apotex Inc*, 2010 FC 1265 at para 484 [*Merck*].

[161] Teva argues that the focus of the second component of the test for the doctrine of sound prediction is the inventors, not the skilled person. As support for this argument, Teva cites the following passage from *Sanofi-Aventis Canada v Apotex Inc*, 2009 FC 676 at para 151, which is

reproduced almost verbatim in *Merck* at para 498 and in *Teva Canada Limited v Novartis AG*, 2013 FC 141 at para 271:

> The inventors must be able to show that, at the relevant time, they were in possession of a factual basis upon which they could articulate the desired result. It is important to note that the perspective being examined at this stage is a subjective one. In assessing sound prediction, we are not confined to examining the invention through the eyes of a person skilled in the art. Rather, the knowledge, activities and endeavours of the inventors themselves must be considered.

[162] Though this passage indicates that the point of view of the inventors must be considered, I do not understand it to exclude the perspective of the skilled person. In fact, it suggests that the skilled person's perspective is relevant when it states that "we are not confined to examining the invention through the eyes of a person skilled in the art." [Emphasis added.] Moreover, the Federal Court of Appeal makes clear that the perspective of the skilled person is relevant in *Apotex Inc v Allergan Inc*, 2015 FCA 137 at para 9:

> As this Court observed in *Eurocopter v. Bell Helicopter Textron Canada Ltée*, 2013 FCA 219, 449 N.R. 111, at paragraphs 152 and 153, the factual basis, line of reasoning and level of disclosure required by the doctrine of sound prediction are to be assessed as a function of both the knowledge that the skilled person would have to base that prediction on and what the skilled person would understand as a logical line of reasoning leading to the utility of the invention.

[163] Since a sound line of reasoning is directed to a skilled person, those elements of the doctrine of sound prediction that would be self-evident to that person in view of the common general knowledge need not be explicitly disclosed in the specification: *Bell Helicopter Textron Canada Limitée v Eurocopter*, 2013 FCA 219 at para 154.

[164] The utility of a patent is not necessarily coterminous with its inventive concept: *AstraZeneca Canada Inc v Apotex Inc*, 2015 FCA 158 at para 11.

(2) Analysis

[165] Teva notes that only one successful formulation of the patented composition is described in the 565 Patent. It comprises calcipotriol as component A, betamethasone dipropionate as component B, and POP-15 as solvent component C. The evidence indicates that Leo also tested formulations containing isopropyl myristate as solvent component C and clobetasol as component B. For all of the other formulations that fall within the scope of the claims in issue of the 565 Patent, Leo cannot rely on demonstrated utility of the invention. The parties appear to agree that Leo must therefore show that the utility of all such other formulations could be soundly predicted as of January 27, 2000.

[166] Teva's arguments on the absence of sound prediction are predicated on the utility of the 565 Patent being a combined formulation of a vitamin D analogue and a corticosteroid that is stable and effective. But as seen above, Teva also argues that the inventive concept of the 565 Patent does not concern the stability of the composition. Mindful of this tension between utility and the inventive concept as regards stability, Teva hastens to add that a patent's utility need not be coterminous with its inventive concept. Be that as it may, there is no dispute that the utility of the invention concerns the stability and efficacy of the claimed composition.

[167] Teva argues on two distinct grounds that the claims in dispute of the 565 Patent fail to satisfy the doctrine of sound prediction:

1. In the absence of limitations in the claims concerning the amount of solvent component C to be included in the claimed formulations, and without information concerning drug-release rates from such formulations and penetration of the skin when they are applied, the skilled person could not soundly predict that all such formulations would be effective; and
2. The claims of the 565 Patent contemplate so many variations of each of components A, B, and C that the claims encompass millions of formulations, not all of which could be soundly predicted to be stable and effective.

[168] In response to these arguments, Leo argues first that they should not even be considered because they were not raised in the NOA. I agree with Leo as regards Teva's first argument above, that no sound prediction of utility could be made without data on release of drugs for different amounts of solvent component C. Nothing in the NOA hints at this argument. Though a portion of the NOA (at pages 20 and 21) is devoted to concerns about the absence of dosing information in the 565 Patent, these concerns are specific to components A and B. The NOA makes no such allegations concerning solvent component C. Moreover, I am not satisfied that this argument by Teva is in response to anything that Leo has raised.

[169] However, even when I consider this first of Teva's arguments on the absence of sound prediction, I am nevertheless led to the conclusion that it lacks merit.

(a) *Absence of Information Concerning Drug Release and Skin Penetration*

[170] Teva points to the Turi paper which indicates that varying amounts of solvent can have an important effect on drug release and skin penetration. Without adequate drug release and skin penetration, the efficacy of a formulation could be negatively affected.

[171] In my view, Teva's concerns about drug release and skin penetration are overblown. Certainly, it is important to ensure that these properties are consistent and stable when a pharmaceutical product is to be administered to patients. The regulatory standard is high, but the standard of utility in patent law is much lower (a mere "scintilla of utility"). This point is addressed in *AstraZeneca Canada Inc v Mylan Pharmaceuticals ULC*, 2011 FC 1023 at para 163. In addition, since the patent need only offer a sound prediction of utility, even this lower standard need not be met with certainty. I am satisfied that the evidence on the record is adequate as regards drug release and skin penetration. The absence of hard data does not lead me to conclude that the 565 Patent lacks a sound prediction of utility. The skilled person would have expected that, using the common general knowledge, limited experimentation would be sufficient to achieve adequate drug release and skin penetration.

[172] Teva refers to a passage during the cross-examination of Dr. Walters in which when asked whether a formulation containing 1% POP-15 would be effective, he stated: "I cannot tell that from the information here, but I should imagine that 1% would be –would give a therapeutic response."

[173] Teva argues that Dr. Walters' response (acknowledging "I cannot tell" but "I should imagine") can hardly be said to be a sound prediction. I disagree. In my view, Dr. Walters' response acknowledges precisely the type of uncertainty that is permitted, even expected, when making a sound prediction.

(b) *Not All Claimed Combinations of Components A, B, and C could be Soundly Predicted to be Stable and Effective*

[174] The second of Teva's two arguments that the 565 Patent lacks a sound prediction of utility is essentially that the number of possible combinations of components A, B, and C is so great (Teva argues it is in the millions) that no sound prediction could be made that they would all be useful, *i.e.* that they would all be stable and effective.

[175] As a preliminary comment, there appears to be support for this argument in the NOA on page 18 under the heading "Untested Components A, B and C Not Demonstrated or Soundly Predicted". Therefore, I conclude that this argument is entitled to consideration.

[176] As a next comment, I note that the analysis of this argument can be considerably simplified by focusing on claim 17. Essentially, claim 17 defines the solvent component C as POP-15, thus excluding all other possibilities for solvent component C, and hence significantly reducing the number of possible combinations claimed in the 565 Patent. Claim 17 encompasses only the combinations of components A (vitamin D analogues) and B (corticosteroids) that are contemplated in claim 1. By Teva's math, that brings the number of possible combinations down from millions to thousands.

[177] Teva points out that Leo has acknowledged that it has never understood why the patented combination of calcipotriol, betamethasone dipropionate and POP-15 is stable. Therefore, Teva argues, Leo was hardly in a position to soundly predict that combinations of other related compounds would be stable.

[178] Here, it is important to bear in mind that Leo's prediction of utility is based on various vitamin D analogues and corticosteroids that were already known for use in treating psoriasis. All of the alternatives for components A and B in claim 1 of the 565 Patent are based on known treatments. Also, in commenting on the soundness of the prediction of utility in the 565 Patent, Dr. Walters relied on the fact that all of the claimed alternatives are based on the same chemical scaffold. For him, this was a sound basis for a prediction that untested compounds would have utility. I agree. Moreover, components A and B are defined in claim 1 as pharmacologically active. It is also important to repeat that Leo need not establish anything close to certainty that all combinations would be useful.

[179] The fact that Leo could not explain why the claimed composition is stable while at least one other similar composition is not stable does not alter the fact that Leo's predictions of utility, as least as regards claim 17, are based on known psoriasis treatment options involving vitamin D analogues and corticosteroids. With the information about the successful Example 1 in the 565 Patent, the skilled person would have understood the factual basis for the utility prediction and the line of reasoning even without discussion thereof in the patent specification.

[180] Further, Leo argues that its choice to test calcipotriol as the component A in Example 1 in the 565 Patent permitted a sound prediction of utility for other vitamin D analogues because calcipotriol is among the most unstable of all vitamin D analogues. Leo's reasoning is that, if calcipotriol could be stable in the patented combination, it was reasonable to expect that other vitamin D analogues would also be stable. [redacted] However, Leo's reasoning is nevertheless sound.

[181] Teva suggests that it is not the solvent POP-15 that is responsible for the stability of the combination of a vitamin D analogue and a corticosteroid in Example 1 described in the 565 Patent. Teva suggests rather that it is the α-Tocopherol that stabilizes the combination. Teva also notes that none of the claims in issue includes α-Tocopherol.

[182] In response, Leo notes that this is a completely new argument that was raised for the first time by Teva during its oral representations, and is not mentioned either in its memorandum of fact and law or in its NOA. Leo argues that Teva's submission on this point should therefore not be considered.

[183] I need not decide the question of whether the NOA supports Teva's submission because, even if I consider it, I do not agree with it. As acknowledged by Teva, α-Tocopherol is an antioxidant. It is not necessary to have expert evidence on the subject to know that an antioxidant can act as a stabilizer against oxidation. However, that quality appears to be entirely unrelated to

stabilization against the pH incompatibility which is at issue in the present matter. I can take judicial notice of the fact that oxidation concerns oxygen, whereas pH concerns hydrogen.

(3) Conclusion on Lack of Utility

[184] For the foregoing reasons, I conclude that at least claim 17 of the 565 Patent does not lack utility.

E. *Insufficiency*

(1) Applicable Law

[185] Subsection 27(3) of the *Patent Act* provides for the obligation to adequately describe the invention in the patent specification:

Specification	*Mémoire descriptif*
(3) The specification of an invention must	(3) Le mémoire descriptif doit :
(*a*) correctly and fully describe the invention and its operation or use as contemplated by the inventor;	*a*) décrire d'une façon exacte et complète l'invention et son application ou exploitation, telles que les a conçues son inventeur;
(*b*) set out clearly the various steps in a process, or the method of constructing, making, compounding or using a machine, manufacture or composition of matter, in such full, clear, concise and exact terms as to enable any person skilled in the art or science to which it pertains, or with which it is most closely connected, to make, construct,	*b*) exposer clairement les diverses phases d'un procédé, ou le mode de construction, de confection, de composition ou d'utilisation d'une machine, d'un objet manufacturé ou d'un composé de matières, dans des termes complets, clairs, concis et exacts qui permettent à toute personne versée dans l'art ou la science dont relève l'invention, ou

compound or use it;	dans l'art ou la science qui s'en rapproche le plus, de confectionner, construire, composer ou utiliser l'invention;
(*c*) in the case of a machine, explain the principle of the machine and the best mode in which the inventor has contemplated the application of that principle; and	*c*) s'il s'agit d'une machine, en expliquer clairement le principe et la meilleure manière dont son inventeur en a conçu l'application;
(*d*) in the case of a process, explain the necessary sequence, if any, of the various steps, so as to distinguish the invention from other inventions.	*d*) s'il s'agit d'un procédé, expliquer la suite nécessaire, le cas échéant, des diverses phases du procédé, de façon à distinguer l'invention en cause d'autres inventions.

[186] The description of the invention in a patent must be such as to enable a person skilled in the art or the field of the invention to produce it using only the instructions contained in the disclosure: *Pfizer Canada Inc v Canada (Health)*, 2008 FCA 108 at para 35, quoting *Pioneer Hi Bred Ltd v Canada (Commissioner of Patents)*, [1989] 1 SCR 1623 at 1638. A patent that lacks a description that satisfies the foregoing test is invalid for insufficiency.

(2) Analysis

[187] Teva makes only one argument concerning the insufficiency of the 565 Patent. This argument arises from a portion of the cross-examination of Dr. Hansen in which he states that

[redacted]

[188] Teva notes that the 565 Patent is silent as to which, if either, of the components A and B described and claimed in the 565 Patent has to be dissolved in the solvent component. Teva argues that the fact that the 565 Patent does not mention that the calcipotriol (component A) must be dissolved leaves the skilled person with insufficient information to put the invention into practice using only the patent description and the knowledge of the skilled person.

[189] Leo argues that this is an entirely new argument that was not raised in Teva's NOA, which therefore should not be considered. Teva responds that this argument is an implicit part of its general insufficiency allegation which is included in the NOA. It also argues that this argument arose from the evidence put forward by Leo to which it is entitled to respond.

[190] I accept that Teva is entitled to respond to evidence adduced by Leo's witnesses. However, that right of response does not extend to introducing entirely new allegations of invalidity that were not contemplated in the NOA: *Alcon* at paras 90-96. Nothing in the NOA could be understood as raising the issue of insufficiency for failure to disclose the order in which the claimed components have to be put together. Teva's allegations of insufficiency are much more general than that. It would be unfair to put the onus on Leo to address an allegation of insufficiency that is as specific as Teva now asserts based on the general allegations made in the NOA.

[191] Moreover, I find no merit in Teva's insufficiency allegation in any case. As Teva itself states in its memorandum of fact and law, processes for making ointments were well-known at the relevant time. Teva relies on the testimony of Dr. Cooper to assert that a skilled person could

have made a number of ointments containing the relevant ingredients in a couple of days and could have tested their stability using standard well-known techniques. In particular, 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. I conclude from these passages 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.

(3) Conclusion on Insufficiency

[192] For the foregoing reasons, I conclude that the specification of the 565 Patent does not lack sufficiency.

VII. Conclusion

[193] Based on the analysis above of the issues in dispute, I conclude that Teva's allegations of obviousness and insufficiency concerning the 565 Patent are not justified. Moreover, Teva's allegations of lack of utility of at least claim 17 are not justified.

[194] Since Leo has been successful in establishing that all of Teva's invalidity allegations are not justified, at least in respect of claim 17, and whereas it is undisputed that Teva's version of the patented ointment would infringe claim 17, it is appropriate that I issue an Order in the form sought by Leo in the present application.

[195] Leo should have its costs. If the parties are unable to agree on the quantum of costs, I will receive submissions from the parties as contemplated in the Judgment below. At this point, I will say that I am not inclined to award increased costs, as Leo seems to urge, on account of the various allegations made by Teva in its NOA but not pursued at the hearing. Though Teva has let drop a number of its allegations (which I assume it felt were weak), it has also pursued a number of others (which I assume it felt were stronger). Parties should be encouraged to recognize and drop weak arguments in litigation, and I would not want to create a disincentive for doing so. If Leo has a legitimate complaint that Teva acted in a way that unnecessarily elevated Leo's costs in this proceeding, and that this should be reflected in my costs award, I have not heard it.

JUDGMENT

THIS COURT'S JUDGMENT is that:

1. The application is granted;

2. The Minister of Health is prohibited from issuing a Notice of Compliance to Teva Canada Limited in respect of 50 mcg/g calcipotriol and 0.5 mg/g betamethasone (as dipropionate) ointment until after the expiry of Canadian Patent No. 2,370,565;

3. Costs will follow the event. If the parties are unable to agree on the quantum of costs payable by Teva Canada Limited to Leo Pharma Inc., Leo shall serve and file its costs submissions, of no more than 15 pages, within 15 days following the date of this decision. Teva shall have 15 days following receipt of Leo's submissions to serve and file its responding costs submissions, which likewise shall be limited to 15 pages. Thereafter, Leo may, within 5 days following receipt of Teva's responding submissions, serve and file reply costs submissions of no more than 5 pages; and

4. No costs are awarded for or against the Minister of Health.

"George R. Locke"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

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