Federal Court  Cour fédérale

Date: 20150911

Docket: T-1599-13

Citation: 2015 FC 1016

Ottawa, Ontario, September 11, 2015

PRESENT: The Honourable Madam Justice Gleason

BETWEEN:

ELI LILLY CANADA INC.

Applicant

and

APOTEX INC. AND
THE MINISTER OF HEALTH

Respondents

and

ICOS CORPORATION

Respondent Patentee

PUBLIC JUDGMENT AND REASONS

(Confidential version of Judgment and Reasons issued August 26, 2015)

[1] In this application, the applicant, Eli Lilly Canada Inc. [Lilly], seeks an order under section 6 of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 [the *PMNOC Regulations*] to prohibit the respondent, the Minister of Health [the Minister], from issuing Notices of Compliance [NOCs] to the respondent, Apotex Inc. [Apotex], for approval to sell generic versions of CIALIS and ADCIRCA until after the expiry of the Canadian Patent 2,379,948 [the 948 Patent] on April 26, 2020. Lilly markets CIALIS principally for the treatment of erectile dysfunction [ED] and ADCIRCA for the treatment of pulmonary arterial hypertension [PAH].

[2] The active pharmaceutical ingredient in both CIALIS and ADCIRCA (as well as Apotex' generic versions of them) is a substance known as tadalafil. Tadalafil was discovered at Glaxo Laboratories and was first claimed in Canada in a patent that expired in January of 2015 (Canadian Patent 2,181,377 or the 377 Patent). Glaxo initially collaborated with ICOS Corporation on the development of tadalafil, which was found to be poorly soluble in water. When the collaboration between Glaxo and ICOS ended, Lilly partnered with ICOS to develop a tablet version of tadalafil.

[3] The 948 Patent, the patent in suit in this case, is a formulation patent for tadalafil that claims formulations with a reduced particle size and certain excipients to address tadalafil's poor water solubility.

[4] The 948 Patent is listed against both CIALIS and ADCIRCA on the Patent Register maintained by the Minister under sections 3 and 4 of the *PMNOC Regulations*. Apotex was

therefore required to address the 948 Patent to obtain NOCs and did so in two Notices of Allegation [NOAs], dated August 16, 2013 (CIALIS) and August 21, 2013 (ADCIRCA), which it served on Lilly. In response, Lilly commenced the present application for prohibition on September 27, 2013.

[5] Although Apotex raised several additional claims in its NOAs, by the time the matter was argued only three of them remained, namely, whether Apotex' products infringe the 948 Patent and whether the 948 Patent is invalid for obviousness or lack of utility.

[6] Justice de Montigny ruled on the same obviousness issue as arises in this case in the context of another prohibition application brought by Lilly against another generic company, Mylan Pharmaceuticals ULC, in his decision in *Eli Lilly Canada v Mylan Pharmaceuticals ULC*, 2015 FC 178, 251 ACWS (3d) 124 [*Mylan Tadalafil III*] and found that Mylan's obviousness allegation was justified. In addition, in *Mylan Tadalafil III* Justice de Montigny was faced with a claim of non-infringement by Mylan that is very similar to the position taken by Apotex in this application. Justice de Montigny ruled that Mylan's generic product did not infringe the 948 Patent. As a result, Justice de Montigny dismissed Lilly's prohibition application in *Mylan Tadalafil III*.

[7] Lilly has appealed Justice de Montigny's decision in *Mylan Tadalafil III* to the Federal Court of Appeal. Mylan has also appealed Justice de Montigny's earlier decision in *Eli Lilly Canada v Mylan Pharmaceuticals ULC*, 2015 C 17, 249 ACWS (3d) 191 [*Mylan Tadalafil I*] in which he granted Lilly's prohibition application with respect to the Canadian Patent 2,226,784

[the 784 Patent], which principally claims the use of tadalafil to treat ED. Both of these appeals are still pending before the Federal Court of Appeal.

[8] Apotex asserts that the decision of Justice de Montigny in *Mylan Tadalafil III* renders the present prohibition application by Lilly against it an abuse of process within the meaning of paragraph 6(5)(*b*) of the *PMNOC Regulations* and therefore says that this application should be summarily dismissed.

[9] Thus, the issues that arise for determination in this matter are the following:

1. Should this application be dismissed as an abuse of process?
2. Do Apotex' generic products infringe the 948 Patent?
3. Is the 948 Patent invalid for obviousness? and
4. Is the 948 Patent invalid for lack of utility?

[10] For the reasons set out below, I have determined that in the rather unique circumstances of this case, this application is not an abuse of process and accordingly may be pursued by Lilly. I have also concluded that Apotex' products do not infringe the 948 Patent, that its allegation of obviousness is justified but that its allegation of non-utility is not justified. I have therefore determined that this application must be dismissed.

I. Is it an abuse of process for Lilly to pursue this application?

[11] Turning to the first of these issues, the starting point for analysis of the abuse of process allegation is paragraph 6(5)(*b*) of the *PMNOC Regulations*, which recognizes this Court's

discretion to stay prohibition applications brought under section 6 of the *Regulations* where they are "redundant, scandalous, frivolous or vexatious" or "otherwise an abuse of process in respect of one or more patents". In *Sanofi-Aventis Canada v Novopharm Ltd*, 2007 FCA 163, 59 CPR (4th) 416 [*Sanofi Ramipril*], the Federal Court of Appeal held that it is an abuse of process, within the meaning of paragraph 6(5)(*b*) of the *PMNOC Regulations*, for a patent holder to re-litigate the same allegation(s) that it was unsuccessful on in a previous prohibition application involving a different generic company, even if the allegations are differently worded in the Notices of Allegation in the two files or even if the patent holder seeks to call better or more detailed evidence in the second file. In writing for the majority in *Sanofi Ramipril*, Justice Sexton determined that allowing re-litigation by a patent holder in such circumstances would constitute an abuse of process because the patent holder is seeking to collaterally attack the earlier decision and, in that case, permitting it to do so created an undesirable risk of conflicting judgments as the earlier award involved a factual determination and was therefore not binding in the subsequent case. Justice Sexton also held that allowing the re-litigation would lead to a waste of judicial resources and would possibly encourage patent holders to divide their cases and engage in serial litigation of the issues, which constituted further *indicia* of an abuse of the Court's process. He thus held that the second prohibition application brought by Sanofi in that case should have been dismissed as an abuse of process. However, in so holding, he noted that there might well be circumstances where fairness would require a different result but found that the case before him was not such a case.

[12] It is important to note that by the time *Sanofi Ramipril* was decided by the Federal Court of Appeal, a final decision had been made in the earlier prohibition application brought by Sanofi

as its appeal to the Federal Court of Appeal and application for leave to appeal to the Supreme Court of Canada in the earlier application had been dismissed. This was not the case when the motion to dismiss was first heard and, by reason of the fact that the application for leave to appeal to the Supreme Court was still pending when the motion to dismiss the second application was first decided, Prothonotary Milczynski initially declined to dismiss Sanofi's second prohibition application in *Sanofi-Aventis Canada v Novopharm*, (Order of Prothonotary Milczynski, May 8, 2006, Court File No. T-1965-05).

[13] Apotex argues that the decision of the Federal Court of Appeal in *Sanofi Ramipril* should be applied in the instant case and that Lilly's prohibition application should be dismissed as Lilly is seeking to re-litigate the same obviousness issue that was dismissed by Justice de Montigny in *Mylan Tadalafil III* and cannot do so because it is an abuse of process.

[14] Lilly disagrees and submits that there is an important distinction between this case and *Sanofi Ramipril* because in the case at bar an appeal of the earlier decision it lost is still pending. It points to both the decision of Prothonotary Milczynski in *Sanofi Ramipril* and to the subsequent decision of Prothonotary Tabib in *Eli Lilly Canada v Novopharm*, 2008 FC 513, 327 FTR 1 as being circumstances where a motion to dismiss was heard while an appeal of an earlier decision was pending and notes that both prothonotaries in both instances declined to dismiss the subsequent prohibition applications.

[15] In *Eli Lilly Canada v Novopharm*, Prothonotary Tabib offered detailed and thoughtful reasons for her refusal, noting that the key consideration in the exercise of discretion as to

whether to dismiss a subsequent application for prohibition under the *PMNOC Regulations* while an appeal of the earlier decision is pending is the potential effect of the appeal on the subsequent application. In that case, she determined that allowing the second prohibition application to proceed would not amount to an abuse of process as the concerns noted by the Federal Court of Appeal in *Sanofi Ramipril* did not arise.

[16] More specifically, Prothonotary Tabib found that there was little risk of possible conflicting judgments as the pending appeal in that case was likely to have been decided before the second prohibition application was decided. She also found that unfairness to Lilly would result if the second prohibition application were dismissed as it would be prejudiced if it were successful on the appeal. She further noted that this chain of events would likely lead to more litigation as, if she dismissed the second prohibition application and the appeal were successful, there would need to be an application to set the dismissal aside, which could well result in a judge being required to decide the second prohibition in an even shorter time frame.

[17] Finally, Prothonotary Tabib found that the best means of ensuring consistency in decision making would have been to stay the second prohibition application, pending a final determination of the appeal of the first unsuccessful prohibition application, but noted that this option was not open to the Court under the *PMNOC Regulations* in the absence of consent from the parties due to the statutory deadlines applicable to the disposition of prohibition applications. In this regard, section 7 of the *PMNOC Regulations* provides for a 24 month stay, following the filing of a prohibition application, during which the Minister is prohibited from issuing an NOC to the generic company for the drug that is referenced in the prohibition application. Unless the

parties to the application consent to an extension of that deadline, the Minister is free to issue the NOC at the end of the 24 month period. Prothonotary Tabib found that, failing consent to an extension of the 24 month period, the next best means of ensuring consistency was through the dismissal of Novopharm's motion for dismissal as Lilly had agreed that it would discontinue the second prohibition application if it were ultimately unsuccessful on appeal. Through this agreement, consistency of result was assured.

[18] As Apotex correctly submits, there is one significant difference in the facts that were before Prothonotary Tabib and the facts in the instant case. In that case, unlike the present, it was likely that the appeal of the refusal to issue a prohibition order would have been decided before the second application was argued. While this fact made it easier to conclude that the second application was not an abuse of process (because there was minimal risk of conflicting decisions), I do not believe that the different timing in the present case should lead to a different result than in *Eli Lilly Canada v Novopharm*.

[19] In this regard, I note that the decision on whether to dismiss an application like the present as being abusive is a discretionary one: paragraph 6(5)(*b*) of the *PMNOC Regulations* confirms that I *may* dismiss this application if I find it to be an abuse of process. In exercising my discretion in this case, I believe the key issue for consideration involves determination of which party will be more severely prejudiced by a negative determination on the dismissal request.

[20] In my opinion, it is Lilly who would be more severely prejudiced if I dismiss this application, as it will lose its ability to have the present application heard on the merits. This will be to its severe prejudice if it succeeds before the Federal Court of Appeal in its appeal of Justice de Montigny's decision in *Mylan Tadalafil III*.

[21] In this regard, the appeal of Justice de Montigny's decision in *Mylan Tadalafil III* has not yet been heard and will not be heard before the 24 month statutory stay expires in this case on September 27, 2015 but may well be decided before the expiry of the 784 Patent in July of 2016. The pending appeal in *Mylan Tadalafil III* is therefore unlikely to be dismissed for mootness.

[22] In the event Lilly is successful in its appeal of Justice de Montigny's decision in *Mylan Tadalafil III*, it would be impossible for this Court to set aside a dismissal of this application and re-examine the prohibition application before September 27, 2015. Therefore, if I grant Apotex' dismissal request, Lilly will lose its opportunity to seek an order of prohibition in respect of the 948 Patent in the context of Apotex' request for NOCs. However, if it wins its appeal, it probably would have been entitled to an order of prohibition in the instant case.

[23] It is no answer to say, as Apotex argues, that Lilly could still maintain an infringement action and obtain damages as Lilly will have lost the benefit of the statutory stay under the *PMNOC Regulations*, which is an important strategic advantage. In addition, in the event Lilly succeeds in its appeal in *Mylan Tadalafil III*, Apotex may enjoy an undeserved competitive advantage over Mylan if I dismiss this application as Apotex would be entitled to obtain an NOC for its ADCIRCA product and for its generic version of CIALIS in 2016 once the 784 Patent

expires whereas Mylan's entitlement to an NOC for its CIALIS product would depend on the outcome of Lilly's pending appeal and potentially also on the outcome of any subsequent application for leave to the Supreme Court of Canada. This is not only unfair but is precisely the sort of potential conflicting result that ought to be avoided as an abuse of process.

[24] On the other hand, Apotex will not lose its ability to argue this case, even if I were to grant the prohibition application, as it can appeal my decision and still have the full opportunity to argue its position and to seek to have the prohibition application dismissed on the merits by the Federal Court of Appeal. Moreover, Apotex could have avoided any cost and inconvenience associated with the pursuit of this application while the appeal in *Mylan Tadalafil III* is pending by simply agreeing to a stay and an extension of the 24 month time limit for the issuance of the NOCs it seeks. However, it was not prepared to do so.

[25] Thus, Lilly will be much more severely impacted than Apotex if this application is dismissed summarily. Accordingly, in my view, fairness requires that Lilly be allowed to pursue this prohibition application.

[26] Many other courts have reached similar conclusions and held that it is not an abuse of process for a party to maintain a second action or application while the first determination is being appealed as a decision under appeal is not a final decision for purposes of application of the abuse of process or issue estoppel doctrines (see, *e.g.*, *Novopharm Ltd v Eli Lilly and Co*, [1999] 1 FC 515 at paras 29-32, [1998] FCJ No 1634 (FCTD); *Wells v Canada (Minister of Transport)* (1993), 48 CPR (3d) 308, 63 FTR 213 (FCTD); *Cardinal v R* (1991), 47 FTR 203, 29

ACWS (3d) 723 (FCTD) (rev'd in part on other grounds (1993), 164 NR 301, 72 FTR 309); *Starlight v Canada*, 2001 FCA 342 at para 4, [2001] FCJ No 1685; *Nordic Laboratories Inc v Deputy MNR* (1996), 113 FTR 168 at paras 23-28, [1996] FCJ No 1067 (FCTD)).

[27] Indeed, in most instances where a prior decision is being appealed, the second case that involves the same issue is simply stayed pending the final determination of the appeal in the first case, which allows for the preservation of the parties' rights and avoids unnecessary litigation and the risk of conflicting decisions. Given the provision of section 7 of the *PMNOC Regulations* and the unwillingness of the parties to agree to a stay in this case, that option was unfortunately not available to me. Thus, the fairest option is to refuse Apotex' dismissal request.

[28] While this may result in unnecessary litigation (in the event the appeal in *Mylan Tadalafil III* is dismissed), this is preferable to the unfairness that would result to Lilly if this dismissal request were granted. I therefore determine that Lilly's pursuit of this prohibition application while its appeal in *Mylan Tadalafil III* is pending is not an abuse of process and that I accordingly will not summarily dismiss this application.

II. The 948 Patent

[29] I turn now to the merits of this application and begin by review of the relevant portions of the 948 Patent.

[30] The 948 Patent is entitled "ß-Carboline Pharmaceutical Compositions" and notes in its opening paragraph that the field of the invention claimed in the Patent relates to the formulation

of ß-carboline compounds "formulated in a manner providing uniform potency, and desirable stability and bioavailability characteristics" (948 Patent, p 1).

[31] The next section of the Patent describes the background to the invention and discusses three other patents: the U.S. versions of the 377 Patent, the 784 Patent and the Butler U.S. Patent No. 5,985,326 [the Butler Patent]. The 377 Patent claimed a number of ß-carboline compounds, including, notably, tadalafil, and the 784 Patent claimed the use of these compounds for the treatment of ED. The Butler Patent discloses a method for the preparation of tadalafil as a co-precipitate with hydroxypropyl methylcellulose phthalate and the manufacture of the co-precipitate into tablets.

[32] After describing these previous Patents, the 948 Patent goes on to state that studies revealed problems with the co-precipitate formulation, which included "difficulties in generating precisely reproducible lots" and the fact that maximum blood concentration of tadalafil was only achieved in 3 to 4 hours, "with the average time for onset of a therapeutic effect as yet not precisely determined" (948 Patent, p 2). The Patent states that a formulation that allows for "a more rapid attainment of maximum blood concentration, along with a greater prospect for rapid onset of therapeutic effect" is desirable as patients prefer a more immediate effect (at pp 2-3 of the Patent).

[33] After discussing the background to the invention, the 948 Patent then summarizes the invention and states that it is a pharmaceutical formulation comprised of tadalafil, in free drug form, where the particle size has been reduced, "in admixture with a diluent, a lubricant, a

hydrophilic binder selected from the group consisting of a cellulose derivative, povidone, and a mixture thereof, a disintegrant selected from the group consisting of crospovidone, croscarmellose sodium, and a mixture thereof, and, optionally, microcrystalline cellulose and/or a wetting agent … [and] optionally … additionally … a second diluent" (at p 4 of the Patent). The most preferred pharmaceutical formulation is stated to comprise "about":

(a) 1 to 5, and preferably about 2 to 4% by weight of tadalafil in a free drug form, where the particle size is milled so that at least 90% of the particles have a particle size of less than about 40 microns;

(b) 50 to 85% by weight and preferably about 50 to 75% by weight of lactose;

(c) 0.25 to about 2% by weight of magnesium stearate;

(d) 1 to 5% by weight of hydroxypropylcellulose;

(e) 3 to 15% by weight of croscarmellose sodium;

(f) 0 to 40% by weight of microcrystalline cellulose; and

(g) 0 to 5% by weight of sodium laurel sulphate.

(948 Patent, pp 4, 8).

[34] The 948 Patent defines or further discusses several terms used in it. The relevant ones for purposes of this application are "free drug", "water-soluble diluent", "hydrophilic binder" and "microcrystalline cellulose" (or MCC).

[35] "Free drug" is defined as meaning solid particles of tadalafil as opposed to tadalafil embedded in a co-precipitate (p 5 of the Patent). A "water-soluble diluent" is defined as referring to compounds typically used in the formulation of pharmaceutical tablets to impart bulk and is

stated as including (but not being limited to) sugars, polysaccharides, polyols, cyclodextrins and mixtures thereof (p 6 of the Patent). A "hydrophilic binder" is said to act as an adhesive to hold the tablet together (p 9 of the Patent). Possible hydrophilic binders falling within the group of cellulose derivatives are listed to include hydroxypropylcellulose, hydroxypropyl methylcellulose, hydroxyethylcellulose and hydroxybutyl methylcellulose (at p 10 of the Patent). Finally, the Patent notes that MCC is present in the formulations claimed at 0 to about 40% by weight and "can serve multiple functions in the formulation, *e.g.*, a disintegrant and/or a second diluent in addition to the water-soluble diluent" (at p 11 of the Patent). This section of the disclosure also states that the invention claimed in the 948 Patent provides improved dissolution and in vivo absorption as well as improved stability over prior formulations (at pp 12–13 of the Patent).

[36] The 948 Patent then goes on to describe the technique to be used to formulate tablets as well as preferred dosage forms. It contains 13 non-limiting examples, showing different formulations of the invention claimed in the Patent.

[37] The 948 patent contains 33 Claims; those in issue in the present case are Claims 1-4, 7-8, 11-15, 17-21, 23-31 and 33.

[38] Claim 1 is the only independent claim. It claims a pharmaceutical formulation comprising tadalafil, provided as free drug and comprising particles wherein at least 90% of the particles have a particle size of less than about 40 microns; about 50 to 85% by weight of a water-soluble diluent; a lubricant; about 1 to 5% by weight of a hydrophilic binder selected from the group

consisting of a cellulose derivative, povidone, and a mixture thereof; and a disintegrant selected from the group consisting of croscarmellose sodium, crospovidone, and a mixture thereof.

[39] Claims 2 to 8, 10 to 15 and 17-18 claim specific components of the formulation of Claim 1. Claims 19 to 21 claim a tablet comprising the formulation of Claim 1. Claims 23 to 25 claim specific particle sizes of the formulation in Claim 1. Claims 26 to 29 claim tablets comprising the formulation of Claim 1 where the compound is present in an amount of about 10 mg, 1 to 5 mg, 2.5 mg and 20 mg per tablet, respectively. Finally, Claims 30, 31 and 33 claim the use of the formulation and the tablets to treat sexual dysfunction and, specifically, ED.

[40] The Claims at issue in this application are reproduced in full in the Annex to these Reasons.

III. The Witnesses

[41] Lilly tendered evidence of a law clerk (merely to introduce the relevant documents as exhibits), of two fact witnesses (Drs. Kral and Pullman) and two experts (Drs. Goldstein and Bodmeier). Apotex tendered an affidavit from Duane Terrill, the Associate Director, Regulatory Affairs at Apotex, to explain the background to the application, an affidavit of a law clerk, to produce additional documents, and an expert affidavit from Dr. Mumper.

[42] Dr. Pullman is a clinical pharmacologist formerly employed by Lilly. He is the co-inventor of another tadalafil patent, the 2,371,684 Patent (which was the subject of another prohibition application in *Eli Lilly Canada v Mylan Pharmaceuticals ULC*, 2015 FC 125, 249

ACWS (3d) 863). Dr. Pullman was involved in the clinical trials of tadalafil and in his affidavit introduces several clinical studies undertaken by Lilly.

[43] Dr. Martha Kral is one of the inventors of the 948 Patent and was a Research Advisor at Lilly. Her affidavit reviews the formulation work for tadalafil, both before and during her involvement, and recounts the work leading up to the invention claimed in the 948 Patent. She appends several studies to her affidavit, including studies done at Glaxo, as well as formulation and clinical studies conducted at Lilly.

[44] Dr. Bodmeier is a professor of pharmaceutical technology at the College of Pharmacy at Freie Universität in Berlin, Germany. He obtained his Ph.D. from the University of Texas in Austin and teaches and researches pharmaceutical sciences, including in respect of formulation and use of excipients. He has held numerous editorial positions for various journals in the pharmaceutical area and has published approximately 170 scientific papers in refereed journals and 10 book chapters on a variety of pharmaceutical topics, including in relation to formulation of poorly water-soluble drugs. Dr. Bodmeier was Lilly's expert on both infringement and validity in *Mylan Tadalafil III*. In his affidavit in this case, he opines on the invalidity issues (including those that are no longer at play) and the non-infringement issue. He offers the opinion that Apotex' generic versions of CIALIS and ADCIRCA infringe the 948 Patent and that the Patent is not invalid for obviousness or lack of utility.

[45] Dr. Goldstein is a urologist and the only clinician to give evidence in this proceeding. He was the Co-Director of the Laboratory for Sexual Medicine Research at the Boston University

School of Medicine from 1981 to 2005 and the editor-in-chief of the *International Journal of Impotence Research* from 2001 to 2004. From 2004 to 2014 he was the editor-in-chief of the *Journal of Sexual Medicine* and is currently the editor-in-chief of the *Journal of Sexual Medicine Reviews*. He is currently a consultant and is also the Director of Sexual Medicine and a Clinical Professor of Surgery at the Alvarado Hospital and the University of California, San Diego. He has belonged to numerous professional organizations and has written broadly in areas associated with sexual dysfunction, with nearly 300 peer-reviewed papers, multiple book chapters and research awards from national and international organizations. In his affidavit, Dr. Goldstein offers an opinion on utility with respect to Claims 30, 31 and 33 of the 948 Patent and is of the view that the promise of these Claims has been demonstrated through the clinical studies Lilly filed and, accordingly, that these Claims are not invalid for inutility.

[46] Finally, Dr. Mumper is a pharmaceutical scientist, similar in profile to Dr. Bodmeier. He is the John A. MacNeill Distinguished Professor and Vice Dean at the University of North Carolina's Eshelman School of Pharmacy and has a Ph.D. in Pharmaceutical Science. He has held several other academic appointments, served on the editorial boards of several leading publications in pharmaceutics and has published and spoken widely on various pharmaceutical topics. Prior to taking up the role of professor, Dr. Mumper worked in industry (for an innovator drug company) and was actively engaged in drug formulation, including in respect of poorly water-soluble drugs. In his affidavit, Dr. Mumper offers opinions on patent construction, infringement, utility and obviousness and takes the position that the Apotex products do not infringe the 948 Patent and that the Patent is invalid because the promised utility was neither demonstrated nor soundly predicted and the invention claimed was obvious.

IV. Do Apotex' generic products infringe the 948 Patent?

[47] With this background in mind, it is now possible to turn to the examination of whether the Apotex products infringe the 948 Patent. As an antecedent to this analysis, it is first necessary to construe the relevant Claims in the 948 Patent and determine their essential elements as infringement occurs when there is replication by the infringer of one or more of the essential elements of the patented invention (*Free World Trust v Électro Santé Inc*, 2000 SCC 66 at para 31, [2000] 2 SCR 1024; *Whirlpool Corp v Camco Inc*, 2000 SCC 67 at paras 43-45, [2000] 2 SCR 1067 [*Whirlpool*]).

A. *Construction of the 948 Patent and determination of the essential elements of Claim 1*

[48] In reviewing the claims of the 948 Patent, it is sufficient to limit the discussion to Claim 1, the only independent claim in the 948 Patent as, if this Claim is not infringed, none of the following dependent claims may be infringed. With one exception, the parties agree as to the essential elements of Claim 1 of the 948 Patent. These are:

(a) tadalafil in free drug form;

(b) with 90% of the tadalafil particles having a particle size of less than about 40 microns;

(c) about 50 to 85% by weight of a water-soluble diluent;

(d) a lubricant;

(e) about 1 to 5% by weight of a hydrophilic binder selected from the group consisting of a cellulose derivative, povidone, and a mixture thereof; and

(f) a disintegrant selected from the group consisting of croscarmellose sodium, crospovidone, and a mixture thereof (Bodmeier affidavit, para 82; Mumper affidavit, para 85).

[49] They disagree, however, on the meaning that should be ascribed to the term "about". On one hand, Lilly and Dr. Bodmeier assert that the term means plus or minus 10 percent. Thus, they would read "about 1 to about 5%" as including an amount between 0.9% to 5.5% and "about 50 to about 85%" as including an amount between 45 and 93.5% (which they round up to 94%) (Bodmeier affidavit, paras 72, 86, 90). Apotex and Dr. Mumper, on the other hand, reject this reading and instead take the position that "about" means "approximate" and posit that the inventor used the word "about" in the 948 Patent to avoid a hard cut-off line so as to allow for small variations of quantities in the formulation, which invariably occur (Mumper affidavit, paras 96-101). They thus say that the amount by which an excipient may vary will be much less than the 5 to 9 % range posited by Lilly and Dr. Bodmeier with respect to the bounds of the infringing range of a water-soluble diluent (Mumper affidavit, paras 135-136).

[50] Of the two positions, I prefer that of Dr. Mumper and Apotex for three reasons. First, it makes much more sense. "About" does mean approximate and it strains credulity to think that a range of "about 50 to 85%" means between 45 and 94% – if that is what was meant, why not simply say so? In short, 45 is not approximately 50 nor is 93.5 or 94 approximately 85. Second, Dr. Bodmeier offers no justification for his selection of the plus or minus 10% interpretation, which, therefore, appears to have been selected to favour a finding of infringement. (He does note at para 72 of his affidavit that the plus or minus 10% calculation applies to the drug content

of pharmaceutical dosage forms but provides no explanation of why a regulatory requirement for allowable variances in the generally very small amount of the active pharmaceutical ingredient in a tablet should apply to the interpretation of the amounts set out by the inventor in the 948 Patent.) Third, and most importantly, I discount Dr. Bodmeier's credibility as I find he has tailored his evidence in this case to favour the result sought by Lilly.

[51] In this regard, in his affidavit, Dr. Bodmeier offered the view that the invention claimed in the 948 Patent was not obvious as there was "no guarantee that any of the options would work to result in a usable formulation" (at para 249 of the Bodmeier affidavit). This was the key statement in his affidavit, summarizing his conclusion on obviousness. Dr. Bodmeier made an identical statement in his affidavit in the *Mylan Tadalafil III* case.

[52] In *Mylan Tadalafil III*, Justice de Montigny rejected Dr. Bodmeier's evidence in part because he found that Dr. Bodmeier set the bar too high for the test for obviousness. Justice de Montigny found as follows at para 150 in *Mylan Tadalafil III*:

> [T]he test is not whether a skilled person would know for certain that a formulation would work or whether there is a guarantee that particular formulations would work, as suggested by Dr. Bodmeier in his affidavit [citations omitted]. This would set the bar too high. The test, rather, is whether the skilled person had good reason to pursue predictable solutions or solutions that provide a "fair expectation of success".

[53] Justice Barnes also discounted similar evidence from Dr. Bodmeier in *Janssen v Teva Canada Limited*, 2015 FC 184 at para 101 for the same reason.

[54] At the outset of his cross-examination in this case, which occurred just days after the release of the confidential version of Justice de Montigny's decision in *Mylan Tadalafil III*, Dr. Bodmeier indicated that he wished to change the word "guarantee" in paragraph 249 of his affidavit in this case to the word "expectation" so the paragraph would read as follows:

> There is no expectation [as opposed to guarantee] that any of the options would work to result in a usable formulation. In other words, it is not self-evident that it would be possible to obtain a workable formulation that provided an early onset of action.

[55] Dr. Bodmeier explained during his cross-examination that he made the decision to change this word in his affidavit through discussions with counsel because it was "a language issue" and he did not understand the word "guarantee" to mean 100%, but rather thought it meant a little more than a 50% likelihood of success. When he learned through discussion with counsel that this is not what the word "guarantee" in fact meant, he says he decided to change it to "expectation" to reflect what he says he originally meant, namely, that there was not more than a 50% likelihood that any of the options would result in a usable formulation (Bodmeier cross-examination, Application Record [AR] pp 8843-48).

[56] Counsel for Lilly submits that this change should not be viewed as an illegitimate attempt by Dr. Bodmeier to alter his evidence, prompted by the need to avoid a similar determination to that made by Justice de Montigny, but, rather, should be viewed as a mere correction that results from the fact that English is not Dr. Bodmeier's first language. I reject this submission. Not only is there no evidence to support it, I find it unbelievable that Dr. Bodmeier – who completed his Ph.D. in Texas and who, according to his *curriculum vitae*, has written and spoken on scientific issues countless times in English – would not know the difference in meaning between the words

"guarantee" and "expectation". I therefore believe that the change was an attempt to adjust his evidence to avoid a conclusion unfavourable to Lilly, which is not how an independent expert ought to conduct himself.

[57] If I am wrong in this and Dr. Bodmeier's English is so poor that he cannot distinguish between "guarantee" and "expectation", then his command of the language is such that it is not suitable for him to be providing expert testimony to this Court. I therefore determine that where there is a conflict between the evidence of Dr. Bodmeier and Dr. Mumper, Dr. Mumper's evidence is to be preferred. I accordingly conclude that the word "about", as used in Claim 1 of the 948 Patent means "approximately" and not plus or minus 10%.

B. *Non-infringement*

[58] Apotex asserts that its generic versions of CIALIS and ADCIRCA do not infringe the 948 Patent as they do not contain approximately 50 to 85% by weight of a water-soluble diluent nor approximately 1 to 5% by weight of a hydrophilic binder selected from the group consisting of a cellulose derivative, povidone, or a mixture thereof.

[59] Drs. Mumper and Bodmeier concur that the composition of the Apotex generic tablets (as disclosed in its Abbreviated New Drug Submissions [ANDSs], filed in support of its request for NOCs) is as follows:

Apotex Component	**Apotex' Stated Function**	**Mg/ Unit Dose (20mg)**	**% w/w (20 mg)**	**Mg/ Unit Dose (10mg)**	**% w/w (10mg)**	**Mg/ Unit Dose (5mg)**	**% w/w (5mg)**	**Mg/ Unit Dose (2.5mg)**	**% w/w (2.5mg)**
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

(Bodmeier affidavit, para 80, AR p 354; Mumper affidavit, para 145, AR p 7533)

[60] The only binder listed in the Apotex formulations is [redacted]. Both parties concur that [redacted] is not a cellulose derivative nor povidone, and therefore does not come within the 948 Patent's definition of a "hydrophilic binder", which is defined as including hydrophilic binders selected from the group consisting of a cellulose derivative, povidone, and a mixture thereof (Mumper affidavit, para 148; uncontradicted by Bodmeier). Therefore, if one accepts that the excipients in the Apotex tablets perform the functions Apotex claims they perform, the Apotex products do not contain approximately 1 to 5% by weight of a hydrophilic binder because [redacted] is not a hydrophilic binder of the type claimed in the Patent.

[61] Moreover, even if it were, the amount present in the Apotex tablets falls outside the essential weight range of approximately 1 to 5% claimed in Claim 1 of the 948 Patent. The tablets contain approximately [redacted], which Dr. Mumper says is not equivalent to being "about" 5% and which also, incidentally, falls outside Dr. Bodmeier's plus or minus 10% range

(Mumper affidavit, paras 152-155). Thus, if the excipients in the Apotex products perform the functions listed in Apotex' ANDSs, they are missing an essential element of Claim 1, namely, the presence of approximately 1 to 5% by weight of a hydrophilic binder selected from the group consisting of a cellulose derivative, povidone, and a mixture thereof.

[62] The Apotex formulations on their face also do not contain approximately 50 to 85% by weight of a water-soluble diluent if the excipients perform the functions Apotex claims they perform. Apotex lists [redacted] diluents in its ANDSs, namely [redacted] and [redacted]. There is no dispute that [redacted] is not water-soluble but that [redacted] is (Bodmeier affidavit, para 86; Mumper affidavit, paras 174-75). The Apotex formulations contain only approximately [redacted]. This falls well below the amounts required by Claim 1 of the 948 Patent of approximately 50 to 85%. Thus, for this reason as well, if the excipients in the Apotex tablets perform the functions that Apotex alleges they perform, the Apotex products do not infringe the 948 Patent.

[63] Lilly and Dr. Bodmeier, however, say that the excipients in the Apotex formulations do not in fact perform the functions Apotex claims and, therefore, that its products infringe the 948 Patent. More specifically, Dr. Bodmeier asserts that the Apotex products contain the required amounts of a hydrophilic binder because 0.9% to 5.5 % of the [redacted] in the tablets function as a binder (Bodmeier affidavit, para 91). He also asserts that they contain the required amount of a water-soluble diluent because the [redacted] and [redacted] function as water-soluble diluents and their combined percentage is approximately [redacted], which Dr. Bodmeier alleges

falls within the scope of Claim 1 of the 948 Patent due to his plus or minus 10% assertion as to how one interprets "about" (Bodmeier affidavit, paras 86-87).

[64] Dr. Mumper rejects these claims and notes that Dr. Bodmeier has offered no evidence in support of his claim that only 0.9% to 5% of the [redacted] (which ranges in weight from roughly [redacted], depending on the amount of tadalafil in the Apotex tablet) acts as a binder nor to support his assertion that all of the [redacted] acts as a diluent as opposed to a binder. In addition, Dr. Mumper disputes that [redacted] is "hydrophilic" and opines that [redacted] is not typically added to pharmaceutical formulations merely to act as a diluent (Mumper affidavit, paras 107-110, 159, 182-83; Mumper cross-examination, AR pp 9185-89).

[65] I reject the position of Dr. Bodmeier and Lilly on these issues for several reasons in addition to the general lack of credibility of Dr. Bodmeier, discussed above.

[66] In the first place, I find that Lilly carries the burden of establishing that the Apotex products infringe the 948 Patent (*Eli Lilly Canada v Apotex*, 2009 FC 320 at paras 37-41, 75 CPR (4th) 165; *Novopharm Ltd v Pfizer Canada*, 2005 FCA 270 at paras 19-24, 42 CPR (4th) 97). Lilly has not discharged this burden through Dr. Bodmeier's evidence, which amounts to nothing more than speculation as to the role of 0.9% to 5% of the [redacted] and of the [redacted] in the Apotex formulations. Dr. Bodmeier makes a bald claim as to the function of these excipients but offers no reasons or evidence to support his assertion that only 0.9% to 5% by weight of a total amount of roughly [redacted] of the [redacted] contained in the tablets acts as a

hydrophilic binder nor to support his claim that all of the [redacted] acts as a diluent. Such bald speculation does not constitute proof of the function of these excipients.

[67] A similar claim was made by Dr. Bodmeier in *Mylan Tadalafil III* and was rejected by Justice de Montigny for the same reason. He held at para 86 that:

> I agree with Mylan that Lilly's argument rests on multiple layers of speculation. First of all, Dr. Bodmeier opines that [redacted] is more binder than would be "typically" added as an excipient in a tablet formulation. Admittedly, Dr. Brittain confirmed that 2% to 5% is a normal amount in cross-examination. However, this is a far cry from establishing that amounts above that range cease to provide the adhesion functionality of the binder. Neither of the two experts categorically exerted that [redacted] cannot act as a binder in a proportion of [redacted] and in any event no testing was conducted to support such a conclusion. Speculation, even by experts, is not evidence and is clearly not sufficient to meet the burden of proof in infringement cases.

[68] Second, given the construction applicable to the word "about" in Claim 1 of the 948 Patent, as discussed above, even if the [redacted] in the Apotex formulations functions as a water-soluble diluent, the total amount of diluent contained in the formulations would not reach the amount required for infringement, namely, 50 to 85% by weight. Rather, the total amount of [redacted] and [redacted] contained in the Apotex formulations amounts only to approximately 45%, which I have determined is not "about" 50%.

[69] Third, even though both experts agree that [redacted] is a cellulose derivative, given the way in which [redacted] is described in the Patent, I agree with Dr. Mumper that [redacted] cannot be considered to be a "hydrophilic binder" within the meaning of the Claims in the Patent. In this regard, as Apotex correctly notes, an inventor may ascribe a particular meaning to

the terms used to define the invention claimed in a patent. The ordinary or "dictionary" meaning of a word is therefore not necessarily determinative. Rather, the Court is to construe the meaning of words in the patent with reference to how the word is used throughout the specification (see *Whirlpool*, above, at para 52; *Western Electric Co v Baldwin International Radio of Canada Ltd*, [1934] SCR 570 at 572, 582, [1934] 4 DLR 129; *Lundbeck Canada v Ratiopharm*, 2009 FC 1102 at paras 51-53, 79 CPR (4th) 243).

[70] Here, the 948 Patent refers to [redacted] at several points as an excipient that may be added to the formulation of Claim 1. For example, in the disclosure, [redacted] is described as either [redacted]. Nowhere does the Patent describe [redacted] as a binder. In addition, Claim 2 claims the formulation of Claim 1 to which [redacted]. I agree with Apotex that these references make it impossible to view [redacted] as coming within the scope of Claim 1.

[71] Finally, I accept Dr. Mumper's evidence that [redacted] is not generally considered by formulators to be "hydrophilic" and that [redacted] is not typically added to pharmaceutical formulations merely to act as a diluent. Thus, the person skilled in the art to which the 948 Patent is addressed, which the parties concur includes a formulator, would not consider [redacted] to be a hydrophilic binder or [redacted] to be a diluent, within the meaning of Claim 1 of the Patent.

[72] Thus, for these reasons, I find Apotex' non-infringement allegation to be justified. This determination is sufficient, in itself, to result in the dismissal of this application. However, given the likelihood of an appeal being pursued, I find it prudent to briefly address the other two arguments advanced by Apotex.

V. Is the 948 Patent invalid for obviousness?

[73] The first of Apotex' additional arguments is the allegation that the 948 Patent is invalid for obviousness.

A. *Applicable principles*

[74] The concept of obviousness flows both from the definition of "invention" in section 2 of the *Patent Act*, RSC 1985, c P-4, and from section 28.3 of the *Act*. Section 2 defines an "invention" as "any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement in any art, process, machine, manufacture or composition of matter". Section 28.3 provides:

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.

[75] Obviousness relates to the lack of inventiveness of the claimed invention, or, essentially, involves a finding that nothing patentably new was discovered in the claimed invention. In *Apotex Inc v Sanofi-Synthelabo Canada Inc*, 2008 SCC 61 at para 67, [2008] 3 SCR 265 [*Sanofi-Synthelabo*], the Supreme Court of Canada clarified the test for obviousness, setting out the following four-step approach to the assessment of obviousness:

1. Identification of the notional person skilled in the art to which the patent relates and determination of the knowledge base of that person as of the relevant date, which in the case of patents filed on or after October 1, 1996 is the claim date (in this case August 3, 1999);
2. Identification of the inventive concept of the claims in question (which may require construction of the claims);
3. Identification of what, if any, differences exist between the matters cited as part of the prior art and the inventive concept of the claims; and
4. Consideration of whether the differences, when viewed without knowledge of the alleged invention claimed, constitute steps which would have been obvious to the skilled person to try or whether they involve a degree of invention.

[76] In answering the fourth question, Justice Rothstein, writing for the Court in *Sanofi-Synthelabo*, provided at paras 69 to 71 the following non-exhaustive list of factors that may be considered in determining whether a matter is "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? and
4. What is the "actual course of conduct which culminated in the making of the invention"? If significant experimentation was required, this may support a conclusion that the invention was not "obvious to try"; conversely, evidence of quick, easy, direct, and inexpensive experimentation may point to an opposite conclusion.

[77] The jurisprudence recognizes that for an invention to be "obvious to try", the solution chosen must be more or less self-evident and therefore that it is not enough if the prior art merely indicates a possibility of finding the invention or shows that it might be worthwhile to conduct the experiments which led to the invention (see *e.g. Sanofi-Synthelabo*, above, at paras 61-71; *Pfizer Canada v Apotex*, 2009 FCA 8 at paras 22-29, [2009] 4 FCR 223; *Ratiopharm Inc v Pfizer Ltd*, 2010 FCA 204 at paras 15, 27-28, 87 CPR (4th) 185; *Pfizer Canada v Pharmascience*, 2013

FC 120 at para 187, 111 CPR (4th) 88). The case law moreover recognizes that it is an error to use the benefit of hindsight to evaluate if an invention was "obvious to try" as inventions may well appear obvious after they are made. As Justice Hugessen noted in the oft-cited passage from *Beloit Canada Ltd v Valmet Oy* (1986), 8 CPR (3d) 289 at 295, 64 NR 287 (FCA):

> 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 the 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?"

B. *Preliminary Argument of Lilly*

[78] Lilly submitted during oral argument that Apotex is forestalled from raising the issue of obviousness as it alleges that Apotex' NOAs were insufficient on the point since Apotex laid out a different inventive concept in the NOAs than Dr. Mumper set out in his affidavit. Lilly argues that Dr. Mumper's evidence on the point is therefore inadmissible and that, as Apotex has therefore failed to put the issue of obviousness into play, its allegation of obviousness must be dismissed.

[79] This argument is without merit. While I agree with Lilly that there are differences in the way in which the inventive concept is detailed in Apotex' NOAs and Dr. Mumper's affidavit, I do not believe that this should result in the striking of Dr. Mumper's evidence, particularly when Lilly cross-examined Dr. Mumper and in so doing did not raise any objection about the admissibility of his evidence and, indeed, did not contest the admissibility of his affidavit until oral argument before me. Thus, it is difficult for Lilly to argue that it was prejudiced through the

somewhat different notions of the inventive concept alleged in the NOAs and set out in Dr. Mumper's affidavit. Moreover, and more fundamentally, determination of the inventive concept is a matter of construction and accordingly need not be raised in an NOA (see *AB Hassle v Apotex*, 2001 FCT 530 at paras 61-65, 12 CPR (4th) 289; TR Hughes & D Clarizio, *Hughes and Woodley on Patents*, loose-leaf (consulted on August 20, 2015), 2d ed (Markham: LexisNexis Butterworths, 2005), vol 1, §23 at 215.

[80] Thus, there was no need for Dr. Mumper's affidavit to mirror the inventive concept laid out in Apotex' NOA and therefore no basis for striking Dr. Mumper's evidence. Hence, Apotex has put the issue of obviousness into play through its evidence and the burden of proof has accordingly shifted to Lilly to establish that the obviousness allegation is unjustified (*Pfizer Canada v Canada (Health)*, 2007 FCA 209 at paras 105-110, 60 CPR (4th) 81). For the reasons set out below, I find Lilly has failed to discharge this burden.

C. *Analysis*

(1) The skilled person

[81] As noted, the first step in the obviousness analysis, as *Sanofi-Synthelabo* teaches, involves determination of the skill set of the notional person skilled in the art to which the Patent is directed as the Patent must be construed from the vantage point of this skilled person.

[82] In this case, there is no meaningful difference between the experts' positions on the attributes of the skilled person to whom the 948 Patent is addressed as all concur that such

person includes a skilled pharmaceutical formulator, who would be aware of standard pharmaceutical texts and who would conduct a search for relevant patents in the course of attempting to formulate a drug.

[83] More specifically, Dr. Mumper offers the view that the skilled person to whom the 948 Patent was addressed is an amalgam of the following skill sets: a pharmaceutical formulator knowledgeable in formulating oral dosages of poorly water-soluble drugs, a pharmacologist, knowledgeable in *in vivo* absorption and bioavailability of orally-administered drugs and clinicians knowledgeable in the use of PDE V inhibitors (one of which is tadalafil) for the use in treatment of various conditions including ED and PAH (Mumper affidavit, para 44).

[84] A similar view is expressed by Dr. Goldstein, who opines that the 948 Patent is primarily addressed to a pharmaceutical formulator but that the notional skilled person would also include a clinician with experience in the treatment of ED and PAH or other conditions related to PDE V (Goldstein affidavit, para 15).

[85] Finally, Dr. Bodmeier is of the view that the skilled person to whom the 948 Patent is addressed is a pharmaceutical formulator, with a university degree in pharmacology and a couple of years of experience working with dosage forms at a pharmaceutical company (Bodmeier affidavit, para 28).

[86] I concur with the experts that the skilled person to whom the 948 Patent is addressed includes (and, indeed, is principally) a skilled pharmaceutical formulator as the Patent is directed

towards new formulations of tadalafil. Justice de Montigny reached a similar conclusion regarding the principal attributes of the skilled person in respect of this Patent in *Mylan Tadalafil III* (at para 76).

(2) The inventive concept

[87] Having identified the addressee of the 948 Patent, I turn next to the second step of the Sanofi-*Synthelabo* analysis, namely, identification of the inventive concept of the Claims at issue. The parties diverge on this point.

[88] On one hand, Lilly and Dr. Bodmeier express the view that the inventive concept of these Claims involves "a particular pharmaceutical formulation of tadalafil … that provides an early onset of therapeutic effect as well as sufficient concentration of tadalafil at the intracellular site of action, which permits relatively prolonged duration of action" (Bodmeier affidavit, para 233).

[89] On the other hand, Dr. Mumper and Apotex assert that the inventive concept of the relevant Claims in the 948 Patent merely involves formulations comprised of tadalafil in free-drug and micronized form, a water-soluble diluent and a hydrophilic binder (Mumper affidavit, paras 143). Dr. Mumper offers the view that the inventive elements claimed in the formulations are only these three, as opposed to the other excipients in the formulations, because these three elements affect dissolution rates but the other excipients in the tablets do not necessarily perform such a function (Mumper affidavit, paras 263-269).

[90] Dr. Mumper rejects Dr. Bodmeier's suggested inventive concept because he is of the view that the 948 Patent relates to formulations *per se* as opposed to their therapeutic effects or actions. He notes in this regard that the 948 Patent only once mentions the concept of early action in the *Background of the Invention* section of the Patent and does not state that the formulations will, in fact, provide early onset of therapeutic action and, indeed, discloses that the inventors were unsure that a rapid rate of dissolution would lead to a rapid onset of therapeutic effect (Mumper affidavit, paras 272-273). Dr. Mumper also notes that there is no mention whatsoever in the 948 Patent of the concentration of tadalafil delivered at the intracellular site, nor of the duration of action of tadalafil, and for this reason as well rejects Dr. Bodmeier's suggested inventive concept (Mumper affidavit, para 277).

[91] In *Mylan Tadalafil III*, Justice de Montigny determined that the inventive concept of the relevant Claims of the 948 Patent was "the improved dissolution and stability of tadalafil achieved by reducing its particle size and formulating it with specific excipients" (at para 138). Justice de Montigny's formulation of the inventive concept is thus somewhat narrower than that posited by Dr. Bodmeier and somewhat broader than that posited by Dr. Mumper in this case.

[92] The determination of the inventive concept of the claims in a patent is a matter of construction and therefore a legal determination (see *Apotex Inc v Allergan Inc*, 2012 FCA 308 at para 50, 105 CPR (4th) 371). As I held in *Eli Lilly* v *Apotex*, 2015 FC 875 at paras 88-92, [2015] FCJ No 870 (QL), the doctrine of comity requires that I adopt a previous finding of law made by one of my colleagues unless I conclude that a departure is necessary and that there are cogent reasons for the departure.

[93] Here, I find that there is no reason to depart from Justice de Montigny's construction of the inventive concept of the relevant Claims in the 948 Patent. More specifically, I concur that the inventive concept is broader than a mere formulation, as Dr. Mumper posits, because it is clear from the specification that the essence of the invention involves the improved dissolution and stability offered by the formulations set out in the Claims. The inventive concept is therefore broader than that posited by Dr. Mumper. However, I concur with Dr. Mumper that the inventive concept does not stretch to include notions of an early onset of therapeutic effect, concentrations of tadalafil at the intracellular site of action or prolonged duration of action, due to the lack of discussion of these concepts in the Claims or elsewhere in the Patent.

[94] I therefore find that the inventive concept of the Claims at issue in this application involves the improved stability and dissolution of tadalafil achieved by reducing its particle size and formulating it with specific excipients. I further find that these excipients are in particular a water-soluble diluent and a hydrophilic binder, for the reasons mentioned by Dr. Mumper.

(3) Differences exist between the matters cited as part of the prior art and the inventive concept of the claims

[95] In terms of the common general knowledge of the skilled person (as referenced in the prior art), it is common ground between the parties that as of the claim date, August 2, 1999, tadalafil was a known compound that had been claimed in the 377 Patent and was the object of the 784 Patent, that claimed its use for the treatment of ED. It is likewise admitted that a co-precipitate formulation of tadalafil was disclosed in the Butler Patent, which indicated that

tadalafil was poorly soluble in water (Bodmeier affidavit, para 187; Mumper affidavit, para 51; Butler Patent, p 2, lines 8-18, AR p 3712).

[96] It is also common ground that it was well-known that reduction of particle size was a common method adopted to increase the solubility of poorly water-soluble drugs (Bodmeier affidavit, paras 237-238; Mumper affidavit, para 294). There is also no dispute that addition of a water-soluble diluent and a hydrophilic binder was known to aid in the dissolution of an oral tablet (Mumper affidavit, paras 305-307; not disputed by Bodmeier). It is likewise common ground that the other excipients mentioned in the Claims, namely lubricants, disintegrants and wetting agents were commonly used in the formulation of tablets (Bodmeier affidavit, paras 45-46; Mumper affidavit, paras 296-297). Finally, it is not disputed that all the specific excipients mentioned in the Claims were known and frequently used in tablet formulation (Mumper affidavit, paras 311, 314, 325; not disputed by Bodmeier).

[97] Thus, the only difference between the prior art and formulations claimed in the 948 Patent is that the particular formulations claimed had not been previously disclosed in combination with tadalafil.

> (4) Do the differences, when viewed without knowledge of the alleged invention claimed, constitute steps which would have been obvious to the skilled person to try or do they involve a degree of invention?

[98] Dr. Mumper offers the view that formulations claimed in the relevant Claims are obvious for two reasons. First, he opines that micronizing tadalafil in its free drug form to reduce its particle size was an obvious step to try as particle reduction was "one of the first, if not the first,

method a skilled formulator would apply to address a drug's poor water-solubility" (Mumper affidavit, para 294). Second, he opines that inclusion of water-soluble diluents, hydrophilic binders and the other excipients mentioned in the 948 Patent were commonly used by formulators to increase the overall dissolution rate and bioavailability of poorly water-soluble drugs and thus were also obvious to try (Mumper affidavit, paras 296-297, 310).

[99] To support his opinion, he offers several citations from standard textbooks, used by formulators, as well as from previous patents. For example, at para 294 of his affidavit, Dr. Mumper reproduces the following passage from Alsaidan *et al*, *Drug Development and Industrial Pharmacy* (1998):

> The solubility characteristics of a drug are consistent with good absorbability. For relatively insoluble drugs, the rate of dissolution is usually the rate-determining step in the overall absorption process. Reduction of particle size remains the accepted method for increasing dissolution rate. [emphasis added by Dr. Mumper]

[100] Quoting from *Pharmaceutics: The Science of Dosage Form Design* at para 298 of his affidavit, Dr. Mumper further notes that:

> The overall dissolution rate and bioavailability of a poorly soluble drug from an uncoated conventional tablet is influenced by many factors associated with the formulation and manufacture of this type of dosage form [citation omitted]. These factors include:
>
> …
>
> 2 the nature and quantity of the diluent, binder, disintegrant, lubricant and any wetting agent,
>
> 3 drug-excipient interactions (e.g. complexation) the size of the granules and their method of manufacture, [emphasis added by Dr. Mumper]

[101] He then goes on to cite from other standard pharmaceutical texts to similar effect.

[102] Dr. Mumper then describes the formulations outlined in United States Patent No. 5811120 [the US 120 Patent], which address the poor water solubility of a class of raloxifene related compounds, stating at para 311 of his affidavit that:

> [t]he formulations described in the US 120 Patent address the poor water solubility and bioavailability of the active ingredients by, among other things, incorporation of a water-soluble diluent (*e.g.* lactose), a hydrophilic binder (*e.g.* polyvinylpyrrolidone, hydroxypropylcellulose, or hydroxypropylmethylcellulose), and a wetting agent (*i.e.*, a surfactant, *e.g.* polysorbate 80).

[103] He further refers to the PCT International Patent Application No. WO 98/23270 that likewise provides an illustration of increasing the water solubility and bioavailability of a poorly soluble drug through the addition of a water–soluble diluent, hydrophilic binder and a wetting agent (Mumper affidavit, paras 319-324).

[104] In addition, Dr. Mumper is of the view that the fact that the [redacted], points to the obviousness of the formulations claimed in the 948 Patent (Mumper affidavit, paras 343-355).

[105] Dr. Bodmeier, on the other hand, takes the position that there was inventive ingenuity in the development of the formulations claimed in the 948 Patent essentially because the Patent sets out new formulations of tadalafil that had not been previously disclosed. He asserts that because every drug is unique, one cannot predict what will be included in the final effective formulation, noting that "there is no guarantee [changed to expectation] that any of the options would work to result in a usable formulation" (Bodmeier affidavit, para 249).

[106] Justice de Montigny rejected Dr. Bodmeier's evidence in *Mylan Tadalafil III* and instead accepted evidence similar to that offered by Dr. Mumper in this case. More specifically, Justice de Montigny found that the improved dissolution and stability of tadalafil achieved by reducing its particle size and formulating it with specific excipients was obvious in light of the common general knowledge of the skilled formulator in 1999 with respect to both the selected excipients and reduction of the particle size of tadalafil (*Mylan Tadalafil III* at paras 156, 159).

[107] With respect to the excipients claimed in the 948 Patent, Justice de Montigny found there was nothing inventive about using them as they were common excipients and would be among the first to try when attempting to form a stable and more rapidly dissolving formulation of a poorly water-soluble drug like tadalafil. He also determined that the amounts of the chosen excipients were among the standard proportions listed in texts commonly used by formulators. He thus concluded that it would have been obvious to the skilled formulator in 1999 to formulate a tadalafil tablet with the excipients claimed in the 948 Patent (*Mylan Tadalafil III* at paras 147-150).

[108] In terms of particle size and the use of tadalafil in its free drug form, Justice de Montigny considered whether these were obvious when the Butler Patent had recommended a co-precipitate formulation. Justice de Montigny analyzed the expert opinions and prior art as well as the actual course of conduct, including the work undertaken at Glaxo leading up to the Butler Patent. Ultimately, he found that the problems with the co-precipitate formula disclosed in the Butler Patent made the use of the free drug form tadalafil with reduced particle size obvious as the poor water solubility of tadalafil was known and particle size reduction was a standard

technique for improving dissolution of a poorly water-soluble drug (*Mylan Tadalafil III* at paras 156-159).

[109] In reaching this conclusion, Justice de Montigny rejected an argument similar to the one made to me by Lilly, namely, that the course of experimentation undertaken by Glaxo before the rights to tadalafil were transferred to Lilly shows that the formulations claimed in the 948 Patent were not obvious, as Glaxo tried several other potential solutions to formulating tadalafil. Justice de Montigny rejected this argument for two reasons: first, because Dr. Kral had no first-hand knowledge of Glaxo's work and there was not enough information about this early work and why Glaxo made the choices it made before the Court to draw any conclusions from the work done at Glaxo; and, second, because he found that the skilled person would be starting with more advanced knowledge than the early formulators at Glaxo as the culmination of Glaxo's work was published in the Butler Patent. He noted as follows on these points:

> [157] Lilly spent much time at the hearing and in its Memorandum of Fact and Law describing the early formulation work on tadalafil at Glaxo, arguing that formulation work went on for over six years. I do not find that evidence on the actual course of conduct very compelling, for a few reasons. First, Dr. Kral only became involved with tadalafil when the project was transferred to Lilly in 1998. Dr. Kral was not involved with the research done at Glaxo, and without an affiant involved in Glaxo's work, the Court cannot weigh the soundness of the course of conduct pursued by Glaxo. For example, it appears from an early Glaxo study report that the oral bioavailability of [redacted] tadalafil was tested in [redacted] and that high bioavailability was observed [citations omitted]. Glaxo nevertheless chose not to proceed further apparently because of adverse effects associated with [redacted], the excipient that was used in that test. Yet, we have no explanation as to why Glaxo did not test the [redacted] tadalafil with another excipient that would similarly assist with [redacted], for example, a routine [redacted] used in the '948 Patent. There is no way to know whether Glaxo should have investigated [redacted] further, as suggested by Dr. Brittain [the Mylan expert –

> citations omitted], or whether there was a good reason not to do so. We also have no evidence of what happened with the oral formulations disclosed in the '377 and '784 Patents. As for the fact that the same study revealed that an [redacted] tadalafil with particle sizes of [redacted] microns only improved bioavailability by approximately [redacted], this study simply showed that mere [redacted] did not work, but did not teach away from the use of [redacted] as one of the tools to increase bioavailability.
>
> [158] I also agree with Mylan that, for the purposes of the obviousness inquiry, the skilled person would not have been in a similar position to the Glaxo formulators. The culmination of Glaxo's work - the co-precipitate formulation of tadalafil - was disclosed in the Butler Patent, and the person skilled in the art would also have had the teachings of the '377 and '784 Patents. Starting from this point, the skilled person's first step would have been to physically characterize tadalafil and the Glaxo co-precipitate formulation, which Lilly did and which Dr. Kral acknowledged is typically done in order to help the formulation people know what to do [citations omitted]. That study would have revealed, as it did for Lilly, that the particle size of the tadalafil was reduced as part of the process to make the co-precipitate and that the increased bioavailability was from a combination of the reduced particle size and the dispersed tadalafil. The study concluded, on this basis, as would the skilled person, that "a formulation that utilizes a [redacted] and maintains it in a [redacted] is likely to be superior to the current [co-precipitate] formulation" [citations omitted].

[110] Lilly submits that Justice de Montigny erred in his assessment of the work done at Glaxo and also applied the wrong test for assessment of whether the inventive concept of the 948 Patent was obvious. In this regard, Lilly submits that Justice de Montigny assessed whether there was a fair expectation of success with respect to the formulation chosen by Lilly and that he ought to have instead asked whether it was more or less self-evident that the selected formulation would be successful. Lilly therefore argues that I should not follow Justice de Montigny's decision and should instead find that the invention claimed in the 948 Patent is not obvious. Lilly contends that Dr. Kral and her team exercised inventive ingenuity in developing the formulations claimed

in the 948 Patent because it was not more or less self-evident that these formulations would be stable and more rapidly-dissolving.

[111] I do not accept either of Lilly's arguments. As concerns the work done at Glaxo, Lilly has failed to call any evidence to substantiate why Glaxo made the choices it did and, like Justice de Montigny, I find that the reports from Glaxo appended to Dr. Kral's affidavit do not establish why Glaxo did not take the more obvious route of reducing particle size and using the frequently-used excipients that were eventually selected by Lilly. This is particularly so because, as Dr. Mumper notes, the co-precipitate disclosed in the Butler Patent is an enteric-type polymer, that is known to prevent release in the stomach and thus would result in decreased dissolution rates and bioavailability (Mumper affidavit, paras 286-289).

[112] As for the allegation that Justice de Montigny applied the wrong test to assess obviousness, nothing turns on this allegation as I find that on the evidence before me it was more or less self-evident that the improved dissolution and stability of tadalafil would be achieved by reducing its particle size and formulating it with specific excipients, including notably a water-soluble diluent and a hydrophilic binder, as these steps were well-known to skilled formulators in August of 1999 as being among the first to try to formulate a stable tablet and increase the dissolution of a poorly water-soluble drug. In short, I accept Dr. Mumper's evidence on these points both because he is more credible than Dr. Bodmeier, for the reasons already discussed, and because, unlike Dr. Bodmeier, he has supported his views with numerous references to the prior art.

[113] In addition, I find that Lilly's course of conduct demonstrates the obvious nature of the invention claimed in the 948 Patent, given the fact that the formulation first selected was found to be effective (with minor modifications). Indeed, one of Lilly's clinical studies attached as Exhibit "J" to Dr. Kral's affidavit notes that Lilly developed the tablet formulation for tadalafil, that it seeks to protect in the 948 Patent, "…based on previous development experience of other Lilly commercial products (olanzapine and raloxifene)" (AR, p 6553). As Dr. Mumper notes at paras 349 and 351 of his affidavit, these drugs, like tadalafil, are poorly soluble in water and had previously been successfully formulated in a similar fashion by Lilly through particle reduction and use of excipients similar to or the same as the excipients claimed in the 948 Patent.

[114] I therefore find that the use of tadalafil in free drug form, reducing its particle size and formulating it with the excipients claimed in the 948 Patent were obvious steps to try in order to achieve a stable and more rapidly-dissolving formulation of tadalafil. I thus conclude that Apotex's obviousness allegation is justified.

VI. Is the 948 Patent invalid for inutility?

[115] I turn, finally, to Apotex' inutility allegation.

A. *Applicable principles*

[116] Patentable inventions must be useful as section 2 of the *Patent Act* defines an "invention" (which may be patented) as "any new and useful art, process, machine, manufacture or

composition of matter, or any new and useful improvement in any art, process, machine, manufacture or composition of matter".

[117] Central to the assessment of usefulness or utility of a claimed invention is the concept of the "promise of the patent", which determines the yardstick by which utility is measured. In this regard, it is not necessary that a patent set out a promise of its utility, and where the patent promises no particular result, the case law has recognized that a "mere scintilla" of utility in the invention will be sufficient for the grant of a patent. Where, however, the patent makes a promise, utility is measured against that promise (*Sanofi-Aventis v Apotex Inc*, 2013 FCA 186 at paras 48-49, 114 CPR (4th) 1 [*Sanofi-Aventis Plavix*]).

[118] Determination of whether a patent makes a promise and, if so, of the content of that promise is a matter of construction and, as such, involves a legal determination that must be undertaken at the outset of the utility inquiry (*Apotex v Bristol-Myers Squibb Co*, 2007 FCA 379 at para 27, 162 ACWS (3d) 911; *Eli Lilly Canada Inc v Novopharm Limited*, 2010 FCA 197 at paras 80, 93, 85 CPR (4th) 413 [*Olanzapine*].

[119] The promise of a patent may be either expressly stated in the patent, or, more typically, arises from construction of the claims in light of the entire specification. The construction of the promise is to be undertaken through the eyes of the person skilled in the art and is to be understood in relation to the science and information available at the filing date of the patent (*Olanzapine* at paras 80, 93). In addition, as Justice Dawson recently noted in *Astrazeneca Canada Inc v Apotex Inc*, 2015 FCA 158 (CanLII), [2015] FCJ No 802 (QL) [*Esomeprazole*

FCA], "some promises can be construed to impose utility requirements across each of a patent's claims, while other promises may touch only a subset of the claims. In every case it is a question of proper construction of the relevant claims" (at para 5).

[120] The case law teaches that the Court ought not be overzealous in finding every statement in the patent to be a promise (*Sanofi-Aventis Plavix* at paras 123-131). As was noted in *Astrazeneca Canada Inc v Mylan Pharmaceuticals ULC*, 2011 FC 1023 at para 139, 96 CPR (4th) 159, cited with approval in *Sanofi-Aventis Plavix* at para 67, not all statements of advantage in a patent rise to the level of a promise and goals that a patentee states he or she wishes to achieve do not necessarily constitute promises.

[121] Where a patent is challenged for inutility, a patentee must establish either that the utility of the patent is demonstrated or soundly predicted as of the Canadian filing date. Evidence of demonstrated utility may be and often is tendered that goes beyond the disclosures set out in the patent (see e.g. *Apotex Inc v Pfizer Canada Inc* 2011 FCA 236 at para 30, 95 CPR (4th) 193 [*Latanoprost*]; *Olanzapine* at para 92). However, such evidence must relate to the state of events as of the date the patent was applied for; evidence occurring after the filing date is not permissible (*Bell Helicopter Textron Canada Limitée v Eurocopter, société par actions simplifiée*, 2013 FCA 219 at para 131, 449 NR 111 [*Eurocopter*]).

[122] On the other hand, where the patent is premised on sound prediction, the evidence must establish that there was a factual basis for the prediction. In addition, to uphold a patent based on sound prediction, the inventor must have had "an articulable and sound line of reasoning" to

support the claim as of the filing date and the specification must contain adequate disclosure of the basis for the prediction and of the line of reasoning supporting it (*Apotex Inc v Wellcome Foundation Ltd*, 2002 SCC 77 at para 70, [2002] 4 SCR 153; *Eurocopter* at para 134).

B. *The parties' positions*

[123] Here, Lilly relies only on demonstrated utility and does not seek to uphold the 948 Patent based on sound prediction as no studies or tests are disclosed in the Patent, and it therefore lacks the requisite disclosure of an articulable and sound line of reasoning to support an argument of sound prediction.

[124] In terms of demonstrated utility, Lilly asserts that the 948 Patent promises rapid onset of pharmacological response of the new formulations of tadalafil and that this promise cuts across all the Claims at issue in the following fashion:

> (a) Claims 1-4, 7-8, 11-15, 17-18 and 23-25 promise effective new formulations of tadalafil that provide rapid onset of pharmacological response;
>
> (b) Claims 19-21 and 26-29 promise tablets made from effective new formulations of tadalafil that provide rapid onset of pharmacological response;
>
> (c) Claim 30 promises the use of the tadalafil formulations to treat sexual dysfunction in a patient with rapid onset of effect;
>
> (d) Claim 31 promises the use of tablets made from the formulations to treat sexual dysfunction in a patient with rapid onset of effect; and
>
> (e) Claim 33 promises the use of tablets made from the formulations to treat male ED in a patient with rapid onset of effect (Eli Lilly's Memorandum of Fact and Law at para 94).

[125] Lilly submits that the studies appended to the affidavit of Dr. Kral demonstrate this promised utility across all the relevant Claims. More specifically, Lilly asserts that the studies attached as Exhibits "L" [redacted], "M" [redacted] and "O" [redacted] to Dr. Kral's affidavit establish that the tablets prepared according to some of the formulations claimed in the Patent dissolve more quickly than the co-precipitate formulation claimed in the Butler Patent and that the tested formulations claimed in the Patent reached a maximum concentration in the blood (Tmax) more rapidly than the co-precipitate formulation. It says that this demonstrates the rapid onset of pharmacological response that was promised, as Dr. Bodmeier noted in his affidavit (Bodmeier affidavit, paras 271-274).

[126] Lilly also relies on Dr. Goldstein's evidence, noting that he was the only clinician who gave evidence, submitting that his affidavit establishes that the more rapid measurement of Tmax in the study appended as Exhibit "L" to Dr. Kral's affidavit correlates to the more rapid onset of penile erection that was observed in the study annexed to her affidavit as Exhibit "N" [redacted].

[127] Apotex, on the other hand, submits that the formulations claimed in the relevant Claims promise the following advantages over the prior art (notably the formulations set out in the Butler Patent):

- more rapid dissolution;
- improved stability;
- improved dosage uniformity; and
- more simplified marketing and handling.

In addition, Apotex alleges that the 948 Patent promises that all the various formulations falling within Claim 1 will be useful for treating sexual dysfunction, including ED and female arousal disorder. Apotex therefore submits that the 948 patent makes much more detailed promises than Lilly alleges is the case.

[128] Apotex further asserts that Lilly has failed to establish the requisite demonstrated utility and makes four principal arguments in this regard.

[129] First, it submits, relying upon *Latanoprost* at para 30 and on *Pharmascience Inc v Canada (Health)*, 2014 FCA 133 at paras 39-40, [2014] FCJ No 573, that Lilly cannot rely on undisclosed clinical studies to establish demonstrated utility, arguing that in order to establish demonstrated utility a patentee must make mention of some evidence of demonstrated utility in the patent.

[130] Second, Apotex submits that under either its or Lilly's formulation of the promises made in the 948 Patent, and even if the studies appended to Dr. Kral's and Dr. Pullman's affidavits can be relied upon to establish utility, Lilly has not met its burden as the studies appended to these affidavits relate only to the market image tablet and not to any of the host of other formulations claimed in the 948 Patent. It notes in this regard that the narrowest claim in the Patent, namely Claim 16, encompasses a very large number of formulations and argues that tests on a single one of them cannot demonstrate utility.

[131] Third, Apotex says that efficacy was only evaluated for ED, and that the broader claims made with regard to efficacy for treatment of female arousal disorder have not been demonstrated.

[132] Finally, even with respect to the market image tablet and Lilly's version of the promises made in the Patent, Apotex claims that the studies relied on do not actually demonstrate utility as not all dosages were tested and, accordingly, one needs to rely on sound prediction to prove utility, which Lilly cannot do as none of the data it relies on are mentioned in the Patent.

C. *Analysis*

(1) The Scope of the Promise Made

[133] Turning, first, to the issue of what the 948 Patent promises, the Patent nowhere makes an explicit promise of any sort and mentions the advantages of the formulations claimed in the Patent only in the disclosure, and then discusses them quite briefly.

[134] More specifically, under the "*Field of the Invention*" section of the Patent, a mention is made that ß-carboline compounds "are formulated in a manner providing uniform potency, and desirable stability and bioavailability characteristics" (p 1, lines 17-19 of the 948 Patent). Later on in the "*Background of the Invention*" section, problems with the co-precipitate formulation claimed in the Butler patent are noted (i.e. difficulties with reproducibility and attainment of Tmax only at three to four hours after ingestion, p 2, lines 19-29 of the 948 Patent).

[135] In the "*Summary of the Invention*" section, mention is made that dosage uniformity, stability and bioavailability are enhanced by formulating tadalafil with the particular excipients claimed in the Patent and by reducing the particle size of the tadalafil in the claimed formulations (p 7, lines 20-30; p 8, lines 10-20 of the 948 Patent). At pages 12-13 of this section of the Patent (at lines 32-35 and line 1 of p 8), the applicants state that "in addition to improved dissolution and in vivo absorption, another important physical property is stability. The present invention provides formulations with improved stability over prior formulations."

[136] There is little in these few statements to found a promise, but, despite this, it is common ground between the parties that this Patent does make a promise. To the extent there is any promise made in the 948 Patent, it cuts across all the Claims and relates to the improved characteristics of the claimed formulations. I agree with the parties that the notions of "improvement" or "enhancement" invite a comparison. In the context of this Patent, that comparison is to be made to the co-precipitate formulations claimed in the Butler Patent as the 948 Patent makes it clear that it is seeking to provide a solution to the problems experienced with the Butler formulations.

[137] In terms of the enhancement over the Butler co-precipitate that is being promised, it is axiomatic that physical stability and reproducibility are required for all tablets that are offered for sale in Canada. Thus, I concur with Lilly that these aspects of the formulations do not constitute promises made in the 948 Patent. Rather, I believe that to the extent the relevant claims in the Patent make a promise, it is a modest one – that the claimed formulations will dissolve more

rapidly and therefore offer improved bioavailability over the co-precipitate formulation claimed in the Butler Patent.

(2) Is this promise demonstrated?

[138] As noted, the parties disagree on whether a patent must reference the studies or data demonstrating utility. In my view, the data demonstrating utility need not be referenced in a patent and, therefore, Lilly may rely on the studies appended to the affidavits of Drs. Kral and Pullman in support of its demonstration of the 948 Patent's utility.

[139] In this regard, the traditional rule was that while there may well be a disclosure requirement for the factual basis for sound prediction, there is no disclosure requirement for demonstrated utility which may be met if the patentee can defend demonstrated utility on a challenge. This demonstration usually requires evidence beyond what is in the patent (see Donald H. MacOdrum, *Fox on the Canadian Law of Patents*, loose-leaf (consulted on 17 August 2015), 5th ed (Toronto: Carswell, 2013), para 6:13(a); *Consolboard Inc v MacMillan Bloedel (Saskatchewan) Ltd*, [1981] 1 SCR 504 at 517-27, 56 CPR (2d) 145 ; *Novopharm Limited v Pfizer Canada Inc*, 2010 FCA 242 at paras 80-82, 88 CPR (4th) 405 [*Sildenafil* FCA], rev'd on other grounds 2012 SCC 60; *Teva Canada Ltd v Pfizer Canada Inc*, 2012 SCC 60 at paras 39-40, [2012] 3 SCR 625 [*Sildenafil* SCC]; *Olanzapine* at para 74; *Sanofi-Aventis Plavix* at paras 38-40).

[140] However, Apotex relies on a statement made by the Federal Court of Appeal in *Sildenafil* FCA, above, and *Latanoprost*, where the Court commented in *obiter* that "[t]here is no

requirement to prove demonstrated utility in the disclosure of the patent; so long as the disclosure makes reference to a study demonstrating that the patent does what it promises to do, this criteria is met" (*Latanoprost* at para 30, citing *Sildenafil* FCA at para 90). Apotex also relies on the recent decision of Justice Roy in *Laboratoires Servier and Servier Canada v Canada (Health)*, 2015 FC 108, [2015] FCJ No 173 (QL), where Justice Roy excluded evidence of demonstrated utility because it was not referenced in the disclosure. Relying on *Latanoprost*, he said that the patent disclosure "must" make reference to studies demonstrating utility (at para 211) and thus refused to admit evidence that was not mentioned in the patent.

[141] With respect, I believe that Justice Roy's determination on this point is erroneous and ought not be followed as it takes the *obiter* statements in *Sildenafil* FCA and *Latanoprost* out of context and does not address the many other cases where an opposite conclusion was reached. In addition to those mentioned in paragraph 139 of these Reasons, Justice Hughes held in *GlaxoSmithKline Inc v Pharmascience Inc*, 2011 FC 239 at para 96, 91 CPR (4th) 189 [*Rosigilitazone*] that "[t]here is no requirement for a patent to demonstrate utility in the disclosure so long as the Court finds it to be proven when challenged in Court". To similar effect, Justice Rennie recently held in *AstraZeneca Canada Inc v Apotex Inc*, 2014 FC 638, 244 ACWS (3d) 180 [*Esomeprazole* FC], aff'd in *Esomeprazole* FCA, that "it is not in dispute that disclosure is not required for the demonstration of utility" (at para 130).

[142] Thus, the weight of authority is to the effect that the evidence of demonstrated utility need not be referenced in the patent for the patentee to rely on it. Lilly therefore may rely on the

exhibits to the affidavits of Drs. Kral and Pullman in support of its demonstration of the 948 Patent's utility in this case.

[143] In terms of what those exhibits establish, I concur with Lilly that Exhibits "L" and "M" to Dr. Kral's affidavit establish that the market image tablet dissolves faster and reaches the Tmax more quickly than the Butler formulation. I further concur that Exhibit "N" to the Kral affidavit establishes that particle sizes of tadalafil of [redacted] microns dissolve more quickly than the larger particle size of [redacted] microns, that was also tested in that study. Finally, I concur with Dr. Goldstein that the more rapid attainment of Tmax by subjects ingesting the market image tablet in the study appended as Exhibit "L" to Dr. Kral's affidavit is a comparable result to the more rapid onset of penile erection in subjects having ingested the market image tablet in the study annexed to her affidavit as Exhibit "N", as the dosages that led to the more rapid Tmax also led to more rapid erections.

[144] While it is true, as Apotex notes, that Lilly did not test all the formulations claimed in the 948 Patent, I find it is not necessary for them to have done so to establish utility, as the Federal Court of Appeal recently affirmed in *Eurocopter* at para 137. In the present case, the testing done was sufficient to establish the claimed utility of the rather self-evident promise that the formulations without an enteric coating would provide more rapid dissolution and enhanced bioavailability over the formulation of the Butler Patent, which contained an enteric coating.

[145] I thus find that Apotex' allegations of inutility are not justified.

VII. Confidentiality and Costs

[146] During the hearing I indicated that I would continue Prothonotary Tabib's confidentiality order of February 5, 2014 and would provide the parties with an opportunity to make submissions on what portions of the Judgment and Reasons should be redacted. They did so and I have produced the public version of these reasons following receipt of their submissions.

[147] Many of the redactions contained in pages 23-27 of the Public Judgment and Reasons may no longer be required if and when the Minister issues an NOC to Apotex and its product(s) are placed on the market as their contents would presumably be disclosed in the product monograph(s) that Apotex would be required to make public. Accordingly, Apotex shall advise the Court within 48 hours of the issuance to it of an NOC for its generic version of either CIALIS or ADCIRCA to facilitate the removal of redactions from the public version of these reasons that will no longer be necessary.

[148] The parties have agreed that costs will follow the event but requested additional time to make submissions on the quantum of costs, which I agreed I would afford them. Accordingly, if the parties are unable to agree on costs, Apotex shall file its costs submissions, of no more than 15 pages, within 15 days of the release of the Confidential version of the Judgment and Reasons. Lilly shall have 15 days following receipt of Apotex' submissions to file its responding costs submissions, which likewise shall be limited to 15 pages. Thereafter, within 5 days of receipt of Lilly's responding submissions, if it chooses, Apotex may file reply costs submissions of no more than 5 pages.

JUDGMENT

THIS COURT'S JUDGMENT is that

1. The application is dismissed;

2. The confidentiality order of Prothonotary Tabib, dated February 5, 2014, is continued. If the Minister of Health issues an NOC to Apotex for either of its products involved in this application, Apotex shall advise the Court within 48 hours of the issuance of the NOC to facilitate amendment to the Public Judgment and Reasons by removing redactions dealing with the content of the Apotex product(s) for which an NOC has issued;

3. Costs will follow the event. If the parties are unable to agree on the quantum of costs payable by Lilly to Apotex, Apotex shall file its costs submissions, of no more than 15 pages, within 15 days of the release of the Confidential version of my Judgment and Reasons. Lilly shall have 15 days following receipt of Apotex' submissions to file its responding costs submissions, which likewise shall be limited to 15 pages. Thereafter, within 5 days of receipt of Lilly's responding submissions, if it chooses, Apotex may file reply costs submissions of no more than 5 pages; and

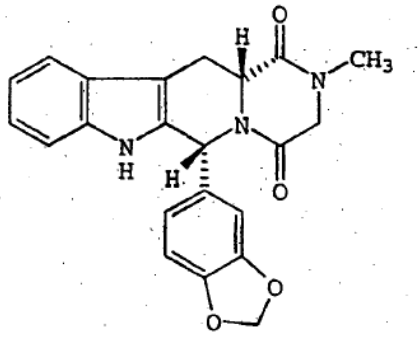
4. No costs are awarded for or against the Minister.

"Mary J.L. Gleason"

Judge

ANNEX

1. A pharmaceutical formulation comprising a compound having the structural formula



wherein said compound is provided as free drug comprising particles wherein at least 90% of the particles of the compound have a particle size less than about 40 microns; about 50% to about 85%, by weight, of a water-soluble diluent; a lubricant; about 1% to about 5%, by weight, of a hydrophilic binder selected from the group consisting of a cellulose derivative, povidone, and a mixture thereof; and a disintegrant selected from the group consisting of croscarmellose sodium, crospovidone, and a mixture thereof.

2. The formulation of claim 1 further comprising microcrystalline cellulose.

3. The formulation of claim 1 further comprising a wetting agent.

4. The formulation of claim 1 wherein the active compound is present in an amount of about 0.5% to about 10% by weight of the formulation.

…

7. The formulation of claim 1 wherein the lubricant is present in an amount of about 0.25% to about 2% by weight of the formulation.

8. The formulation of claim 1 wherein the lubricant is selected from the group consisting of talc, magnesium stearate, calcium stearate, stearic acid, colloidal silicon dioxide, calcium silicate, a starch, mineral oil, a wax, glyceryl behenate, a polyethylene glycol, sodium benzoate, sodium acetate, sodium stearyl fumarate, hydrogenated vegetable oils, and mixtures thereof.

…

11. The formulation of claim 2 wherein the microcrystalline cellulose is present in an amount of about 5% to about 40% by weight of the formulation.

12. The formulation of claim 3 wherein the wetting agent is present in an amount of 0.1% to about 5% by weight of the formulation.

13. The formulation of claim 12 wherein the wetting agent is selected from the group consisting of sodium lauryl sulfate, docusate sodium, ethoxylated castor oil, a polyglycolyzed glyceride, an

acetylated monoglyceride, a sorbitan fatty acid ester, a poloxamer, a polyoxyethylene sorbitan fatty acid ester, a polyoxyethylene, a monoglyceride, a diglyceride, and mixtures thereof.

14. The formulation of claim 3 wherein the wetting agent is selected from the group consisting of sodium lauryl sulfate, polysorbate 80, and a mixture thereof.

15. The formulation of claim 1 wherein the compound is provided as particles of a free drug wherein at least 90% of the particles have a particle size less than about 10 microns.

…

17. The formulation of claim 15 further comprising about 5% to about 40% by weight of the formulation of microcrystalline cellulose.

18. The formulation of claim 15 further comprising about 0.1% to about 5% by weight of the formulation of sodium lauryl sulfate.

19. A tablet comprising the formulation of claim 1 wherein the compound is present in an amount of about 1 to about 20 mg per tablet.

20. A tablet comprising the formulation of claim 1 wherein the compound is present in an amount of about 5 to about 15 mg per tablet.

21. A tablet comprising the formulation of claim 1 wherein the compound is present in an amount of about 5 mg or about 10 mg per tablet.

…

23. The formulation of claim 1, wherein the compound is provided as particles of a free drug wherein at least 90% of the particles have a particle size less than about 30 microns.

24. The formulation of claim 1, wherein the compound is provided as particles of a free drug wherein at least 90% of the particles have a particle size less than about 25 microns.

25. The formulation of claim 1, wherein the compound is provided as particles of a free drug wherein at least 90% of the particles have a particle size less than about 15 microns.

26. A tablet comprising the formulation of claim 1, wherein the compound is present in an amount of about 10 mg per tablet.

27. A tablet comprising the formulation of claim 1, wherein the compound is present in an amount of about 1 to about 5 mg per tablet.

28. A tablet comprising the formulation of claim 1, wherein the compound is present in an amount of about 2.5 mg per tablet.

29. A tablet comprising the formulation of claim 1, wherein the compound is present in an amount of about 20 mg per tablet.

30. Use of an effective amount of a formulation according to any one of claims 1 to 18, or 23 to 25 to treat sexual dysfunction in a patient.

31. Use of an effective amount of a tablet according to any one of claims 19 to 21 or 26 to 29 to treat sexual dysfunction in a patient.

…

33. The use according to any one of claims 30 to 32, wherein the sexual dysfunction is male erectile dysfunction.

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-1599-13
STYLE OF CAUSE:	ELI LILLY CANADA INC. v APOTEX INC. AND THE MINISTER OF HEALTH AND ICOS CORPORATION
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